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PREPARING FOR REALITY: PROTECTING AGAINST WEAPONS OF MASS DESTRUCTION

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PREPARING FOR REALITY: PROTECTING AGAINST WEAPONS OF MASS DESTRUCTION

FRIDAY, JUNE 28, 2002

U.S. SENATE,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:38 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.
Present: Senators Lieberman, Akaka, Cleland, and Dayton.

OPENING STATEMENT OF CHAIRMAN LIEBERMAN

Chairman Lieberman. Good morning, all. This hearing will come to order. I want to welcome you to the Senate Governmental Affairs Committee’s fourth hearing on the reorganization of our Federal Government to improve America’s domestic defenses.

I want to begin for the moment by thanking Senator Akaka (in absentia) who is Chairman of this Committee’s Subcommittee on International Security, Proliferation and Federal Services, for his thoughtful and tireless work on many of the issues that we will be discussing today.

Our task this morning, building on Senator Akaka’s work, is to examine how a Department of Homeland Security can best meet the technological challenge of protecting Americans from attacks by weapons of mass destruction, and, of course, by that we mean chemical, biological, or nuclear weapons.

It is self-evident, but worth repeating, that there is no greater threat and no graver danger than the use of such weapons on our soil, notwithstanding the terrible damage and death and destruction that we suffered from more traditional attacks, although used unconventionally, on September 11.

The fight against terrorism might be described as brain-to-brain combat. On those terms, America is very well-equipped to win. Our computer scientists, biotechnology innovators, electrical and mechanical engineers, doctors, chemists, physicists, and a whole range of other scientific and technological experts are the best in the world. They have repeatedly worked wonders and will continue to keep our Nation on the cutting edge of innovation.

But our enemies will also improvise and innovate in ways to hurt more Americans, so we have got to marshal our scientific and technological strength to both defend and go beyond the capacity of those who would do us damage. We have got to leverage America’s wealth of technological resources to counter current threats and anticipate new ones.
In this hearing, we are going to consider both this Committee's proposals and the President's proposals for doing exactly that in the framework of a new Department of Homeland Security. In this particular area of homeland security, there is significant common ground between our legislation and the President's plan, but there are also differences and I want to briefly lay them out at the start and then hope to consider them as we go through this hearing.

The first is organizational structure. Our proposal would create a Division on Emergency Preparedness and Response with FEMA, the current FEMA, at its center, and that division would be focused on response and preparedness, without regard to the nature of the particular threat. We would then also establish in our bill a separate Office of Science and Technology within the new Department of Homeland Security with the focused mission of coordinating all research and development related to homeland security, including but not limited to detection, prevention, and response to weapons of mass destruction.

The President's proposal would place greater emphasis on emergency preparedness and response to threats from weapons of mass destruction, as I understand the proposal, and the separate division, which we call here the fourth division, called Chemical, Biological, Radiological, and Nuclear Countermeasures.

So I want to explore today the nature of our response in structure in this new Department to chemical, biological, and nuclear attacks and to ask whether our preparedness and response for those attacks might not better be included in a division that oversees emergency preparedness and response generally, rather than in a separate division.

Also, the President's proposed structure for the Department would embed science and technology development within the division devoted to countermeasures when, in my view, it is more productive and logical to place all R&D efforts, ranging from detection to protection to response, in an office focused solely on that task and to elevate that office to the highest level within the Department. That is why our proposal would create—the initial proposal that passed out of the Committee would create—an Office of Science and Technology to carry out that function.

That brings me to a second area of concern and difference between the two proposals, which is research capability. The President's plan would transfer many research and development functions from existing Departments including: Health and Human Services, Department of Energy, Department of Agriculture, and the Department of Defense—to this new fourth Division on Countermeasures within the new Department.

I want to make sure that when we bring these entities into the new Department, if we do, we leave the agencies and departments from which they came in good stead. We should also ensure that these entities are carefully and logically organized within the new Department, if, in fact, they are moved there, with clean and clear lines of authority.

For example, the President's proposal suggests that the Department of Homeland Security will jointly manage biological research efforts in conjunction with the Secretary of HHS. As far as I can tell, and we have the experts at the table, there is no precedent for...
co-direction of Federal programs in this way, and I want to explore the wisdom of such an arrangement and how it might work if it were going to work.

Third, rapid technology development and deployment. Here, since the initial bill was reported out of the Committee, I think some of my own ideas have developed, and that is why I want to explore the possibility of creating a new development agency within the new Department which might be called SARPA, which is Security Advanced Projects Research Agency, modeled closely after DARPA, the Defense Advanced Research Projects Agency in the Pentagon, which has become one of the great engines of innovation in American history.

DARPA, as the witnesses know, was created by President Eisenhower in 1958, originally called ARPA, in response to the launch of Sputnik by the Russians. From the beginning, it was designed to be something different, a lean, flexible agency that identifies our military’s technological needs and then leverages with funding the best minds in our country, in government—at the laboratories, for instance—in academia, and in the private sector to meet those needs.

DARPA’s nimble, aggressive, and creative approach has produced remarkably impressive and effective war-fighting technologies and has done so relatively quickly. And in the course of fulfilling that central mission, DARPA has also developed technologies with broad commercial and societal application, including something we now, today, call the Internet. That came from DARPA.

I have high hopes and expectations for SARPA, the homeland security counterpart, which would be located possibly in the Office of Science and Technology that I mentioned. I think we need dozens of new security technologies and we need them quickly, and that includes devices and systems to detect chemical, biological, radiological, and nuclear devices, for instance, at borders, ports, and airports, but also devices that protect our cyberspace from devastating attacks and that safeguard our physical infrastructure from sabotage, or biometric devices that could do a better job at allowing for entry into secure facilities or filtering entry into secure facilities, or work to pioneer the next generation of so-called smart buildings that detect intruders and protect vital systems from being sabotaged. The range of potential projects is literally endless.

One of the critical functions of the new Department must also be developing diagnostics, drugs, and vaccines to treat those who have been exposed to or infected by a bioterror agent, and this is a massive undertaking because, right now, the truth is, we have very few medical countermeasures available. That is why I think we have got to direct the Department to develop a national strategy for engaging the Nation’s biotechnology and pharmaceutical firms as critical homeland defense allies and resources.

In the end, we will need to consider enacting tax incentives, procurement provisions, liability reform, and a revised drug approval process to spur the development of these countermeasures, and I have actually drafted in legislation that would do some of those.

Finally, I want to point out that if we are to muster all of America’s brain power to win this fight against terrorism, the new Department of Homeland Security must work closely with and learn
from the Department of Defense. The Pentagon has better technologies for detection, prevention, protection, and response to attack than anyone, anywhere. If our Department of Homeland Security is designed to reinvent all those wheels rather than selectively adapting, applying, and focusing DOD resources, that would be a mistake.

Senator Cleland is here. He is the source of some of the best quotes I ever hear, so I want to just share with him one that I read recently from Winston Churchill, who we are both—actually, all of us are fond of quoting, particularly in these days because of the challenges we face that are so different. In 1941, Churchill said in a speech to the British people in which he intended to both inspire the Allies and challenge, confront the Axis powers, he said to the Axis powers, our enemies, “You do your worst and we will do our best.”

Today, we know that our enemies will do their worst to apply technology to try to terrorize our people and disrupt our way of life. We have an urgent duty now to do our best to develop better technologies, to preempt, prevent, and protect against even their most advanced and unpredictable attacks, and I have no doubt that, working together, we will achieve that mission.

Senator Cleland, thank you for being here.

OPENING STATEMENT OF SENATOR CLELAND

Senator Cleland. Thank you very much, Mr. Chairman. I find the title of the hearing, quite frankly, engrossing, “Preparing for Reality: Protecting Against Weapons of Mass Destruction.” I think that really is where we are.

Senator Sam Nunn, who is running the National Nuclear Threat Initiative Program, of which Dr. Hamburg is a part, and who had this Senate seat before I did for 24 years and was the former Chairman of the Armed Services Committee, has given me a couple of concepts that I am working off of that, I think, to embrace the new reality of certainly bioterrorism.

First, Senator Nunn said the organizing principle of the Cold War was massing against the Soviet Union numbers of missiles, and nuclear warheads, and measuring that mass in throw weights and our ability to, in effect, mutually destruct ourselves. He said the new era should be marked by the organizing principle of working against catastrophic terrorism, not just terrorism, but catastrophic terrorism, I think he puts it in a proper light, that the real arms race now is not about missiles and throw weights and nuclear warheads. The real arms race is a race between now and the time that the terrorists get their hands on tools of catastrophic destruction—biological, chemical, or nuclear.

So I think we are in a new era here. The whole challenge, it seems to me, for this country is pretty much two-fold. First, to go on the strategic initiative abroad, fighting terrorists abroad in their jungles, their caves, but being on the strategic defensive here. That means that we have to get our act together. It means we have to improve our coordination, cooperation, and communication in order to properly defend ourselves.

That is why I support the Homeland Security Department initiative that came out of this Committee. I am an original cosponsor.
It is one reason why I feel very strongly that the CDC in Atlanta should be the place where we place a center for bioterrorism preparedness and response. Thirty-four percent of the CDC’s workload now has to do with bioterrorism. It is just not focused. It is not a place where either the Director of HHS or the Director of Homeland Security can call and get the word, the definitive word, on what is happening in terms of bioterrorism preparedness and bioterrorism response. I think we need that. That would improve coordination, cooperation, and communication tremendously.

My questions today, Mr. Chairman, will be along the lines of what the panelists feel about how we can improve this Nation’s preparedness and response, particularly in terms of bioterrorism, and particularly where we have, in effect, two main pieces of guidance in the Federal Government that split the Federal Government. One piece of guidance is a 1995 directorate by President Clinton by Executive Order mandating the FBI to be the lead agency on terrorism, then in 1998 a law by the U.S. Congress naming the CDC as lead agency on bioterrorism.

And in a case like the anthrax situation, you had both agencies going to the scene at the same time, one hopefully identifying it properly, the CDC, then the FBI shutting the crime scene down. So we have two conflicting pieces of guidance here. We need to straighten that out, get that protocol right before the next biological attack.

Thank you, Mr. Chairman.
Chairman LIEBERMAN. Thanks very much, Senator Cleland. I appreciate your being here. Senator Akaka.

OPENING STATEMENT OF SENATOR AKAKA

Senator Akaka. Thank you very much, Mr. Chairman. I want to say good morning to our witnesses and thank you for being here today as we discuss how the new Department of Homeland Security should address threats from weapons of mass destruction.

I want to particularly thank my good friend, Chairman Senator Lieberman, for calling this hearing and to commend him for being what I consider the man of the hour and a distinguished leader by proposing legislation in the Senate on homeland security and holding hearings to deal with the critical issues that face our Nation. His bill, as you know, was considered and passed by this Committee before the President issued his and so I want to give him that credit and pronounce him as a great leader here in the Senate.

I have been working with him on emergency preparedness and bioterrorism now, Mr. Chairman, for some time. We first asked, can a bioterrorism attack happen? This is a little while ago. Today, we ask, how can we reduce the threat? So it is a different kind of question that we ask today.

The threats we face will continue to change as our adversaries mature and new adversaries emerge. Therefore, whatever format we choose for this new Department must be flexible, and flexible enough to adapt to these changes quickly.

Unlike the Chairman’s bill, the President’s proposal would establish a fourth division in the Department of Homeland Security to develop policies against weapons of mass destruction. However,
transferring bioterrorism and public health activities out of the Department of Health and Human Services and into a new agency has the potential to fracture rather than consolidate functions. We must be very careful to enhance rather than diminish our capability to meet emerging threats.

This new agency should coordinate and facilitate research and development activities, which would encourage cooperation across agencies and disciplines. The new Department should identify research priorities. The proposed division can make sure that new countermeasures meet the needs of local, State, and Federal partners.

American ingenuity and creativity are among our greatest assets, no question. We must harness this spirit and draw upon the vast resources of the private sector in our search for effective countermeasures.

I recently met with inventors from Hawaii who are developing environmental detection techniques and air filtration devices. They contacted me because of their confusion over who they should approach within the government. Why not make this new Department a one-stop clearinghouse for information and guidelines on R&D opportunities?

Research and development alone will not be effective if used inappropriately in preparedness efforts and training. The ability of local fire fighters, police officers, and doctors to respond to WMD terrorism must be improved.

I am not convinced that splitting mitigation and response activities between two different under secretaries as proposed by the President will do this. Will shifting the authority for biomedical research to a Department of Homeland Security while leaving the expertise within HHS improve our ability to fight disease? Such actions seem unnecessary and could degrade our emergency preparedness efforts.

The goal must be to reduce the loss of life and property and restore public confidence following a terrorist attack. We should focus our efforts not only on R&D, but in training appropriate individuals and the general public in what actions to take should we face a WMD event.

As we work toward the objective, we should enhance the government’s response to natural disasters and public health events. For example, we would need to ensure that APHIS has the resources and personnel to continue to protect Hawaii’s fragile ecosystem while meeting its proposed new homeland security functions. We must be careful not to create a system that will divert personnel and resources to homeland security from core agency missions, thus making both less effective. We need a national strategy to identify how this new Department will make America safer and her people more secure. That is what we are here to do and we look forward to your thoughts on this matter.

Thank you very much, Mr. Chairman, and I look forward to the testimony.

Chairman LIEBERMAN. Thanks, Senator Akaka. Before you arrived, when I gave my statement, I thanked you for your leadership in this area through your Subcommittee over many years. I regret that I did not repeat it when I introduced you, although
somebody told me years ago that in Washington you know you are doing well when somebody compliments you when you are not in the room. [Laughter.]

Senator Akaka. Thank you very much.

Chairman Lieberman. So you are doing well, Senator Akaka. [Laughter.]

Senator Dayton, thanks for being here.

OPENING STATEMENT OF SENATOR DAYTON

Senator Dayton. Thank you. I have nothing to say at the outset. I look forward to hearing from our witnesses. Thank you.

Chairman Lieberman. Thanks. I want to give my three colleagues here a medal. I am the Chairman of the Committee, so I have to be here. Surprisingly—and I am thrilled to be here, may I say to the witnesses. [Laughter.]

This is an important hearing. But what I am about to say to the three of them is, the Senate surprisingly finished its pre-July 4 recess work yesterday, which it was expected to do today, so these three are here out of a sincere desire to be involved in these deliberations and I thank them very much.

Senator Dayton. Mr. Chairman, I will just say these hearings have been outstanding. I have said that before, but it bears repeating. This series has been among the very best hearings I have attended in my 1½ years in the Senate, so thank you and your staff.

Chairman Lieberman. Thank you, Senator Dayton. We have been very fortunate to have a great group of witnesses on an important topic and thanks for your substantial contribution to the hearings.

Two announcements. There is an empty chair there, and sadly, it is Dr. John Hamre, who has terrible flu. He has submitted testimony and it will be part of the record. I believe we can release it to the press if there is interest, or maybe we already have. We will see him on another occasion.

Second, Senator Thompson wanted very much to be here today but he could not and he wanted me particularly to welcome Dr. Madia, who he is very proud to have here.

Let us begin with Dr. Lewis Branscomb, Professor Emeritus, Public Policy and Corporate Management, JFK School of Government at Harvard, and co-chair of a very important committee about whose work he will report. Dr. Branscomb, we look forward to your testimony.

TESTIMONY OF LEWIS M. BRANSCOMB, PH.D., EMERITUS PROFESSOR OF PUBLIC POLICY AND CORPORATE MANAGEMENT AND EMERITUS DIRECTOR OF THE SCIENCE, TECHNOLOGY AND PUBLIC POLICY PROGRAM, CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY

Dr. Branscomb. Thank you very much, Mr. Chairman. I do want to discuss very briefly the work of the Committee on Science and Technology for Countering Terrorism at the National Academy’s
National Research Council. Our report, entitled “Making the Nation Safer: The Role of Science and Technology in Countering Terrorism,” came out last Monday. I am very proud that Peggy Hamburg was a member of that Committee. So, too, was Ash Carter, who testified, I believe, on Wednesday——

Chairman Lieberman. Yes.

Dr. Branscomb [continuing]. And a number of other distinguished Americans.

Our report was completed and was in the final stages of report review when the President made his statement that he intended to send forward a bill, though we were complete and in press before I actually saw the details of it. But our report, in fact, was able to address two very important features that we believe ought to be in a Department of Homeland Security. But perhaps more important than that, this report, written by 119 experts, vetted and very skillfully evaluated by 46 independent experts, contains 134 detailed recommendations discussing the science and technology responses to a great variety of threats, which we said as little about as we had to in order to justify the conclusions.

It is very important that you appreciate that ours was a report about catastrophic terrorism. We believe very strongly that there are many kinds of attacks that could be catastrophic—defined in terrorist sense. It is very important to appreciate that the legislative meaning, at least, of the words “weapons of mass destruction” do not cover all the—by any means—threats of catastrophic terrorism. Many of those threats could be caused by combinations of the use of conventional explosives, perhaps with a cyber attack, or perhaps with a radiological attack, which is surely not part of the weapons of mass destruction. Nevertheless, it is a source of terror, nonetheless.

Chairman Lieberman. Dr. Branscomb, excuse me. How would you describe what happened on September 11? I was finding myself in my opening statement reaching for——

Dr. Branscomb. Clearly catastrophic terrorism——

Chairman Lieberman. Catastrophic terrorism.

Dr. Branscomb [continuing]. But not done with weapons of mass destruction——

Chairman Lieberman. Exactly.

Dr. Branscomb [continuing]. Unless you want to accept a broader definition of that term, which I would be happy to do in the President’s bill, in which the R&D function is attached to one of four divisions concerned with weapons of mass destruction as normally defined, as in the Department of Energy, as nuclear, biological, and military chemical weapons. Of course, we may interpret chemical as including explosives, indeed in tank cars of industrial chemicals which, under certain circumstances, could produce catastrophic consequences.

So we believe it is very important to look at the full range of possible attacks that would be intolerable if carried out against the United States.

Senator Dayton. Mr. Chairman, may I just interject?

Chairman Lieberman. Yes, please.

Senator Dayton. I am sorry, and I know you do not intend this, but there was an attempted catastrophic attack of mass destruc-
tion, I do not know about the term, but we were told by Mayor Giuliani when we were at Ground Zero the following week that there were 25,000 people evacuated from the two towers because they did not collapse immediately. The Pentagon plane fortunately hit a relatively unpopulated area. The other plane was heroically crashed before it could reach its intended target. The losses to those individuals and the psychic damage to the country, was massive. So I do not dispute your characterization, but I do not want anyone here listening to think that we do not treat this as an attempt of a mass destruction which was partially executed.

Dr. Branscomb. Indeed, Mr. Dayton, that is exactly what I meant to say. We regarded that as a catastrophic terrorist attack and our report is about catastrophic attacks. The reason I have avoided using the word “weapons of mass destruction” is because in prior legislation and in a lot of public policy work, those words do not include the cyber attacks, they do not include ordinary chemical explosives, they do not include two tank cars full of two industrial chemicals of the appropriate kind being brought together side-by-side and somehow combined.

I really do not want to talk about things that I would just as soon al Qaeda not know about, but I can tell you, there are many major catastrophes that could involve more than 1,000 people killed, more than $10 billion worth of damage done, or even with less than that that cause the people to be so horrified and so frightened that they lose confidence in the government’s ability to protect them. This is my personal definition of catastrophic terrorism.

Chairman Lieberman. This is an interesting and important discussion. I think your point is well taken, and in some ways, we have grown a little bit sloppy by referring as if it were an exclusive definition to chemical, biological, and nuclear, as weapons of mass destruction, as if they were the only weapons of mass destruction. In fact, as you point out, there was obviously mass destruction on September '11 without the use of chemical, biological, or nuclear weapons. It was catastrophic. That is perhaps a more inclusive term.

Dr. Branscomb. When we became aware that the President intended to submit legislation and, therefore, there was a high likelihood that we would have a bipartisan conclusion and there would be a Department created, we were still in operation so we were able to draw two very important—well, really three very important conclusions about any department, however it was structured.

One was that it must have a senior technical officer. Counter-terrorism is a technology problem. This Department is going to be a technology department and the best asset we have in this country, as you yourself said, are the brains and talents and enthusiasm, indeed, of the technical community to get behind this problem and see what we can do to substantially reduce it.

The other recommendation was something that we always had in there because we think it ought to be done now, even while there is an Office of Homeland Security and not yet a department, and that is the creation of what we call the Homeland Security Institute. What we have in mind here is a very specific notion. We believe very strongly that the biggest problem in utilizing scientific and technical capability is to truly understand what the problems
are, that is, what the threats are, what the vulnerabilities are, and how to do the risk analysis, how to model and simulate the threats and the vulnerabilities, how, in fact, to design test beds to determine what kinds of technologies actually work, to put together red teams, to test the technologies, at least virtually, and find out if they are working.

Ours is not a report with an R&D list of things to fund. This is a report that is aimed at giving the Nation truly the capability that it requires, no nonsense business. Therefore, we do deal extensively with our concerns about how the government goes about getting this work done, even though it does not deal specifically with the structure of a department.

Let me also say that the report does provide, we believe, a very useful tool to the Congress and the administration for testing what alternative forms that the Department might take would most effectively permit the government to use the science and technology capability to good use because we do, we believe, describe the criteria or the conditions that really are important for this R&D to be effective. As I just said a few minutes ago, the first of those conditions is that we truly know how to set the priorities. There is an enormous range of vulnerabilities. I do not think we can cover them all with the same level of effort, or even should try. The critical ones deserve the attention.

Now, one other principle I would like to address is not so explicitly given in our study but it is something that Dr. Klausner and I—we were the co-chairs of this study—believe is an important principle, and the principle is not addressed in either of the two bills, although the bills imply how this would be done.

The issue is this: We know that even if the administration puts R&D activities into a department, it is only going to put a tiny fraction of the government’s capability in science and technology. We had a huge capability developed all through the Cold War. So the question is, how would the Department acquire or access the capabilities of those departmental resources for getting urgent research done, and there are three possibilities.

The first, nobody wants to do. That is to move the entire enterprise and have the Department be the government.

The second one is to do what I believe the President’s bill suggests they intend, at least with respect to NIH, and that is to say, well, we can leave the people where they are in the current Department. We just take their money away and then give it back to them. But this time, it comes back with micromanagement.

Now, we have done that experiment. Take a look at DOE. Ask any set of witnesses whether they think the DOE system of managing its national laboratories is effective and they will tell you that there is a long history of micromanagement. It is not intended. It is just that the structure is such that the money that flows to those DOE labs comes from very large numbers of different line items in various appropriations managed by different offices, each of whom has control over a little piece of the budgets of one of those laboratories.

The third alternative, which we believe is the right one, is to ensure that there is a strong capability in the Executive Office of the President to create strategy for Homeland Security, at least for the
S&T piece of it—I believe it should be for all of it—to create that strategy and to get commitments from the whole government to support that strategy, so that the agencies that are qualified to contribute will know what the strategy is, will put proposed programs in their proposals to the President and the Office of Management and Budget. Those will be vetted at the Executive Office of the President on the advice of the Department, and let me say, with the support of OSTP, and then there will be a line item placed in that agency’s budget to do the work, and they know what they are supposed to do, they are given the money to do it, and they run the program.

They, of course, can be asked to be responsible to the Department to provide reports, briefings, whatever the Department needs to assess whether the work is well done or not. But this is a different method than taking the money away from the Department and then giving it back to them. Just give the money to the Department and make them commit what they are going to do.

Now, if I may, I would like to take off my academy hat and speak for this Lewis Branscomb who has spent 20 years running government R&D, 15 running IBM’s R&D, and 15 years studying it at Harvard. Because I was finally able to get your bill just a couple days ago and I studied it very carefully, I have an appendix to my testimony that separately is my personal evaluation, not the academy’s, the R&D dimensions of the proposed bills, each bill analyzed separately.

What I would like to do, if I have a few minutes left, is to take you through a comparison of the two bills, through at least eight of ten very important attributes the bills need to satisfy.

Chairman Lieberman. I am going to ask if you would hold that and then I will come back during the questioning period. I appreciate very much not only your testimony today, but the efforts you made in preparing the written testimony, which we will go over. So for now, I thank you, Dr. Branscomb. It has been very helpful testimony.

Our next witness is Dr. Margaret Hamburg, former Commissioner of Health of New York, Assistant Secretary of HHS, and now the Vice President for Biological Programs at the Nuclear Threat Initiative. Thank you.

TESTIMONY OF MARGARET A. HAMBURG, M.D., VICE PRESIDENT OF BIOLOGICAL PROGRAMS, NUCLEAR THREAT INITIATIVE

Dr. Hamburg. Thank you. I very much appreciate the invitation to discuss the policy implications for public health in bioterrorism threats that would stem from the creation of a new Department of Homeland Security, and my remarks will be much more focused on that particular question, although I am delighted to talk more broadly in the question and answer period.

The formation of such a Department is clearly needed, yet we should move forward carefully, as you are doing, to define what are the goals and how best to achieve them. The opportunities for greater efficiency, effectiveness, and accountability are fairly evi-

1The prepared statement of Dr. Hamburg appears in the Appendix on page 66.
dent in realms of overlapping activities, such as border security, Customs procedures, and aspects of emergency response.

How best to organizationally address the activities related to bioterrorism prevention, preparedness, and response is a more complicated question. Bioterrorism is fundamentally different from other security threats we face. Meaningful progress against the biological threat depends on understanding it in the context of infectious and/or epidemic disease. It requires different investments and different partners.

Unless we recognize this, our Nation’s preparedness programs will continue to be inadequately designed. The wrong first responders will be trained and equipped. We will fail to build the critical infrastructure we need for detection and response. The wrong research agendas will be developed. And we will never effectively deal with the long-term consequence management needs that such an event would entail. We may also miss critical opportunities to prevent an attack from occurring in the first place.

There are certain real advantages to placing these programs within a new Federal Department of Homeland Security. The biological threat—and the public health programs required to address it—is of profound importance to our national security. By residing within this new Department, it may command more priority attention and support. It may help ensure that experts in biodefense and public health preparedness are full partners at the national security table.

However, including biodefense and public health programs in the new Department has some serious drawbacks. A fundamental concern is they will lose program focus and organizational coherence by combining biodefense activities—which are largely within infectious disease, medicine, and public health—into a department devoted mainly to a very different set of security functions and concerns. These biodefense activities could well be swallowed up in this huge new agency, which will likely lack the expertise and technical leadership necessary to plan and direct vital bioterrorism preparedness functions.

In addition, most of the public health activities required for bioterrorism are just as important for the day-to-day functions of public health and medical care. In the months since September 11, the Bush administration, through programs developed and administered by the HHS Office of Public Health Preparedness and the Centers for Disease Control and Prevention, has made significant progress building the programs necessary to strengthen public health infrastructure for bioterrorism preparedness within this broader context.

If these programs are carved out and moved into this new Department, it will disconnect certain functions, such as bioterrorism surveillance, laboratory networks, and response from other essential components of infectious disease response and control. It will thin out already limited expertise and enormously complicate the ability of our public health partners at the State and local level to work effectively. Rather than consolidating functions in a single agency, transferring the bioterrorism preparedness activities into this new Department may actually require the creation of parallel and duplicative capabilities.
I would certainly recommend that HHS and CDC should continue to have direct responsibility for programs related to the public health infrastructure for infectious disease recognition, investigation, and response, including bioterrorism. However, we will need to integrate these activities into the framework for homeland security. To achieve this, a public health professional with appropriate expertise could be placed within the Department of Homeland Security with dual reporting to HHS. This person could work closely with CDC to achieve mutually agreed upon national security and public health priorities for bioterrorism preparedness and response.

Similarly, future preparedness requires a comprehensive bio-defense research agenda that links national security needs and research and development priorities and that shows proper balance and integration of relevant research activities across various departments and includes threats to humans, animals, and crops. Coordination of such an agenda could well be in the domain of a new Department of Homeland Security, engaging the expert input of Departments like HHS, DOD, Commerce, DOE, and USDA.

However, the role of the Department of Homeland Security should be that of coordinator-facilitator only. The actual design, implementation, and oversight of the research agenda and its component programs must remain at the level of the mission agencies where the scientific and technical expertise resides. HHS, in the unique role played by NIH, represents the primary department with responsibility for biomedical research and should remain central in setting priorities and directing and administering resources.

To address concerns raised across many domains, a new Department of Homeland Security will require significant expertise in public health, infectious disease, and biodefense. This must be seen as an important priority. The appointment of an Under Secretary for Biological Programs should be considered to oversee and integrate the various activities going on within the Department that relate to the biological threat. In addition, that individual might be charged with liaison responsibility to the various other departments with significant responsibilities and programs in the biological arena.

In the final analysis, strengthening our homeland security programs will depend on achieving dramatically improved coordination and accountability across many agencies, as well as the private sector. This could be achieved in many ways. Furthermore, no matter where the lines are drawn to define the components of a new Homeland Security Department, critical activities will fall outside. So whatever the new Department may look like, we must establish additional mechanisms to assure adequate oversight and coordination.

There are many more outstanding concerns that we could discuss and that will need to be clarified before such important legislation is passed, but in the interest of time, I have limited my comments.

I deeply respect your efforts, Mr. Chairman and the Members of this Committee, in taking on this vital but difficult challenge. I welcome the opportunity to work with you on this and would be happy to answer any questions you may have.
Chairman Lieberman. Thanks, Dr. Hamburg, for an excellent opening statement.

Next, we are going to hear from Janet Heinrich, who is the Director of Health Care and Public Health Issues with the U.S. General Accounting Office. Thanks for being here.

TESTIMONY OF JANET HEINRICH, DR.PH, RN, DIRECTOR, HEALTH CARE—PUBLIC HEALTH ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Ms. Heinrich, Mr. Chairman and Members of the Committee, I appreciate the opportunity to be here to discuss the establishment of a Department of Homeland Security. My remarks will focus on the aspects of the President’s proposal concerned with public health preparedness found in Title V of the proposed legislation and the transfer of research and development programs found in Title III.

The consolidation of Federal assets and resources for medical response to an emergency, as outlined in the proposed legislation, has the potential to improve efficiency and accountability for those activities at the Federal, State, and local levels. The programs with missions closely linked to homeland security that would be consolidated include FEMA, certain units of DOJ, and the HHS Office of the Assistant Secretary for Public Health Emergency Preparedness. The Strategic National Stockpile currently operated by CDC would be transferred to the new Department, as would the Select Agent Registration Enforcement Program.

Issues of coordination will remain, however. The proposed transfer of the MMRS does not address the need for enhanced regional communication and coordination and the NDMS functions now as a partnership between or among HHS, the Department of Defense, the Department of Veterans Affairs, FEMA, State and local governments, and the private sector. Thus, coordination across departments will be required.

The President’s proposal to shift the authority, funding, and priority setting for all programs assisting State and local agencies in public health emergencies from HHS to the new Department raises concern because of the dual-purpose nature of these programs. These include the CDC Bioterrorism Preparedness and Response Program and the HRSA 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 identify and respond to bioterrorist events.

Just as in the West Nile virus outbreak in New York City, which initially was feared to be a bioterrorist event, when an unusual case of disease occurs, public health officials must investigate to determine the cause. Although the origin of the disease may not be clear at the outset, the same public health resources are needed to investigate.

While under the proposal the Secretary of Homeland Security would be given control over these programs, their implementation would be carried out by another department. The proposal also authorizes the President to direct that these programs no longer be

1 The prepared statement of Ms. Heinrich appears in the Appendix on page 75.
carried out in this manner without addressing the circumstances under which such authority would be exercised.

We are concerned that the separation of control over programs from their operations could lead to difficulty in balancing priorities. Although HHS priorities 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 meningitis outbreaks or providing alerts to the medical community about influenza. The current proposal does not clearly provide a structure that ensures that both the goals of homeland security and public health will be met.

The new Department would also be given overall responsibility for research and development for Homeland Security. In addition to coordination, the role of the Department should include forging collaborative relationships with programs at all levels of government in developing a strategic plan for research. The new Department will need to develop mechanisms to coordinate information on research being performed across the government as well as end user needs. It should be noted that the legislation tasks the new Department with coordinating civilian events only, leaving out DOD and the intelligence agencies and also would allow it to conduct relevant research.

The proposal would transfer parts of DOE’s nonproliferation and verification research program to the new Department. For example, it is not clear whether only the programmatic management, the dollars would move, or that the scientists conducting the research would move. Again, because of the multi-purpose nature of these research programs, it may be more prudent to contract with the laboratories to conduct the research rather than to move the scientists.

The proposal would transfer the responsibility for all civilian health-related biological defense research programs, but the programs would continue to be carried out through NIH. These dual-use programs include efforts to understand basic biological mechanisms of infection and to develop and test rapid diagnostic tools, vaccines, and drugs. For example, research on a drug to treat patients with HIV is now being investigated as a prototype for developing drugs against smallpox.

The proposal to transfer responsibility for research raises many of the same concerns we have with the public health preparedness programs. Although there is a clear need for the new Department to have responsibility for setting policy, developing a strategic plan, and providing leadership for overall coordination for research, we are concerned that control and priority setting responsibilities will not be vested in the entity best positioned to understand the potential of basic research efforts or the relevance of research being carried out in other non-homeland defense programs.

In summary, many aspects of the proposed consolidation of response activities and research are in line with our previous recommendations to consolidate programs, coordinate functions, and provide a statutory basis for leadership of Homeland Security. We have, though, several clear concerns.

Mr. Chairman, this completes my prepared statement and I would be happy to answer any questions.
Chairman LIEBERMAN. Thanks, Ms. Heinrich. That was very helpful.

Next, Dr. William Madia, Director of the Oak Ridge National Laboratory and also Executive Vice President of Battelle Memorial Institute, which puts you on both coasts.

Dr. MADIA. Both sides, exactly.

Chairman LIEBERMAN. Thank you.

TESTIMONY OF WILLIAM J. MADIA, PH.D.,1 DIRECTOR, OAK RIDGE NATIONAL LABORATORY AND EXECUTIVE VICE PRESIDENT, BATTELLE MEMORIAL INSTITUTE

Dr. MADIA. Thank you, Mr. Chairman and Members of the Committee. It is a pleasure to appear before you this morning and provide my testimony. I will focus my remarks on how we can best apply the U.S. research enterprise in support of the proposed Department of Homeland Security, particularly as it applies to weapons of mass destruction threats.

The homeland security challenges we face are enduring, daunting in scope, and technically complex. Therefore, we require a science and technology response that is equally comprehensive.

With its emphasis on the critical role of science and technology, I would like to express my strong support for the President’s proposal for the creation of a Department of Homeland Security. I will make four points regarding science and technology in this new Department, which I believe are fully consistent with the President’s proposal.

First, I support the new Department being formally assigned the role of leading the Nation’s technology development and deployment efforts as they apply to homeland security. The proposal properly establishes that cross-cutting responsibility for science and technology with the new Department’s Under Secretary for Chemical, Biological, Radiation, and Nuclear Countermeasures.

Next, since we will never be able to protect ourselves against every threat, nor will there be unlimited resources, we must set our science and technology priorities based upon the best understanding of our vulnerabilities, the possibilities offered by science and technology, and the cost effectiveness of proposed solutions. Thus, it is essential for the new Department to establish a dedicated risk analysis and technology evaluation capability, obviously informed by the threat identification and analysis functions of our intelligence community.

Third, I support the establishment of a problem-directed technology development program in the new Department. This program should be responsive to the specific challenges and needs of the customers of the new Department, both those inside of DHS as well as other State and local agencies, those who actually will end up the technologies developed here. These programs should be designed to “close the gap” between new ideas for fighting terrorism and deployable solutions. The mode in which DARPA operates comes to mind as a good management model, as has been suggested by Dr. Marburger and also previous panelists.

1The prepared statement of Dr. Madia appears in the Appendix on page 89.
In addition, the elements of management flexibility and control outlined in the President’s proposal will be particularly important in managing the R&D function of the new Department.

Finally, the reason our Nation was able to deploy relevant and impactful technologies almost immediately in response to the terrorist attacks is because of past investments in the basic research which underpins these technologies. To ensure our long-term national capacity to create new and better solutions, we should provide continuing strong support for basic research programs in such areas as information technology, modeling and simulation, biotechnology, nanosciences, and advanced center technologies.

Like others, my comments do not imply the creation of extensive research capabilities in this new Department. Rather, DHS should draw broadly on our existing government, university, and industrial research base.

In particular, the national laboratories under the stewardship of DOE should play a very substantial role, since these laboratories have a wealth of specialized capabilities associated with weapons of mass destruction, and in particular in addressing nuclear, radiological, chemical, and biological threats. There are numerous examples of these capabilities, but they are in the written testimony and I will not cover them here.

The national labs, however, must, in turn, focus on and deliver against this new Department’s science and technology agenda. The Homeland Security Technology Center proposed at Lawrence Livermore provides a needed focus for this coordination and the intended Centers of Excellence at the major DOE national laboratories provides for an effective way to obtain the necessary commitment of resources.

In closing, I would like to reflect that only twice before in our history have we seen the Nation’s scientific community be so galvanized around a critical national issue as they are today on meeting the needs of homeland security challenges. The first occasion, which was the development of the atomic bomb through the Manhattan Project, ended up creating the Atomic Energy Commission, which later became the Department of Energy.

The second occasion was a response to Sputnik and President Kennedy’s challenge to place a man on the moon within a decade. That led to the creation of NASA.

With the formation of the Department of Homeland Security to give leadership and a focal point to our science and technology community, I am confident that today’s scientists and engineers will meet our homeland security challenges in a way that is every bit as successful as they have been in earlier times.

Thank you, and, of course, I would be glad to answer any questions you have.

Chairman Lieberman. Thanks very much, Dr. Madia, for an excellent statement.

Our final witness is Dr. J. Leighton Read, who is a General Partner of Alloy Ventures. In a general sense, Dr. Read is here to represent the private sector and the considerable contribution that the private sector can make to marshaling our technological and scientific strength in the war against terrorism, so I thank you very much for being here.
TESTIMONY OF J. LEIGHTON READ, M.D.,¹ GENERAL PARTNER, ALLOY VENTURES

Dr. Read. Thank you, Senator, and it is also not only a privilege to address the Members, but also to hear my fellow witnesses’ comments, informed by their experience and thoughtful work.

I am a physician by training. My academic research dealt with cost effectiveness and balancing of risk and benefit and costs in evaluation of new medical technologies and important medical decisions, but for the last 14 years, I have been starting biotechnology companies, helping them get funded, and now financing them as a venture capitalist.

I do not know that I can carry the full weight of representing the private sector in this country, but I would be delighted to share some thoughts with you about how people representing these vast pools of capital are standing by to invest in technology. There are about $75 billion of capital committed to venture capital partnerships that are not yet committed to new companies. So there are vast pools of capital out there.

Chairman Lieberman. Just repeat that again so we all appreciate it.

Dr. Read. There are $75 billion committed by America’s pension funds and endowments and individuals to venture capital partnerships that are ready to be invested. This is current——

Chairman Lieberman. It is sitting, waiting for appropriate opportunities, right?

Dr. Read. That is correct. By the way, talking about a few numbers, I saw a report the other day that venture capital-based companies now produce about 11 percent of the GDP, over $1 trillion, and if you add up all the direct and indirect jobs, you can get to something like 27 million jobs. So this is an important part of the economy.

These vast flows of capital include also the public markets, and in general, these investments are focused not on companies that earn their profits by doing contract R&D or by providing service businesses. The real attraction for this kind of capital is to invest in relatively high-risk, high-opportunity companies that can generate explosive growth into huge markets with really clear unmet need. That really brings us to the gap or the problem that the creation of a Homeland Security Department can address, because right now, it is not clear that there are those markets and that there are those opportunities in developing countermeasures.

There is a lot of marvelous and important groundwork being laid with R&D that is being sponsored inside the government and outside the government that will help provide a basis for that, but we usually—almost always—need the private sector to finish the job for countermeasures such as vaccines and drugs, biologicals, diagnostics—and it has to be clear that there is a market.

So I would like to emphasize the importance of including a focus on the results, the outcome, rather than just the process. The creation of a strong, centralized prioritization focus in the Department is absolutely essential to get this done. It is also very important that the incentives be clear. I do not think markets fail with re-

¹The prepared statement of Dr. Read appears in the Appendix on page 94.
spect to these kinds of products. Markets signal us about what the incentives really are, and some of your proposals, Mr. Chairman, are very welcome and deserve very serious thought.

In my opinion, in many cases, the most useful incentives are going to be quite particular to both the nature of the threat, whether it is biological or otherwise, and maybe even within the realm of biological, there may be important particularities in terms of how to design the incentives, whether a purchase fund or other types of incentives related to intellectual property or tax are important.

It would be a terrific opportunity to actually ask that the Department engage in dialogue with appropriate experts and that the Department have the ability to help influence and design incentives that will then require legislation to move forward, so I hope that the Committee will consider making that part of the authorization.

From my own experience, trying to figure out who is the go-to person to help make a decision or indicate whether there is going to be government interest, a customer, in other words, it is very hard. You have read report after report from Hart-Rudman, the DSB reports, and others that we have got this massive problem of duplication and silos and lack of coordination. Clearly, that is one of the opportunities that this Department can address.

We are going to have to make some tough choices. We are going to have to pull some things out of departments where people have been comfortable and there is a lot of expertise in order to get the coordination that we need, and I would advocate that we do make those tough choices, and then we also have to deal with the matter of coordination. I am concerned about having parallel functions that provide too many parallel groups. It will just continue to compound the problem of more silos.

So it should be clear to the private sector players that we want to engage, who to go to, who has got the decisionmaking authority, and what the ultimate rewards will be for those that are successful.

Now, one more point I would like to make. Some people have pointed out, or argued, worried, that this is too hard. There are just too many threats. Well, actually, if we think carefully about where the real damage could come from, infectious agents and specific biological agents that are readily available to our opponents now represent an opportunity to go ahead and commit to significant programs, as you said before in your opening remarks.

We generally have been successful when we try and build vaccines, for example, for particular targets. HIV is a counter-example. It remains very stubborn and elusive, but in general, when we have really focused our basic science at NIH, our applied research in industry, we have been successful in creating vaccines for important targets. So there is a lot of room for hope there. There is dual-use. There are going to be cases where the government is the only customer, but it is not just this government.

There was a little earthquake in Taiwan that produced a 10-day delay in the shipment of chips, disk drives, flat-panel displays to my home in Silicon Valley and a few dozen companies in Silicon Valley missed their quotas, missed their financials for the quarter.
This was the September 1999 event in Taiwan. That was just a 10-day delay.

Imagine five cases of confirmed smallpox on the island of Taiwan, how many months it will be before a shipping container in the Port of Oakland or a 747 full of those parts lands in the San Francisco airport? We and our trading partners are actually in an interconnected web. There has not been enough discussion about how we can get our trading partners and our allies engaged to pay their share of this so that we can create large enough markets to get the countermeasures that we need.

I look forward to a chance to discuss this further in our hearing.

Chairman Lieberman. Very interesting testimony.

Let me just go back to—as I begin my questioning—the $75 billion, to be clear. This, quite literally, is money that is waiting for the right opportunities, correct?

Dr. Read. That is correct, Senator.

Chairman Lieberman. I must say, and I do not know whether my colleagues on the Committee have found it—that since the tragedy of September 11, you have a sense that there are people in the private sector who have been active in relevant areas and are rushing to see if there is some way they can do business with the Federal Government, and that is part of the genius of our system. Obviously, we have to be discriminating customers, but it is a tremendous source of strength for us.

Obviously, the overall question we are asking here today is how best to marshal our public and private scientific and technological resources to aid us in the war against terrorism. For us, this becomes, in some senses, a much less imaginative but daunting challenge, nonetheless, which is where do we put the boxes and how do we organize them with lines of accountability and responsibility to make this work most effectively and efficiently.

So the first question I want to ask is that in the President’s proposal, interestingly, they have combined in this fourth section not only response to weapons of mass destruction but, if you will, science and technological responses. For now, I am wondering, why do that? In other words, why not take the actual response to the weapons of mass destruction functions and put it into the FEMA center division that both we and the President create and then do something separate for the science and technology.

I welcome contrary points of view, obviously. I wonder what the panel’s reaction, any of you, is to that. Dr. Branscomb, or any of you?

Dr. Branscomb. I believe that the Committee’s bill, S. 2452, is in many respects a cleaner—from a managerial point of view, a cleaner structure than the President’s. It clearly identifies the whole collection of border issues, that is, trying to control what comes in in the way of a threat, that is, trying to prevent the threat from being realized. That is one set of functions. And the other set of functions are those that involve a response to an actual realization of a threat.

Chairman Lieberman. Right.

Dr. Branscomb. Those are two different things. I think you have it sorted out just right.
I would comment that I found it very surprising that your Borders Directorate does not have the Transportation Security Administration from the Department of Transportation in it, but that is really not an R&D organization. In some ways, I wish it were. It has very little such capacity, but it is very much concerned with the fact that we do not have a single border. We have a very porous border. We live in a coupled world in global economies and the border ends up wherever that container ends up. So I think that unit needs to be in the program.

I am not happy with the notion that a number of specific research capabilities outside, such as the NIS Computer Security Division, would be picked up and moved into the Division. It can be more effective where it is.

Chairman LIEBERMAN. And which division is it moved into?

Dr. BRANSCOMB. In the President's bill, I believe it is moved into their first one, the Title II one.

Chairman LIEBERMAN. Correct. Incidentally, two things. One is that the President’s bill did add the new Transportation Security Agency to the border, the so-called “prevent” division, which we did not do. We did not do it because we heard some disagreement, but also because the new Transportation Security Agency was just being formed. Governor Ridge spoke to me before the President and the administration put out their bill and I told him then and I say it again, that I think they did the right thing. TSA should be in the new department.

Second, I hope members of the panel have gotten the sense, that even though there are differences between the President’s bill and the Committee bill, we are really working in a cooperative way now—without a lot of rigidity or pride of authorship—to figure out from the various proposals which is the best.

Any other responses to that? Yes, Dr. Madia.

Dr. MADIA. Mr. Chairman, to me, there are two very important issues on the question you asked. The first is addressed in the President’s bill. It clearly identifies the cross-cutting nature of science and technology in that fourth directorate, and so it is essential that that role be clear. We are talking about the role. And so this is not an organization dedicated just to weapons of mass destruction R&D, but it has got a broad cross-cutting R&D function.

The second, and probably the more important factor, is who you select for that position. Boxology is kind of nice, but the actual person in that role, as mentioned by a previous panelist, I think becomes the most important factor. Having an R&D person with the kind of culture and understanding of how to move science to technology to application will ultimately be more important than the structure, in my opinion.

Chairman LIEBERMAN. That is a good point. Yes, sir. Dr. Read.

Dr. READ. Just a brief addition. It seems to me that there are going to be opportunities to organize around the threat, as well, rather than the boxology that reflects our current governmental structure, and I would just urge, for example, that there be a decisionmaker at a high enough level related to the bio issues and a supporting panel at a high enough level that that is not lost. In some ways, there may be good models from the military that could be borrowed there in terms of——
Chairman LIEBERMAN. Say a little more about that, in terms of organizing for the threat.

Dr. READ. What I have in mind is that, and particularly with respect to engaging the private sector, I think that the nature of the problems are quite diverse. In fact, going back to an early discussion, it may be time to retire the term “weapons of mass destruction” because it is so confusing. There are very important issues related to bio that may be unique to bio. And while the management of science and management of research and some of that infrastructure is common, I think having people who are really the right experts for chem and nuclear sitting in on those discussions is not an efficient use of resources and that we ought to be able to concentrate the prioritization within bio. The interaction with the private sector and this huge task of coordinating all the places in the government should be concentrated at a high enough level that it is really meaningful by the specific threat.

Chairman LIEBERMAN. Good point. Again, I think from my point, I am going to try to stop using the term “weapons of mass destruction.” It takes a little more time to say chemical, biological, radiological, and nuclear, but as we learned on September 11, a plane can be a weapon of mass destruction.

Dr. Hamburg.

Dr. HAMBURG. I just wanted to add that while I recognize there are enormous pressures to move swiftly to create this new Department, there is a strong argument to be made, as my colleague, Dr. Branscomb did, that we really need a strategic framework as we shape this new Department, really defining the goals and objectives in the different arenas and the roles and responsibilities of the various component departments and agencies and also recognizing that, in addressing this problem, how the private sector and voluntary organizations interact is also key to a comprehensive and ultimately effective approach.

Perhaps it is a timid proposal, but perhaps one can do this effort in a somewhat incremental way, really focusing first on consolidating those programs, policies, and activities that clearly support a set of well-defined homeland security missions and concerns, the border security, Customs activities, some of the law enforcement and emergency response activities.

Recognize that some of the science and technology and research enterprises that we have been discussing really need to be closely embedded in the technical and scientific expertise that resides within a broader range of departments and that we need to be careful about disrupting many of those activities, including the public health activities that I discussed in my oral testimony. Coordination and accountability are key to making integrated, coherent, and comprehensive strategy in this area.

Actually moving the component pieces, taking away the money, giving it back to micromanage within those departments and other strategies that have been proposed may not ultimately be the most effective approach, and so in those arenas, we may want to first establish a much more structured coordination and accountability mechanism and then make decisions about how to move some of the actual pieces into an organizational structure.
Chairman Lieberman. That is helpful. My time is up, but Dr. Branscomb, do you want to say a quick word?

Dr. Branscomb. I just want to say there are three serious problems with the President’s proposal for how to organize the R&D in the Department. The first is that I believe it is totally unmanageable to give one of the four operating executives in the Department not only the responsibility for this enormously important problem of nuclear weapons and biological warfare and chemical warfare, they are also assigned by law and R&D function in support of those problems, and then they are also assigned an R&D function in support of the whole Department.

They are never going to be able to make those trade-offs between their R&D obligations to their own operational mission. Nobody will ever be satisfied they have done enough against those threats, and they simply will not do it for the rest of the Department.

The second problem is that the people you would most like to have doing that work on the nuclear problem and on the biological problem are the scientists at Livermore Laboratories. Those are wonderfully brainy people, very smart, long record of worrying about security. I do not think there is a one out there who has a clue what a fireman needs and can use. What if you give it to the fireman and he tries it and it does not work? He throws it down and says, "I have been fighting fires all my life. I am just going to go do it." That is the spirit of our first responders, and the R&D has to be very sensitive to the nature of those people’s real requirements.

The third problem is that even if that Title III division did not have this conflict of mission problem, you still have the problem that you have got four operating executives sitting at the table, one of whom is also the corporate R&D manager. I do not think that works either. I think there has to be a corporate R&D manager, which, indeed, your bill provides.

Chairman Lieberman. Thanks. That is very helpful. Senator Cleland.

Senator Cleland. Yes, sir. Thank you very much, Mr. Chairman. What a fascinating series of hearings we have had. I hope the American people are tuning in and listening. As Dr. Madia has indicated, this is one of those key turning points, moments, or pivotal times when the country has been shocked and—or from Aldous—if you like my quotes, here is one more. Aldous Huxley, the great British author, said, “Experience is not what happens to a man, it is what a man does with what happens to him.”

So here we are. We know what happened to us, and part of this Governmental Affairs challenge here on this Committee is to figure out now what we do about it, and there are lots of ideas.

But I will say, Dr. Branscomb, that I have often thought, coming from a very small town where I know the firemen and the policemen and the EMS people by name, and their dog and their cat—[Laughter.]

Senator Cleland [continuing]. That unless homeland security works at the hometown level, it is not going to work. So I think that is part of our challenge.
I do favor the Homeland Security Department, but I think it has ultimately hometown mission. That is the bottom line for it to work there.

I will say, Dr. Read, that if you know where you can lay your hands on $75 billion, you can buy ImClone, you can buy WorldCom—— [Laughter.]

Senator CLELAND [continuing]. You can buy Tyco, you can buy Enron cheap—— [Laughter.]

Senator CLELAND [continuing]. And save the American economy. I just thought I would throw that out there for you. [Laughter.]

Dr. Hamburg, I would like for you to think about this. The GAO has pointed out about the President’s proposal that the proposal does not sufficiently clarify the lines of authority of different parties in the event of an emergency, such as between the FBI, and public health officials investigating a suspected bioterrorism incident. This is exactly what we went through with the anthrax attack.

Again, the CDC, the bug FBI, was called into the case and they identified the bug quickly. Then the FBI itself was called in, shut down the crime scene, and in many ways, the CDC and the FBI then competed for their own piece of the pie, I guess, and there were two competing interests. The FBI is basically the law enforcement agency. As we saw in testimony yesterday, it is basically an 11,000-person law enforcement agency which is involved in secrecy, which is involved in non-dissemination of information, and probably building a court case over a long period of time.

An agency like the CDC is a public health agency that is interested in responding quickly to emergencies and getting information out, disseminating information quickly in order to prevent either further attacks or to deal with an attack underway. So two competing interests here.

Again, the President’s proposal has the CDC, for bioterrorism purposes, responding policy-wise to the Secretary of Homeland Security. But for operational purposes, I guess rations and quarters as we used to call it in the military, to the Secretary of HHS. I wonder if you feel that is a problem.

One of the ways I would solve it is create a center at the CDC, not move these wonderful people out who have wonderful synergy with the other public health officials in the other centers, but create a center at the CDC. Because 34 percent of the CDC’s work now has to do with bioterrorism, except it is, OK, you do this for a few hours and you do this over here. There is no real dedicated center. You have got a lot of experts, but there is not a dedicated center to that focused on it 24 hours a day, 7 days a week, that is, in effect, the Center of Excellence for what you do to prepare for a biological attack and what you do to respond to it.

If you had the center, then I think that dual master responsibility would work for policy, the Homeland Security. For administration, operational purposes, coordination with the other elements of the CDC, you would answer to HHS and the public health interests in there. Do you see this dichotomy creating problems, or is this the way to go?

Dr. HAMBURG. I think that your question really gets to the heart of the fact, as I discussed in my testimony, that the biological
threat is different and it is intrinsically embedded in the broader threat of preventing and controlling infectious disease threats. The CDC is really a unique national and international resource in terms of expertise and leadership in the area of infectious disease prevention and control and I do believe that we need to ensure that it is adequately supported in its activities that are broadly based and that we do not start to cut up the pieces, labeling some as bioterrorism preparedness and others as infectious disease control.

The anthrax letters that were disseminated last fall in some ways were misleading for what a bioterrorism attack might look like. I do not think the next time we see anthrax powder it will be delivered in a letter with a note saying, “This is anthrax. Take penicillin.” Most likely, there will be a silent release and without a fortuitous discovery or an announcement by the perpetrator. We will not even know that an attack has occurred until individuals start to appear in doctors’ offices, emergency rooms, or intensive care units, now spread out in time and place from the initial site of release.

We will not know whether it is a naturally occurring outbreak or an intentionally caused event in many of the scenarios that are likely or might potentially occur. Therefore, we need to have a well-coordinated and certainly well-funded and adequately supported infectious disease detection investigation and response capability and CDC is clearly our Nation’s agency to lead that effort.

Senator Cleland. And clearly, that is the key. Who is the go-to person when something like this happens? Other agencies are involved. Initially, I had legislation that said that, yes, based on the Presidential directive in 1995, the FBI in terms of a terrorist attack was the lead agency. In 1998, the Congress says CDC is the lead agent in terms of a bioterrorist attack.

I resolved that dilemma by legislation saying that the Secretary of HHS, in effect, had the power by the stroke of a pen to declare a national public health emergency and then, boom, the CDC would automatically be the lead agent. Maybe it should be the Secretary of HHS. Maybe it should be the Secretary of Homeland Security. I do not know, but the point is, there seems to be a threshold here in a terrorist attack that all of a sudden you realize, hey, this is not just a naturally occurring outbreak here. We have got a problem, and we had better get on it.

So I think there is a threshold level there where, ultimately, the experts, the 8,500 scientists and experts that deal with this are keyed in as the lead agent. That is why I am such a big advocate for a center.

Dr. Read. This is a very constructive observation that you have made about localizing that. I have worked with the CDC quite a bit in connection with a company developing a new flu vaccine. One of the most unique clubs in medicine are these doctors who wear these neckties or scarves with a picture of a shoe with a hole in the bottom. These are the guys and women who have served in the epidemiologic intelligence service who are the first responders to investigate. We really have two classes of events that actually call, I think, for very different skill sets and responsibilities.

Most of the white powder episodes, we are not going to know whether it is a disease or a false alarm, an influenza epidemic com-
ing around, and it is going to require that kind of medical detective work and the huge, competent laboratory back-up that our current CDC provides.

At some point in the future, someone will make the discovery that flips a switch and says, this is not a naturally occurring disease. This is a terrorist attack. And there will be the need for criminal law enforcement investigatory work, but more urgently, and especially if it is a transmissible agent, this is a whole different category than what we faced with anthrax, a completely different category.

We are going to face some really tough new issues that we should be preparing for now. The quarantine that must be enforced, and let us face it, it is a military operation, our National Guard, our police function, and maybe even our regular military are going to be involved.

This is not part of the culture of the current CDC, so we need to think about different phases, sort of the screening and the public health role that they do so well, and maybe that is the right place to put that center for after the switch has been flipped, but it is a different set of skills and responsibilities and I just urge careful thought about putting them in that role, in a police and quarantine role. We are going to face some very tough challenges as a society when that happens and we can minimize the pain by really thinking it through in advance.

Senator CLULAND. I think that is the point. I think that is one of the reasons for the hearings that we have had is to establish the— is it your understanding the best thing we can do is establish the protocol? Work these kind of relationships out before the popcorn hits the fan? Because we really did not have those relationships spelled out. Agencies just kind of reacted to the anthrax thing and a bunch of agencies got their fingers in the pie and—

Dr. READ. They did not do that bad of a job, by the way.

Senator CLULAND. Right, but there was a lot of miscommunication up front and early, and who speaks for the government and who does not. Dr. Madia.

Dr. MADIA. From the national lab perspective, we would support your idea of the Centers of Excellence because it does deal with the fundamental question you asked. It allows the laboratories, or CDC, in your case, to retain its own organic capability, the people, the infrastructure, the community that is necessary to do that. Yet, it gives DHHS a single point of contact to focus on that problem.

So what the Department is planning through its implementation is to establish these Centers of Excellence in the various national laboratories to meet your model. In our opinion, that would be applicable to other agencies who have major assets to bring to bear on this.

Senator CLULAND. Thank you very much. Dr. Hamburg, my time is up. Go ahead.

Dr. HAMBURG. I just wanted to underscore what Dr. Read had said and I certainly did not want to leave the impression that I thought the CDC could or should be in charge of the law enforcement/criminal investigation activities. But the challenge of responding to the threat of bioterrorism very much requires that these different cultures and agencies with different missions figure
out ahead of time how they are going to relate to each other and how they can support each other’s distinct missions in pursuit of a common goal. However, when you are dealing with control of a disease epidemic, one must be sure that the needs for disease control are clearly understood and that the criminal investigation activities do not undermine the ability of public health agencies and medical professionals to actually do everything they can in a swift and timely way to control spread of disease, treat individuals who are affected, and provide preventive therapy to those who have been exposed and are not yet sick.

I think that those activities can occur in a coordinated way, but it really depends on intensive planning and practice so that in a crisis, we are not thinking through these issues for the first time.

Senator CLELAND. Thank you very much, a key point, Mr. Chairman. My time is up. Thank you.

Chairman LIEBERMAN. Thank you, Senator Cleland. That was a very important exchange and you gave me another quote, which I think might be your own, “before the popcorn hits the fan.” It is a good one. [Laughter.]

Senator Akaka.

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

Dr. Hamburg, I particularly am interested in how we can bring things together to deal with the problem of bioterrorism. Two months before September 11, I chaired a hearing on Federal response capabilities to bioterrorism. There were three underlying concerns. First, the medical and hospital community needs to be more engaged in bioterrorism planning. Second, the partnership between medical and public health professionals needs to be strengthened. And third, hospitals must have the resources to develop surge capabilities. At that time, we talked about them halving their staffs, and what has happened to their surge response capabilities.

My question to you is do you believe we are better off 1 year later, and have the concerns raised at our hearing been met?

Dr. HAMBURG. I believe that we are better prepared today than we have been in the past to address the threat of bioterrorism, but there is still an enormous amount that we need to do and we need to do it swiftly.

I think that there are several critical elements of a comprehensive national strategy to prevent and respond to bioterrorism. Certainly, the most desirable strategy is to prevent an event from occurring in the first place and there is more than we can do, although steps have been taken to secure dangerous materials and to make sure that dangerous pathogens are only used in legitimate government, industry, and academic laboratories. So there are things we need to do to improve biosecurity.

Clearly, we need to strengthen the public health infrastructure, including the on-the-ground disease surveillance, investigation, and response capabilities, the laboratories needed to support those efforts, and the communication of information to all who need it. Those disease surveillance capabilities, depend very heavily upon the partnership between medicine and public health.

We need to make sure that our medical system can surge in response to either a bioterrorism attack or any other catastrophic event that will involve mass casualties, and the current competitive
environment in which the health care system operates has led to very significant downsizing of our health care capabilities and even a mild flu season can overwhelm our health care facilities, let alone a catastrophic terrorist event. So we need to really put enormous resources and attention to that problem and look at how we can plan to support surge, looking at local capabilities and how those could be augmented by State and Federal resources.

We also do need to have a continuing focus on research because that lays the foundation for future preparedness and that needs to involve better basic understandings of the organisms that might be threats and how the human body responds to those threats. We need to look at threats to plants and animals as well. We need to develop new strategies for rapid detection, new drugs, vaccines, and we also need to look at what we sometimes call systems research. We need to better understand issues about environmental safety and decontamination. We need to know more about how you make buildings safe through improved ventilation systems, what kinds of masks are really effective, etc.

So there are, I think, a number of critical domains. In many of those areas, we have established effective programs. Most of those programs need to be quite significantly strengthened and extended, and in some areas, we are still at ground zero in terms of developing the policies and putting in place the programs that are needed.

Senator AKAKA. Dr. Read, as I mentioned in my statement, the private sector has much to offer in fighting the war on terrorism. In your experience, what has been the greatest challenge for private researchers and small businesses to become involved in homeland security countermeasures efforts?

Dr. READ. Senator, as you mentioned in your opening remarks, there are so many stories of people that try and figure out who in the government they should go talk to to get feedback on whether their plan or their invention or their ideas are useful. We desperately need to identify the clearinghouse. It even has to start before that. There has to be a decisionmaker who has to have a strategy, and out of that strategy there have to be priorities, and those priorities have to be coupled with resources so that we can create incentives so that then the clearinghouse can actually do the work of starting to produce the outputs that we need. So we have a lot of work to do. I think this Department is going to help. So finding the go-to person, that is a big part.

The other really important part, and as a venture capitalist now, I have one of the most wonderful jobs in the world. I see entrepreneurs, inventors, college professors, and best of all, former entrepreneurs who have been successful who really know how it works and help them think about business plans that we might want to invest in. When we invest, we always get very involved in helping them build their businesses.

And right now, if somebody said, look at this terrific vaccine for Ebola, I really think we can do it, we have really figured it out, we have had this key insight, just to pick an example, but it could be a diagnostic or a drug, or better yet, some system where you could respond in the midst of an epidemic, to respond to some
brand new threat, some kind of research tool, and we want to build this thing.

Then when they get to the market estimate side of their business plan, you know, the worst thing you can put in a business plan for a venture capitalist is, “If we build it, they will come.” There has to be some conviction. There has to be some evidence that whenever you built something like this, they did come.

Well, we do not have that track record right now. There is no bio-defense industry—just to pick the bio area—right now because there is no market for a biodefense industry if it were successful, and that can be addressed.

So I think those are the two biggest issues, where do you get feedback and guidance, what the heck are their priorities, and then if we did hit the target, met the specification and built just what we need, who would be there to buy it?

Senator Akaka. You are correct. I meet with people who come to ask, where do we go, who do we see? They hear that funding is available but are not sure how to apply for it. These are the important questions if we are going to ensure we have the technology to address the problems.

You and I raised the idea of a clearinghouse. We need a Research and Development Outreach Office that encourages contributions from small businesses and nontraditional contractors. Do you believe that such a clearinghouse should be placed in the Department of Homeland Security?

Dr. Read. I believe that the new Department is the place where the private sector should be able to ask their questions and get real answers about whether they are working on the high-priority stuff and whether there will be markets there. Whether we call it a clearinghouse or not, I will leave that to you. But I do think that the function that you have described the need for and I commented on has to exist in this new Department.

Senator Akaka. Dr. Hamburg and Ms. Heinrich, I am concerned that Hawai‘i’s first responders and State and local authorities nationwide do not have access to reliable and timely information from Federal authorities regarding terrorism.

My question is, what kind of information do public health and emergency managers need, and what would be the best way to distribute this information in an effective and secure manner? Dr. Heinrich.

Ms. Heinrich. I think that at this juncture, the CDC programs to provide assistance to the States, in fact, not only help build the infrastructure for reporting of diseases from the State and local areas to the Federal Government, they are also building communications systems so that information can go from the Federal Government quickly down to the State and local area and also to physicians and emergency rooms.

We found out from our experiences with anthrax, for example, that there was not a clear message from the Federal Government about what the threat was and also what the possible treatment should be, or if somebody thought they were exposed, what they were to do. I think that with the programs now put in place from CDC, there is a real opportunity to correct those problems.
I do want to add on to what Dr. Hamburg said before, though, about State and local preparedness, which includes Hawaii. We are not there yet. Certainly, we are much more aware, but in our work in doing an assessment of State and local preparedness and also in our work right now on assessing emergency room crowding, we are finding that the people at the local level are planning. They are making assessments, or they will be making assessments of their needs.

They are not necessarily yet in the implementation mode and I just think that is really important for us to understand as we are trying to develop new policies and consolidate programs. We really do need to understand that our best information is going to be coming from the State and local areas and they still need a lot of assistance in bringing their systems up to where they need to be.

Senator AKAKA. Mr. Chairman, I know my time has run out, but I have another question or two.

Chairman LIEBERMAN. Go right ahead, Senator Akaka. We have got time.

Senator AKAKA. Let me ask a question to Dr. Madia. The President's proposal states," the technologies developed must not only make us safer but also make our lives better. While protecting against the rare event, they should also enhance the commonplace."

Dr. Madia, do you believe the Department of Homeland Security can reduce everyday low-consequence risks while focusing on catastrophic terrorism?

Dr. MADIA. That is a very important question, because as a Nation and as a Department, it is unfortunate, but we cannot protect against every threat, every day, of every consequence, and that is a reality we have to deal with in this country. I know we would like to be able to deal with that and give the public 100 percent assurance that low-consequence, low-profile events will be taken care of, but that is simply not the fact. That cannot happen.

So no department can do that because it would take unlimited resources to do that. So functionally, the answer has to be, of course, we could. But operationally and practically, it is never going to happen that way. One of the sad problems we face as a Nation right now is that there are lots of localized low-consequence events that this Department or any construct of government will not be able to deal with.

Dr. READ. Could I just comment on that?

Senator AKAKA. Please.

Dr. READ. First of all, I would urge that the mission for this new Department be really clear and that we not saddle it with traffic safety, which is, of course, much bigger on an annual basis, current harm to our population than the actualized terrorist attacks, but we should keep the mission as clear as we can.

But we should also look for the opportunities, which will be many, I believe, to exploit the beneficial dual use of investments in technology and infrastructure. When we improve our infrastructure, for example, I was at a meeting of some California public health officials soon after September 11 and we had public health officers exchanging cell phone numbers with fire officials. These people did not have them. The databases did not exist for that.
So creating infrastructure to deal with a rapid response to detect certain kind of attacks like bio and more obvious attacks, we are going to create infrastructures that absolutely help us with the day-to-day, with emergency response and that very important network. That is going to be a consequence.

The technology we build in the form of new drugs and vaccines and new research tools will undoubtedly have spin-off results in some cases. We have to be prepared to do the stuff that does not, as well.

So I see a lot of benefit, but I would not want to in any way saddle the mission with anything other than a really clear focus on this newly recognized and focused problem of homeland security.

Senator Akaka. Mr. Chairman, I have one final question.

Chairman Lieberman. Please, go right ahead.

Senator Akaka. Since we are talking about communication, Dr. Hamburg, as a public health official, you know the important role that veterinarians play in disease control. How do we increase communication among the Nation's veterinarians, medical doctors, and public health officials? Even more important, and let me ask this question, would the President's proposal do this?

Dr. Hamburg. I think, as we have learned from many naturally occurring events and now thinking about the threat of bioterrorism, we recognize that we have been too stovepiped in approaches and that we really need to engage the veterinary community. Particularly with respect to bioterrorism, many of the diseases, the pathogens of greatest concern are, in fact, animal diseases that can affect humans. And in addition, we certainly know that even without the loss of one human life, the enormous disruption and economic devastation that could occur from an attack on animals or crops would be a very effective strategy for a determined terrorist.

So we need to look at it. We need to broaden our thinking. I think you asked me before, are we better prepared? I think in most elements of response to bioterrorism, we have been moving forward. We are not anywhere near where we need to be. But one of the areas where we have lagged the furthest behind is engaging on the threats of agricultural terrorism and it needs to be a major priority.

In terms of engaging the veterinary medicine community in particular, it starts with awareness. They need information. They need to be brought into existing systems and programs. They need to be at the table when the others are at the table discussing this problem and we need to develop the working relationships and situational awareness that will allow for a more comprehensive approach.

Senator Akaka. Thank you, I just wanted to inject that the terrorist threat is also to our livestock.

Ms. Heinrich, as Dr. Madia has said, we are faced with new risks. We cannot protect ourselves from every threat that comes. How do we make the general public aware of this new reality while maintaining their confidence?

Ms. Heinrich. I think this is a role that public health officials can play in terms of educating the public and making sure that we have programs that help people understand what are the real risks, and what are the potential threats. It is not easy, because
I think the messages are complicated. I think that people really do need to understand that infectious diseases are real, emerging infectious diseases are real and that they need to be aware of their pet’s health as well as the health of themselves and their children and they need to know that it is no longer just the chronic diseases that we need to be concerned about but that we do need to be thinking about infectious diseases. And they need information on what to do, what they should do in terms of seeing their physician or primary care provider or the need to even go to the emergency room.

In response to your question to Dr. Hamburg, I think it is important for us to understand that, again, in the President’s proposal, there are some efforts there to bring in some aspects of the Department of Agriculture and there is discussion of food safety, which, of course, involves veterinary health. But again, you have to ask yourself the question, or we have to ask ourselves the question if the approach that is used is necessarily the best one to make sure that you have the coordination of effort that you want.

I would just emphasize again that the real critical components are that you have that strategic plan and that you do have the opportunity for risk assessment, but there are a variety of methods for coordination of these overarching scientific programs.

Senator AKAKA. Mr. Chairman, you have been very generous with the time, and I thank you and our witnesses.

Chairman LIEBERMAN. Not at all.

Senator AKAKA. I will submit my other questions.

Chairman LIEBERMAN. Thanks, Senator Akaka. I appreciate your questions very much. I do have a few more questions myself. Let me come back to what one of you nicely called the boxology part of this, because that is where our work begins, but hopefully, our work and the work of the government does not end there.

One of the key questions raised is—assuming for a moment, we set up a Science and Technology Office in the new Department—what comes under it and where the funding streams go. The administration’s proposal kicked up a fair amount of dust and anxiety by seeming in the first instance to take all of the Lawrence Livermore Laboratory and put it into the Department, and then parts of NIH. As it turned out, as there has been clarification or adjustment, it seems that part of Lawrence Livermore and NIH are involved. Specifically, while the money for the personnel and the research goes through the Department of Homeland Security Science and Technology Office, the people stay at the laboratory and NIH.

I still think there is a lot of anxiety, certainly, from members of the Senate who are close to, for example, these two institutions or agencies, NIH and Livermore. I wanted to ask you, so far as any of you want to respond, and we could begin with Dr. Madia, since you represent another laboratory, what your reaction is.

The other alternative here clearly is not to do that and to create an additional funding stream, an agency—I am calling it SARPA—within the Homeland Security Department which would set the goals and agenda for science and technology with regard to homeland security, have additional funding, hopefully, of its own, but not in any sense move personnel or money from the existing agencies.
So I want to invite your reaction to both of those, Dr. Branscomb, and then we will come right back to Dr. Madia.

Dr. BRANSCOMB. Thank you. As I said earlier, I think what is essential when we are looking at the R&D activities, that the technical talent for the moment, at least—and by moment, I mean the next year or two, until this Department is a reality and can function, in fact, stay where it is.

The key to being able to do that is, in fact, to ensure that it can be funded where it is and that the agency undertake commitments, program commitments, that are responsive to a technical strategy for homeland security. The Department should be the principal origin for that strategy. But since the strategy clearly calls for other departments of the government to commit their resources or their people, their talents and their capabilities to the effort, that decision has to get made at the Executive Office of the President level.

And I would like, if I may, to comment on the proposal in your bill to create a National Office for Combating Terrorism, because you have not only identified the necessity for that strategy being constructed, you have, in fact, equipped this statutory office with quite a number of authorities which would ensure, if it were accepted, it would ensure that it had a major role in the preparation of this governmentwide budget for counterterrorism which OMB then would have to work into the rest of the government program.

I suspect that there will be people, OMB executives present and former, who will object to that much legislative effort in the budget process in the White House, but I think you are absolutely after the right goal. I would call attention to the fact that the President’s bill makes no mention whatever of how a national strategy is going to be put together that would engage on line items, budget items, at Commerce, at NIH, at Energy, where they commit to do things, to give reports to the Department, but they have got the money, they are responsible for it, and they know how to spend the money fruitfully.

I suspect the reason why the President’s bill does not contain any mention of that is because the President did, in fact, when he announced his intention to promote the Department, noted there would still need to be an Office of Homeland Security at the White House.

Chairman LIEBERMAN. Right.

Dr. BRANSCOMB. And, indeed, he recognizes that. I also suspect that he did not put it in the bill because he does not want it to be a legislated office.

Chairman LIEBERMAN. That is also correct. That is clear.

Dr. BRANSCOMB. Because he can appoint it without having to have Congress’s permission.

Chairman LIEBERMAN. Right, no advice and consent or a requirement to testify before Congress.

Dr. BRANSCOMB. But my concern is that because it is not mentioned—also, there is very little in the President’s bill about how that global strategy would even be worked on in the Department. But I think that capability is crucial to not seizing the research capability and putting it in the—all of it and trying to put it in the Department.

Chairman LIEBERMAN. Dr. Madia.
Dr. MADIA. Mr. Chairman, when I heard you initially describe the SARPA concept, what immediately came to mind was this Homeland Security Center at Livermore, which is intended to be a DARPA-like organization. It would understand the needs of the various customers of this agency and would fund, like DARPA does, research at various institutions, including the laboratories, bring that back and provide that to the Nation. So I did not hear from a functional standpoint much difference between——

Chairman LIEBERMAN. That is interesting. So you would say that part of Livermore might do what we are thinking——

Dr. MADIA. As far as I understand what is in this proposal, functionally, when you were speaking this morning, that is what immediately came to mind.

And from an R&D provider standpoint, that is very common. National laboratories work across the full range of government. Our customers include DOD, DOE, EPA, NASA, HHS, CDC, and so there are already providers which are scattered around the country, are ready, willing, and able, as Senator Akaka mentioned, to bring their talents to bear on this problem. What they need, as Dr. Read pointed out, was a single point of contact, whether it is SARPA or the proposed Center at Livermore, to me, that meets that functional need.

Chairman LIEBERMAN. Right.

Dr. MADIA. The second point of your question, it was not as if government was not doing anything at all on homeland security. Spread across government agencies, including the Department of Energy, were certain programs that one would look at from a national perspective and say, this looks like a counterterrorism or a bioterrorism or a counter-nuclear weapons activity, and those kinds of transfers, I think now are appropriate, because they would be core, programmatically, core to this new Department, in whatever incarnation it ends up.

There are many places where there is a dual-technology application, where the benefit would go to CDC and DHS. In my opinion, those are best left in their home institutions through these Centers of Excellence we talked about earlier with Senator Cleland.

Chairman LIEBERMAN. Dr. Branscomb, the Committee which just made its report earlier this week recommended the creation of a Homeland Security Institute. Now, why have another institution different from the Science and Technology Office, however it is constructed, that we are talking about in the new Department of Homeland Security?

Dr. BRANSCOMB. The reason is that this supposed institute supports the decisionmaking, the strategic decisionmaking by the chief technical officer and the Secretary and Deputy Secretary of the Department. It plays exactly the same role—for Homeland Security that organizations like Mitre Corporation, Aerospace Corporation, Project Rare Force at RAND, the Institute for Defense Analysis play in support of defense. These are all contractor-operated dedicated facilities to a single customer. They work only for that customer. And what they do is systems analysis, they analyze the problems. These are very complex systems problems.

Chairman LIEBERMAN. Right.
Dr. BRANSCOMB. When you look at infrastructure and its vulnerabilities, one section of the infrastructure, if it collapses brings down the next one. These are complex problems and setting the priorities is not a trivial problem. And indeed, if the industry comes in and says, “I have got a great idea, is there a market for it in the government?” You cannot answer that question unless you have done this kind of systems analytic work.

So it does not need to be a very big organization. I would guess 200 to 300 people. We did not try to size it specifically. But I think that the authority to create it is absolutely essential.

Chairman LIEBERMAN. OK. That helps me understand it better. Let me go back to the dialogue with Senator Cleland, and I want to direct the question first to Dr. Hamburg, but Ms. Heinrich and others may have an opinion on it. As you know, the Department of Health and Human Services responded to last year’s anthrax attacks by forming the Office of Public Health Preparedness, which coordinates all departmental efforts to combat terrorism within HHS, including managing the public health care required during an attack and directing research efforts to fight bioterrorism.

The President’s proposal would transfer this entire office to the new Department. I wanted to ask you all, and first Dr. Hamburg, based on your personal experience, what you think of the idea, particularly given the dual role of the office to manage public health readiness and advise the Secretary on biomedical research issues. Can it operate effectively outside of HHS?

Dr. HAMBURG. I think that the creation of an Office of Public Health Preparedness within HHS was a very important and appropriate step. Actually, it was a recommendation of the outgoing administration to create such an office, recognizing that there really needed to be much more focused attention and coordination on issues of public health preparedness, particularly bioterrorism. Also there was a requirement—just as we have been talking about with respect to the creation of a Department of Homeland Security—to make sure that all of the components of response and preparedness for HHS were, in fact, being addressed; that there was a strategic framework and that someone was accountable for making sure that there was a comprehensive, integrated program, and that budget priorities reflected that strategic framework. The best way to do that was with an Office of Public Health Preparedness so that the needs of CDC, NIH, FDA, and other important components of HHS responsibility and public health preparedness and response could all be addressed and accounted for.

Taking that and moving it lock, stock, and barrel to a Department of Homeland Security, I think is problematic because it will disconnect many important functions that have broader public health preparedness roles from those that are more directly related to bioterrorism preparedness. That is of enormous concern to me, because of my bias that I have stated here that, really, the only way to effectively address these concerns is to think about the continuum of infectious disease threats with bioterrorism being at the extreme end.

Certainly, there are elements of public health preparedness and response that are cross-cutting. The needs to support mass casualty care are very important to integrate closely with the functions of
a new Department of Homeland Security, for example. And so I
think that there are components of the HHS public health pre-
paredness response that can be pulled out and integrated into a
new Department of Homeland Security, but I think one has to take
a very systematic look at those elements and the functions they
support and where they can best be housed.

If this new Department of Homeland Security is effectively defin-
ing homeland security quite broadly, and I think this is one of the
dilemmas that you face, then those functions could find a com-
fortable and natural home. If all of FEMA is now part of the new
Department of Homeland Security so that the emergency response
functions of FEMA are all being managed within that new Depart-
ment, then I think you really almost need to integrate some of
those components from HHS into that framework. But I think that
the elements that support the public health infrastructure and re-
response at the national, State, and local level are much harder to
label as, this is bioterrorism related or this is homeland security
related and move it, because it is part of a much more broad-based
and complex system for public health in this Nation.

Chairman Lieberman. That is a very helpful answer.

Let me take us beyond the boxology now into what this is all
about, which is maybe to give us a little bit of a sense of what
science and technology can, in the years ahead, do to help us in the
war against terrorism.

I am going to start with you, Dr. Madia. Actually, Senator
Thompson left a few questions for you. Most of them have been
asked, but this one has not and it is a good way to lead in and then
I will go to Dr. Read or anyone else who wants to comment.

First, if you can describe some of the work being done at Oak
Ridge now that either is already related to homeland security or
might be in the next couple of years.

Dr. Madia. I thank you. Your question can be answered in three
basic time domains, what we can do today and has been done
today, an intermediate term, and a long term. Fortunately, there
is a lot of activity today that is directly applicable to homeland se-
curity.

In a really exciting program that connects both the laboratory
and private sector in Oak Ridge, we are developing a concept called
SensorNet. SensorNet literally uses the existing cell phone tower
infrastructure, which is ubiquitous across the United States. Those
towers in public buildings and post offices have an interesting ca-
pability that we do not think of in terms of homeland security.
They have the power and the telemetry necessary to transmit early
warnings to first responders on a very, very short time frame.

We have successfully demonstrated this technology now both in
Nashville, Chattanooga, and Knoxville, Tennessee, where you just
hang on cell phone towers chemical, biological, nuclear detectors,
and they are just prolific. You tend not to see them, but they are
in high population densities.

Chairman Lieberman. You mean they are constantly sending out
reports over the system?

Dr. Madia. Senator, what we found is that these towers are in
constant contact with emergency operations centers used by the
private sector in their normal cell phone communication, full
diagnostics. If you would break into a cell phone tower, it is known immediately at the emergency operation centers by these cell phone companies. They are in constant contact, literally.

So, therefore, if you hang a radiological sensors on a downtown cell phone tower and it begins to pick up a mass release, very quickly, you can begin to transmit, not to national lab folks, but to first responders, something is happening in downtown Washington. Here is the meteorological data, which is also available on those towers. Here is the evacuation path.

So there is a lot of very near-term, actually quite pedestrian technologies that are, in fact, available today for deployment, and these are some of the concepts the new Department needs to look at as it does its triage on the thousands of ideas in front of it.

Chairman LIEBERMAN. That is a great idea. Let me make sure I understand. The radiological testing device or sensor would immediately convey a report. It is not just that something went off, it would send——

Dr. MADIA. It gives you a concentration——

Chairman LIEBERMAN [continuing]. Some data across the wires, or across the wireless.

Dr. MADIA. The reason I used the radiation example is because in those cases, the sensor technology is far more sophisticated there than you have in the chemical and the biological arenas. So you do not have such ability to give you such absolute accurate information on the biological side as you do primarily on the chemical and nuclear side.

Chairman LIEBERMAN. Yes.

Dr. HAMBURG. Can I just interject? I may have misunderstood, but I think it would be a very dangerous concept to pursue sensors that would immediately send information about a possible attack to first responders. There needs to be a mechanism to assess the quality of the information, whether it is radiological, chemical, or biological detection, and confirms that the threat is real and verified and then provides the first responders the information that they need for how to respond.

Certainly, you want to get quick information that is an early warning that something may be out there, but I think the goal is not to create a system that sort of immediately beams information out without any quality control. We know certainly from the anthrax experience that our technologies just are not there. Maybe some day that would be great, and certainly going into a threat situation, you want first responders to be equipped with something that will tell them of a possible threat so they can protect themselves, but——

Chairman LIEBERMAN. Yes. But you are saying that——

Dr. MADIA. Dr. Hamburg’s comments are actually correct.

Chairman LIEBERMAN. Right.

Dr. MADIA. When the demonstrations were actually done in Tennessee, the information first went to the Tennessee Emergency Operations Center, and then was qualified by the EOC directors of the State. Then they went through the first responder alert.

Chairman LIEBERMAN. But the important point you are stating is that here is a resource that you could build on to——
Dr. MADIA. The Federal Government, by the way, could never invest in it. You would never rebuild the national cell phone tower network, with 30,000 towers around the country.

Chairman LIEBERMAN. No, it is a good example. Anything else?

Dr. MADIA. That exists currently in the private sector and this is a good partnership between government needs and private sector needs, and so it is a good example for that.

Chairman LIEBERMAN. Good idea.

Dr. MADIA. But you are absolutely correct. You filter the data, do the analysis, and do not just call some fire department and say, go north.

Chairman LIEBERMAN. Do you want to give us another example?

Dr. MADIA. What you see on the energy side—one of our big long-term problems is the fragility of the energy grid in this country. It is taken down by natural events, quite often. Some very interesting technology——

Chairman LIEBERMAN. Do you consider Enron to be a natural event? [Laughter.]

Dr. MADIA. Unfortunately, it is a very unnatural event.

Chairman LIEBERMAN. That is another part of this Committee's work. We will leave it aside for now.

Dr. MADIA. This whole concept of self-healing energy grids is coming out of multiple national laboratories. If a main part of the grid goes down, through smart technologies that run all the way from the power stations to your refrigerator, they can literally now begin to sense a problem on the grid as it is occurring, can begin to shut down certain parts of the grid and reroute power.

There are certain printers, I am sure you have in your office, that today can sense an upcoming problem on the printer for your computer and send a signal back to some command post saying your printer is about to go out. Those same kind of technologies are clearly deployable in our energy infrastructure over the next 5 to 10 years. That is a really long-term example of the kind of technologies that are applicable.

Chairman LIEBERMAN. Great. Dr. Madia.

Dr. MADIA. One quick comment. A lot of our discussion today has been about the bio threat, and I do not mean to diminish the bio threat at all.

Chairman LIEBERMAN. Sure.

Dr. MADIA. But it would be a huge mistake for us to ignore or not give sufficient attention to the nuclear threat. Now, again, we are the national laboratories and we play a substantial role there. But the unfortunate reality of nuclear threats is the materials exist, the science exists, and the technology exists. A weapon that could sit on this table could completely devastate a major U.S. city.

And yes, we should talk about threats to agriculture, chemical threats, biological threats, anthrax threats, but in reality, this Department, I think this government, has to deal with the extraordinary consequences possible if a terrorist coming out of a country that has the assets available tries to deploy or use a nuclear weapon.

So there is a lot of talk about biology this morning. It is very important, but it would be a huge mistake for us not to explicitly deal with the overwhelming consequences of a nuclear event.
Chairman LIEBERMAN. And here, you are not talking about a nuclear weapon delivered by a ballistic missile, or are you?

Dr. MADIA. I am not, and I am not talking about a radiation weapon, either, which has certain consequences. I am talking about a low-yield, a poorly-developed nuclear device. Take the technology deployed from the Manhattan Project, very pedestrian technology. If someone has the right kind of material, and that is the central issue here, but access to that material unfortunately is in question, especially in the former Soviet Union, those kind of threats, to me, are the kind of enormous consequence threats that the American public expects this government to deal with.

Chairman LIEBERMAN. Right. And here, we are talking about something being brought in in a suitcase or on a truck or——

Dr. MADIA. A poorly-constructed low-yield device is deployable in at least a truck.

Chairman LIEBERMAN. Are the labs doing work on——

Dr. MADIA. Absolutely. My point was, there was a lot of biology talk this morning.

Chairman LIEBERMAN. No, understood. Good point.

Dr. MADIA. It is still very important, but——

Chairman LIEBERMAN. Dr. Branscomb.

Dr. BRANSCOMB. I agree with his assessment that that is the critical risk. The level of the risk is 100 percent, if you believe that the terrorists can come by the appropriate, relatively modest amount of highly enriched uranium. We know that if they can, they can get it in the country. There is no way now we could stop it. And if they get it in the country, they can rent a loft in downtown Manhattan and in a relatively short time assemble a nuclear weapon out of that material. It is well known how to do that. It will not be very efficient, but it will kill tens of thousands of people, if not more.

Chairman LIEBERMAN. Yes.

Dr. BRANSCOMB. What can the government do about that? There is almost nothing R&D will do about that, but there is something to do. It is terribly important. We have an arrangement right now with the Russians in which they are cooperating with us on our helping finance the cost of taking their hundreds of tons of highly enriched uranium sitting there in storage. It is well protected where it is now, but they have agreed to reprocess some of that material down to where there is only 20 percent enrichment level. It cannot be made into a weapon at that level, and that is fairly cheap to do. Later on, you can improve its concentration sufficient for use in a power plant, but still will not be able to make a nuclear weapon.

That is a case where the Russians are willing to work now. If the government does not put up the money and complete the program while they are playing the game, we will regret it for the rest of our lives.

Chairman LIEBERMAN. There is a lot of support here for what started out as the Nunn-Lugar program of cooperative threat reduction. There was some uneasiness about this administration’s initial response to it. It looked like it was going to cut back support. But I think we are turning that around, and that is critically important.
I presume one of the other things science and technology might do is to increase our capacity to detect when uranium might be brought in by a container——

Dr. BRANSCOMB. We should certainly work at that, but it is very difficult to do because the materials are not very radioactive and they are easy to shield.

Chairman LIEBERMAN. We have had testimony here that one percent of the containers coming into the country are opened or checked in any way, mostly through paperwork, and not even opened.

Dr. MADIA. Detecting those kinds of materials is far easier than detecting the precursors to chemical or biological weapons.

Chairman LIEBERMAN. Yes.

Dr. MADIA. It is not easy, but it is far easier there than it is on chemical and biological.

Chairman LIEBERMAN. Dr. Read, talk to us a little about the state of activity in the private sector today. I know you are focused particularly on biotechnology responses. A new industry may emerge from this crisis which might be called the biodefense industry.

But it is my impression both in this area, biodefense, but also in a whole host of other areas, that proposals are coming through the door to us about biometric devices to check people coming in through airports, for instance, etc. Part of this is the good old healthy American spirit of entrepreneurship, that this is a need, this is a new market, and so people want to be part of it, part of it because of profit motive, part of it patriotism. Am I seeing this correctly, and what kinds of activities are you seeing in your field that already hold some hope to protect the security of the American people here at home?

Dr. READ. Well, clearly in the last 9 months, Senator, there has been a lot of new excitement about how people could apply technology they have already been working on to some of these problems, and we have already discussed the confusion that follows from trying to find a customer for that.

DARPA, by the way, is a marvelous model for funding high-risk early-stage work. I have had some fair interaction with them and various individuals there. It is a good team. They have a great culture to do this, and they have something else that I hope if you create SARPA that you will endow it with, which is a freedom to operate away from the unbelievably burdensome procurement rules that are part of most defense procurement. And so they have this other category. I do not know all the names here, but you know what I am speaking about. This is terribly important for small companies that cannot invest in all the infrastructure to comply with the FARs and the various rules. So that would be worthwhile.

It should also be noted that the folks at DARPA often, at least in private, will express some concern that their customer, the DOD, when they throw a successful DARPA-sponsored research project over the wall that they do not even hear the splash on the other side. We should be careful not to focus on the process of getting a bunch of research started in these areas without very careful thought about who the customer is, the kind of deployment issues that were just discussed about the radiation sensors, for example,
and also about how much of this ought to be done in the government and how much ought to be done in the private sector.

The ground has been laid in the case of countermeasures against specific biological agents based on huge and successful investments in the basic science, underlying virology and microbiology, largely at and through the NIH. We have fabulous groundwork. It is our unique asset in terms of being able to deal with this. We really are prepared to then start translating that into specific vaccines for the highest risk threats, highest in terms of their availability, the agents' availability to the bad guys, highest in terms of their deployability, and highest in terms of their potential to cause panic and economic disruption because they are transmissible, for example, as opposed to a non-transmissible agent.

So I am quite optimistic, and I have seen research programs targeting many of these animal pathogens or pathogens of people who live in the poorest parts of the world where we have the beginnings of programs that could be accelerated. Much of what is going to need to happen and most of the dollars to actually have something in a vial that could be drawn up in a syringe or given by a nasal spray or one of these other approaches is in the application research, the applied research, development research, the creation of manufacturing facilities, and so on, and that has historically been successful in the private sector and not as a function of the direct government facility or under government direct internal control, and so we need to organize for that. That is an important part that is missing right now, is the market signals that would justify the flow of private capital to finish the job.

I am also very encouraged about high-risk, far-out ideas, which Dr. Hamburg might want to comment on the plausibility of. In the middle of an epidemic—perhaps you remember the movie "Outbreak," where Dustin Hoffman manages to get some serum from this fictional primate that is spreading the outbreak and something magical happens in test tubes and columns and stuff and they get a serum that he gives to his girlfriend in the movie and she survives.

Well, Don Francis, who is one of our great AIDS researchers and discoverers, advised on that movie and he took me through it. Every part of that is unproven, but it is not completely implausible that we could develop tools that would allow a rapid response. We should not set expectations too high. These are long-term ideas. But, I see unbelievable stuff every day in business plans from very plausible, credible scientists related to biology and high technology. We do need to invest in some of that. We need to make it clear that there will be a market if we are successful.

Chairman LIEBERMAN. And this Department can send out some signals and give some incentives that would do that.

Just to go back, what you are foreseeing is an age in which we are all going to be looking to take a vaccine that will protect us preventively. We are not just talking about treatment once, God forbid, a chemical or biological attack occurs, but to prevent it proactively.

Dr. READ. These are complex threats that are going to roll out with more and more sophistication over many years as our opponents gain more technology, sophistication, and as state-sponsored
resources come to bear. We need things that can be held in reserve for the worst possible case.

These may be products we would never dream of giving people under times of low threat. They may be vaccines or drugs with very high side effects, very serious mortality rates that we would never tolerate, but we want them in the stockpile. In fact, we may even want them forward deployed so on a hair trigger we could get protected.

We may need to have things that are right out there available, and there may be threat levels, for example, in which we rethink the recent decision, which I would agree with, that we not vaccinate with the smallpox vaccine. But we can imagine a threat level, and maybe even future generations of smallpox vaccines that are so safe that the right thing to do is go ahead and immunize the population.

Chairman LIEBERMAN. Sure.

Dr. READ. So it cannot be scattered throughout DOD and HHS and all these other departments. This new Department has to be the focus for getting the interplay between the characteristics of a particular countermeasure, its risks and benefits and pragmatic deployability, whether it needs freezers to be stored and so on, balanced with the——

Chairman LIEBERMAN. I find this exciting and also reassuring. I think part of our responsibility as leaders now is to be reassuring and part of our capacity to do that is to bring our enormous science and technology prowess to bear on these problems.

I do not know if anybody else wants to give us a response. We always like to end optimistically.

Dr. BRANSCOMB. I would just like to pick up on this last point, because I believe that one of the keys to the success of this enterprise is to adopt a technology strategy that does, in fact, look for the concurrent development of technologies that do address the homeland security threat and at the same time either enable you to do that much cheaper than anybody thought you could, or equally important, provide civil benefits, just as, indeed, improving the public health capability will do.

Chairman LIEBERMAN. Sure.

Dr. BRANSCOMB. Our report gives a lot of examples of that. One of the reasons why I think that is very important is because there is another role for industry here. Industry owns and operates almost all the systems that are the vulnerable systems in the country, with the single exception of the cities. So they have to worry about being attacked as well as the fact that they do, in fact, do three-quarters of the Nation’s R&D and clearly are a major asset there. If they are going to be the targets, why have they not made themselves less vulnerable? Answer: There is no market for being less vulnerable than they are. They are at equilibrium with the business justifications.

And so there has to be a partnership between the government and those industries that will cause those, in some cases, very glaring vulnerabilities to be addressed collaboratively. Obviously, we can regulate them into doing it. We do not want to do any more of that than we have to. We could bribe them into doing it. We surely do not want to do that. So what is left, other than maybe
some antitrust provisions that might be possible that would allow an entire industry sector to get together with the government present and discuss what they are all going to do voluntarily.

But the other interesting one is the role of the insurance industry. I do not know if that has been brought to the Committee's attention——

Chairman LIEBERMAN. No.

Dr. BRANSCOMB [continuing]. But it is already true. I know people who are in the profession. They are engineers and technical experts in vulnerability analysis and risk analysis who are consulting with insurance companies who are now setting their rates so that the rate of the insurance depends on the extent to which the customer has, in fact, dealt with some of these terrorist vulnerabilities. But getting that technically correct is a big job, not just from individual consultants. That is, in fact, the job for the full brainpower of this Department.

But there is an opportunity here for three-way collaboration between the technical capacity of the government that understands the risks and the likelihood of various technological ways of minimizing them, the insurance industry that can be the vehicle for translating that into a legitimate market force, and the industry itself that needs to buy that insurance.

Chairman LIEBERMAN. Very interesting, and it is optimistic because I will carry that news right back to Hartford with me. [Laughter.]

I thank you all. You have been a very informed, constructive and helpful panel. We would like to keep in touch with you over the next couple of weeks as we begin to draft our bill.

I am going to leave the record of this hearing open for 10 days, if any of you would like to submit additional testimony for the record or if any of my colleagues who could not be here today want to submit questions to you.

In the meantime, I thank you. I wish you a good weekend. The hearing is adjourned.

[Whereupon, at 12:06 p.m., the Committee was adjourned.]
APPENDIX

Revised

SCIENCE AND TECHNOLOGY FOR HOMELAND SECURITY

Statement of
Lewis M. Branscomb
Emeritus Professor of Public Policy and Corporate Management; and Emeritus Director
of the Science, Technology, and Public Policy Program, Center for Science and
International Affairs

and

Co-chair, Committee on Science and Technology for Countering Terrorism
National Research Council
The National Academies

before the
Governmental Affairs Committee
U.S. Senate

June 28, 2002
Good morning, Mr. Chairman and members of the Committee. I am Dr. Lewis M. Branscomb, Emeritus Professor of Public Policy and Corporate Management; and Emeritus Director of the Science, Technology, and Public Policy Program in the Center for Science and International Affairs at the John F. Kennedy School of Government of Harvard University. I also served as co-chair of the Committee on Science and Technology for Countering Terrorism of the National Academies’ National Research Council. I am here today to discuss the contents of this committee’s report, *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism*, and also to offer my views as an individual on issues related to effective use of science and technology by the proposed new Department of Homeland Security.

*National Academies Report on Science and Technology for Countering Terrorism*

Let me thank the committee for the opportunity to describe the National Academies’ Report on science and technology strategies for responding to the threat of catastrophic terrorism (hereafter called the Report). While our report was completed before the President’s Bill to create a Department of Homeland Security (DHS) and thus does not contain an analysis of this proposal, the committee did have the chance, following the President’s June 6, 2002 speech, to consider the possibility of such a department. The Report makes two important recommendations in that area. In any case, we believe that useful guidance on how effective any proposed organization for the new department might be could be gained from looking at whether

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that organization allowed the government to carry out the recommendations made throughout the Report.

The report identifies key actions that can be undertaken now, based on knowledge and technologies in hand, and, equally importantly describes key opportunities for reducing current and future risks even further through longer-term research and development activities. However, science and technology are but one element in a broad array of potential approaches to reducing the threat of terrorism. Diplomacy, international relations, military actions, intelligence gathering, and other instruments of national policy well beyond the scope of this study all have critical roles to play.

Our society is too complex and interconnected to defend against all possible threats. As some threats are diminished others may arise; terrorists may change their goals and tactics. While this report describes what in the committee's best judgment are the top-priority actions and research objectives for harnessing science and technology to meet today's threats, the most important conclusion of this report is that the nation needs a well-organized and disciplined ability to respond as circumstances change. In that sense this is not an enduring plan for technical work, but rather a starting point from which the nation can create defenses-in-depth against the new threat. For that reason it is especially important that strengthening the national effort in long-term research that can create new solutions be a cornerstone of the strategy for countering terrorism.
The Report provides a technical roadmap to guide the initial response to the threat of catastrophic terrorism. It is not a plan. Our primary concern is the competence of the governmental units to undertake the tasks they now confront. The main body of the report contains a very large number of technical recommendations (some 134 of them). The committee felt strongly, however, that give the unusual nature of the threats the terrorists pose and the fact that the federal government is structured for Cold War, and not for this new threat, that we must confront the question of how our technical recommendations could most effectively be put to good effect.

Research performed but not exploited, and technologies invented but not manufactured and deployed, do not help the nation protect itself from the threat of catastrophic terrorism. In this report, the committee urgently recommends a number of steps to ensure that technical opportunities are properly realized. In particular, in recognition of the importance and difficulty of determining goals and priorities, the committee discusses how the federal government might gain access to crucial analytic capabilities to inform decision making—allowing improved assessment of risk and of the effectiveness of measures to counter risk.

Most important is that there be a federal office or agency with central responsibility for homeland security strategy and coordination and that this organization have the structure and framework necessary to bring responsibility, accountability, and resources together to effectively utilize the nation's science and engineering capabilities. The committee believes that the technical capabilities to provide the analysis necessary to support this organization do not currently exist in the government in a unified and comprehensive form. Thus the committee
recommends the creation of a Homeland Security Institute to serve the organization setting priorities for homeland security.

This institute would provide systems analysis, risk analysis, and simulation and modeling to determine vulnerabilities and the effectiveness of the systems deployed to reduce them; perform sophisticated economic and policy analysis; manage red-teaming activities; facilitate the development of common standards and protocols; provide assistance to agencies in establishing testbeds; design and use metrics to evaluate the effectiveness of homeland security programs; and design and support the conduct of exercises and simulations. The committee believes that to function most efficiently, this institute should be located in a dedicated, not-for-profit, contractor-operated organization.

In the current structure, the primary customer for this Homeland Security Institute would be the Office of Homeland Security, which is currently responsible for producing a national homeland security strategy. Whether this office will also be responsible for monitoring progress on this strategy and revising it in the future is not clear. On June 6, 2002, the President proposed a reorganization in which many of the agencies and programs operating on the front line of counterterrorism would be brought together to form a new Department of Homeland Security. However, even within this department, the programs with the expertise and experience in science and engineering research would not necessarily be closely connected to the units with the responsibility for technology deployment. Perhaps more important, the federal agencies with the best access to the nation’s sources of scientific, engineering, and medical research capability lie
outside the proposed department, and close connections with these groups will be needed to allow the department to produce the best-quality effort on counterterrorism.

Thus, however the leadership of the federal effort in homeland security is organized, the government will need mechanisms to engage the technical capabilities of the government and the nation’s scientific, engineering, and medical communities in pursuit of homeland security goals. Today the focus is on determining these goals, and the link between the Office of Homeland Security and the Office of Science and Technology Policy is a key element in setting the science and technology component of the national counterterrorism strategy. This link will continue to be essential, but if a new department is formed it will not be enough. A new department will need an Undersecretary for Technology to provide a focal point for guiding key research and technology development programs within the department and connecting with relevant technology agencies outside it. In addition, the Office of Homeland Security, or in the terms of S 2452 the National Office for Combating Terrorism (NOCT), in the Executive Office of the President will need to work closely with the Office of Science and Technology Policy, perhaps through the National Science and Technology Council, to create the architecture of the national program for countering terrorism and to coordinate the multi-agency projects and their linkages to related programs devoted primarily to other high-priority national objectives.

Finally, let me address the principle that Dr. Klausner and I believe should govern the way a new Department should purchase and finance the R&D it believes is necessary for its counterterrorism mission. The Department should have its own R&D organization and the authority to support R&D in laboratories inside and outside government like all the other “mission-oriented”
technical agencies of government. Applied research and development in support of operations in DHS should be funded by DHS, either in its own laboratories or by a transfer of DHS funds to another agency -- or to industry, universities or other independent laboratories -- more able to do the work quickly and well.

However, where DHS needs research leading to new capabilities, and there are science and engineering research skills already in place and already contributing to the homeland security mission, those capabilities should remain in place and should be funded by a line item in their agency budgets. Examples would include the work of the NIAID in NIH and the computer security division of NIST. Once the OHS (or COST) has made their strategy for this longer term research, and OHS and OSTP have found agreement on the resources available, the funds would be added to those agency budgets by OMB. The recipient agencies would remain accountable for the quality and value of the research and should be willing to make appropriate reports back to the EOP agencies and DHS.

This in the NIH case, we feel strongly that the OHS strategy should inform the NIH on its research needs, and NIH should undertake to respond to them with line item funding that would be included in the NIH budget by OMB. The alternative of removing the funds from the NIH budget, and then transferring them back under the control of OHS officials creates an unnecessary and inappropriate relationship between the agencies and we fear it will lead to a pattern of micromanagement such as is often seen in DOE in its relationship with its national laboratories. Of course if there are operations support activities needed by DHS, it would be
appropriate for these to funded by DHS as required, or for some of the capability to be built up in DHS.

Effective use of science and technology by the proposed new department

Let me now provide you my own views, which the committee requested, on both the President's Bill and S 2452. These questions go beyond the work of the Academies, which, as noted above, did not have the opportunity or the assignment to evaluate alternative structures for a Department of Homeland Security. Thus, I am pleased to respond to your request to me, speaking as an individual and not for the Academies or its committee on counterterrorism, to give you my personal views about the structure of the President's proposal. I am happy to do so, with that understanding— that I speak for myself, with my views largely colored by over 20 years of service in the federal government, 14 years as chief technical officer and member of the management committee of IBM corporation, and 16 years as a professor of S&T policy at Harvard University.

I will present here a comparison of the two bills, strictly from the point of view of their suitability for taking full and effective advantage of the scientific and engineering skills in this country. I then attach two appendices, with a somewhat more detailed commentary on each bill separately.
A comparison of the President’s Bill and S 2452

1) Structure of the department: its component agency elements

The President’s Bill includes a number of technical units (such as the NIST computer security division, and certain research programs in DOE national laboratories). S-2452 includes fewer units from departments and agencies, sticking to those with clearly operational missions. However S 2452 fails to include the Transportation Security Administration of the Department of Transportation, which seems an essential part of border control for materials as well as persons. The President’s Bill extracts technical research capabilities from places where they are now highly productive and where their research could be made available to DHS without the disruption of removing the activity from its current environment. Both bills have two divisions or directorates, one for control of borders, the other for emergency preparedness and response, which supports the Emergency Operation Centers and first responders. These seem quite logical elements to be identified in any structure.

2) Structure of the department: and the internal organization

S 2452, being composed of fewer units, and in particular containing few units with substantial activities serving non-security missions, is structured in a form that creates relatively few overlaps and conflicts among the three directorates as noted above. The President’s Bill has four divisions whose functions tend to have more overlaps or at least ambiguities in how their missions relate. Each division has both operational missions and responsibility for analytical or
research support of all the other divisions. Significant confusion and conflict can be predicted if these overlaps are not clarified. However, if by critical infrastructure, the President's Bill means only information technology related infrastructure in the Division established in Title II, that division would have a clear and logical mission that starts with intelligence evaluation, threat analysis, protection of the nation from cyber attacks and protecting the IT industry from attack.

3) How the RDT&E part of the homeland security strategy is created

The President's Bill does not address the process for creating a national strategy and does not assign responsibility for it to any unit internal to the department. Perhaps the assumption is that the responsibility for overall strategy lies in an Office of Homeland Security in the White House. However that OHS is not mentioned in the President's Bill. Since the current OHS is not a statutory agency, perhaps the administration prefers to keep it that way. If so, one can be skeptical about it having the resources and connections required to perform that highly complex task. Furthermore there is nothing in the Bill to create DHS that describes how the department participates in the creation of the strategy for the government as a whole.

S-2452 has a very specific mechanism, involving the OHS, which S-2452 replaces with a statutory agency in the Executive Office of the President (EOP) called the National Office for Combating Terrorism (NOCT). Title III clearly spells out a process through which NOCT, working with the DHS, creates a national strategy and participates with specific authority in the process of assembling not only the programs in all agencies in support of homeland security but their budgets as well. Of course OMB has final say. One can imagine that the President and the
OMB may feel the authorities given the NOCT infringe on the President’s flexibility and OMB’s authority to control the budget process, but at least the issue of a strategy is addressed.

The weak point in the provision for a national strategy in S 2452 is that no special provisions for S&T part of the strategy are offered, despite the fact that the DHS as S 2452 would structure it has almost no internal R&D capability to start with. Furthermore the Office of Science and Technology Policy in the EOP is not mentioned; yet its role in the formulation of the S&T policy would seem to be important, as is its help in the coordination of the work.

4) Provisions for R&D and other technical activities within the department

Both bills provide for some internal R&D funding. S-2452 contains a $200 million authorization for something called ‘acceleration funding’ of R&D in support of the homeland security mission, to be managed by an Office of Science and Technology, which advises the Secretary. It is not clear whether the Office is to have any internal R&D activities, nor is there any mention of R&D being performed in any of the operating units. It is questionable, in my opinion, whether a highly responsive and competent technical performance can be expected from the operating units if they must depend entirely on contract research to external parties. Furthermore there is a rather unworkable proposal in the bill that a Coordinating Committee, in which both internal executives and technical executives from other agencies (who might be recipients of the funding) participate will not only share ideas and other beneficial activities but they will “administer” the fund, including soliciting proposals, selecting winners and designating program managers to look after each of the projects. I have never seen an interagency committee in the federal
government capable of administering anything, especially a series of high priority projects on which the lives of many Americans may depend will rest.

The Administration Bill has provision for research in its divisions and specifically an R&D organization for the entire Department, run by one of the operating divisions, namely the one responsible for weapons of mass destruction (WMD). These people with professional credentials in nuclear, biological and chemical warfare also must perform the R&D for their own WMD mission. To ask them to also provide support to the rest of the department is unrealistic both because of the obvious conflict of mission priority but because their skills are not obviously appropriate for creating better protection for first responders or doing the research to develop building codes for blast and fire and for protection against toxic gases. In addition, the President’s Bill makes no provision whatever for a senior executive in the department responsible for its scientific and technological needs and activities.

5) How the department acquires R&D activities from other agencies outside DHS

Neither bill describes the policy principles that should govern how the Department acquires research support from other parts of the government. The President’s Bill suggests, through one example – the acquisition of research and other services from the NIH – that it proposes that DHS would find the appropriation for the identified partner agency transferred to DHS, which would then buy back what it wants by specifying the work to be done and the priorities within it. As noted in the first part of this testimony, I believe this is an unworkable arrangement, as has long been demonstrated by DOE whose laboratories have suffered from micromanagement from multiple sources for years. Thus I see no workable alternative to having these requirements
brought to the annual budget process by the DHS and through the homeland security strategy process in the executive office of the President the agency in question would receive a line item in its budget for the work. It would then be responsible to provide reports to DHS on the output from the work. This approach, of course, requires a workable strategy and priority process in the EOP. OSTP seems clearly to be needed here, and its role should be recognized in the legislation. S-2452, on the other hand, does rely heavily on the specified EOP process and also has mechanisms for encouraging cooperation and communication among the technical agencies.

6) The provisions for senior management of S&T in the department

Here both bills are inadequate. The President’s bill makes no provision whatever for a senior technical executive at the level of undersecretary, and all the undersecretary positions allowed in the statute are allocated to other roles. [One might say that the line executive in charge of the division established by Title III, responsible for WMD operations, is intended to be the senior S&T executive, but I have already pointed out the combination of line and staff this envisions will not work.] S-2452 clearly provides for a Director in charge of the Office of Science and Technology, but there is no indication of his rank, or, for that matter, the rank of the three operating executives running the directorates. Her or his rank should equal that of the operating unit directors.

7) Provisions for an analyzing, modeling, simulating and evaluating threats, target systems and proposed technology deployments in defense.

Neither Bill proposes the functions envisioned for the Homeland Security Institute recommended by the Academies Report. The division established by Title II in the President’s bill covers some
of those activities, but neither envisions an independent third party contracted to serve as decision support to the senior technical executive and the Secretary’s office.

9) Provisions for addressing the role of industry in hardening critical infrastructure.
This is a critical issue, mentioned in both bills but no specifics of how the federal-industry relationship is to be addressed or what authorities it will require is addressed. This will prove to be both thorny and critical.

10) Provisions for readjusting the Departments structure and policy after it has been formed.
Each bill has a somewhat different mechanism for causing or allowing a reconfiguration of the department after a period of experience. This provision is important and will be needed, I predict.
Appendix A  The President’s Bill to create a Homeland Security Department

A casual reading of the missions of the four operating units of the proposed department (Titles II – V) clearly shows DHS to be a highly technical organization. The Department is to be comprised of the agencies and units that have important operating responsibilities required for combating terrorism. I believe the list of component parts, taken together with the mission and authority of the Department, covers most of the identified threat types and areas of vulnerability, although not with equal emphasis. Because the terrorist threats are unlike those of conventional war, and their targets are elements of the civil population and infrastructure, the response by the Department must be not only technically sophisticated but highly creative and flexible.

The divisions created by Titles II through V are structured so that the agencies and units of which they are comprised can continue with as little disruption as possible, except for the primacy of homeland security as the new priority for their activities. Also the bill has a commendable provision to allow creative human resource policies. I also commend the provision allowing the President to restructure the Department internally, once experience suggests changes to make it work better.

I have three primary suggestions about the structure as it stands in the President’s Bill:

- Operating and support functions are mixed and the missions of the divisions are highly interdependent in the Divisions established by Titles II – V;
- An R&D function that serves all the responsibilities of the department is needed;
- It is very important that the Department have a senior technical officer at the rank of undersecretary for the whole department, with responsible for the Department’s R&D budget.

Mix of operational and support functions in each of the divisions.

There is probably no way to avoid the fact that many if not most of the threats our study identified will require collaborative effort by all four divisions. That is certainly better than two dozen agencies with no central management as we have now. The first problem I see is that each of the four operating units have both divisional operational missions and support functions for all the other divisions. This split responsibility is likely to cause a loss of focus and to make the balance of internal and external responsibilities hard to manage.

Title II has not only an operating mission in intelligence and infrastructure protection, but also has what I see as vital staff support functions required for making the strategy in support of all the divisions: tasks (2), (3) and (4) in section 201 of Title II. If task (5) – “taking...necessary measures to protect the key resources and critical infrastructure...” implies that the assignment is for all critical infrastructure, then if that responsibility were assigned elsewhere, this Title II division could become the analysis, planning and evaluation division of the Department. On the other hand if “critical infrastructure” in (5) means only information and communications
infrastructure, this should be made clear and the responsibility should stay in the Title II division.\(^2\)

The Title III division has vital operational roles in interception and countering of weapons of mass destruction (WMD) - task (1) in section [301 Title III] Task (3) specifically charges this division with establishing priorities for and conducting R&D and procurement of systems for protecting against weapons of mass destruction. Yet task (2) assigns to this division responsibility for R&D support of the entire for the whole mission of the Department. It is almost certain that the division's responsibility for both WMD operations and WMD research and development will cause it to give short shrift to the array of threats that depend on weapons not considered WMD - explosives, industrial chemicals, food contaminations and agricultural attacks, radiological or cyber attacks. Thus the division has not only a mix of operational and support roles in this division, but its duty to provide R&D in support of all the Department’s needs will be in conflict with the R&D needs of the WMD mission.

The Title IV division has mostly an intercept mission, except for the broader charge to protect the transportation systems, and I assume to prevent them from being used as delivery systems for attacks. This is a very broad and difficult challenge, involving much more than threats from aviation. This capability depends on (a) what the division can get in the way of R&D support from the Title III division, (b) analytical support from the Title II division, and (c) the capability of TSA. TSA is to be a 60,000 person, multi-billion dollar agency, but no one that knows it well is optimistic about its ability to do the technical analysis, planning, R&D, acquisition and deployment of systems in support of all the modes of transportation and protect their infrastructures. Giving TSA this capability will be one of the highest priority tasks of the new department. Substantial R&D funds will need to be allocated to TSA; it should not have to depend on the nuclear physicists and biologists in the Title III division.

The Title V division creates the plans for response and recovery, but this mission is separated from the threat analysis done under Title II. They need to be tightly linked. Also the response and recovery operations need to be supported by the same sensor networks and data mining capabilities required for detection and prevention of attacks.

In none of the task statements in Titles II - V, do I see the assignment of responsibility for an array of important issues that lie outside information technology (Title II), WMD (Title III), Borders and transportation (Title IV), and support for emergency services (Title V). These include standards for combined explosion and fire in buildings, filtering the air in high population buildings, developing biometric technologies, tagging explosives, protection of water supplies, etc...

Need for an integrated (over threats and over vulnerabilities) technical capability.

\(^2\) In the Academies Report, and in common usage, "critical infrastructure" includes all the commonly understood infrastructures - energy, information, transportation, food systems, health systems and cities - thus most of the scope of the entire department. But in some government documents, "critical infrastructure is taken to mean only IT infrastructure.
The most important conclusion of the Academies' study is that an integrated, systemic approach is needed to all of the threats and vulnerabilities, so that the threat analysis, the protection and recovery strategies and the final forensic measurements are consistent. Furthermore there are technologies that cut across all the threats. The Report has a specific institutional recommendation for an non-profit, contractor operated organization of systems analysts and technical domain specialists to assist the Department with threat analysis, modeling vulnerabilities, threats and proposed protective systems, generating tests of their effectiveness. These capabilities are needed to support decisions that the Secretary will have to make. In the Report this is called the Homeland Security Institute.

A chief technical officer at the rank of undersecretary for the whole department.

The department must have a chief technical officer reporting to the Secretary. No high tech corporation tries to operate without this structure. The key choices involving technology investments are too important to leave to lower levels; they rise to the level of the Secretary. But the Secretary needs a senior executive (at the Undersecretary level) with the technical skill and legitimacy to support the secretary's decisions, to be the Department's key person in the government wide technical councils such as the NSTC, to build the relationships with the vital science and engineering agencies of the government: the NSF, NIH, DOE, DOD, NASA.... Most important, it is to this executive that all the flows of technical analysis and strategy should come. She or he would also be responsible for the quality of all the R&D in the department and have the right of review and approval of top technical manager appointments. The Homeland Security Institute, described in the previous section, should report directly to the undersecretary for technology.

Need for an R&D function that serves all the responsibilities of the department.

Each division should have unambiguous and distinct operational roles, and each should have its own R&D capability in support of those operational responsibilities. This R&D should be designed primarily for identifying needs, evaluating solutions that are offered, and doing the actual procurement, and managing the deployment (often in collaboration with other federal agencies, with industry or with local government.) The budgets for all of the R&D in the Department should be the responsibility of the undersecretary for technology, but this R&D should be managed by the divisional executives.

There should be a central R&D function headed by a Director of Research reporting to the undersecretary for technology. It should not be managed by one of the operational managers who have to decide how to split their R&D resources between their own divisions priorities and those of other divisions, as suggested in the President's Bill. A council chaired by the undersecretary for technology comprising the director of research and the senior technical manager in each of the divisions would be a useful mechanism for collaborative planning and program coordination.

Adapting the current bill to meet these needs
I see no way to avoid asking Congress for an additional high level position (undersecretary) for the chief technology officer. This will be a hard job to fill well; the incumbent will have to command the respect of the operating executives and have good enough access to the Secretary to force decisions to that level when necessary.

Stepping back from the Bill as it stands, the problem of the mixed operational and support functions in most of the divisions is best met by restructuring the department into one group of units providing support functions – analysis, strategy setting, acquisition and forensics and intelligence – and a second group of units with primarily operational responsibilities – border control, hardening targets, deploying tools, response to attack and services for recovery. These two groups might be managed two under or deputy secretaries. But I acknowledge that this is not a “green field” management creation; agencies come as they are, and it will be hard to dismantle and reconstruct them while they are adapting to their new missions. But if something approaching this cannot be done, the Department will not look very different from what we have now, except for a unified management chain at the top.

Homeland Security activities outside the Department

Finally, one last point: the full architecture of the S&T response to terrorism must include important research activities outside the new department. A properly staffed Office of Homeland Security in the White House, working with the Office of Science and Technology Policy, is essential to take leadership for defining the responsibilities in DoD and in other agencies outside DHS for contributing to homeland security. There remains the question of how these external services can best be obtained. There are three alternatives: bring the capabilities into the department (certainly not practical), bring the other department or agency funds into the department and then repurchase the services from that department of agency (which I believe the Bill intends as the way to access NIH services), and creating a requirement by the Department to which external agencies and departments are encouraged to respond in their own planning and budgeting. If the Office of Homeland Security in the White House is strong, and is supported by OMB and a strong OSTP, This third alternative is the mode of choice in my view. I am very concerned that the repurchase approach will lead to micromanagement and a diffusion of responsibility. This system prevails in the way DOE relates to its national laboratories, and is widely criticized. It should not be emulated in the new Department if it can be avoided.
Appendix B  Analysis of S 2452

The federal elements of which the Department would be comprised (section 102) are those with specific operational responsibility in homeland security – FEMA, the “border” agencies including the Animal and Plant Inspection service, and three offices concerned with evaluating and mobilizing the national response to the threat of terrorism. There is real merit to beginning with the core functions and not attempting to add all of the research and technology organizations that will have split responsibilities between homeland security and their prior and continuing civil duties. It is perhaps surprising that the list does not include the Transportation Security Administration from the Department of Transportation. The transportation system is such an integral part of the “border” control necessity that it probably should be included in the new Department. It is hard to see how the Border and Transportation Protection Directorate can function without it.

Section 103 creates the operating structure of the department, with three directorates. This is a managerially “clean” structure, separating three core functions:

- Border and Transportation Protection
- Critical Infrastructure Protection
- Emergency Preparedness and Response

The virtue of this form of organization is that it distinguishes the three central phases of countering terrorism: Prevention of attack, hardening the targets, and managing the attack and recovery from it. It would appear that these functions are readily understood so the amount of confusion and conflict between the directorates should be minimized.

Section 103 also creates an Office of Science and Technology, whose function is to advise the Secretary. The ranks of the head of this office (and indeed of the managers of the three directorates) are not specified. To have only an advisory function would not be a sufficient responsibility to manage the technical needs of the department. Section 104, however, further defines the responsibilities beyond advice to the Secretary; some reflection of these larger responsibilities (which includes managing an R&D fund) might be reflected in the description of the Director’s duties in Section 103.

Section 104 says that the Director of the Office of Science and Technology (OST) establishes [RDT&E] priorities and forwards recommendations to the Secretary on homeland security technology. The Office would manage a RDT&E fund (authorized at the level of $200 million in FY 2003). The fund is described in Section 104 as “acceleration funding for R&D...,” implying that the funds would not be used to initiate R&D that was not already established somewhere in the government. If this is congressional intent, it is an unfortunate and unwarranted restriction. However, later this adjective does not appear. The legislation should be unambiguous in allowing the degree of novelty and risk of research to the judgment of the Director and the Secretary, and in allowing funding either shared or fully paid by the Department.

A Steering Group and a Coordination committee, both with senior technology and research officials from inside and outside the department (but not from government), would assist the Director in setting priorities [the Steering Group] and the use of the DHS R&D fund [the Coordinating committee]. Surely only one such group is needed. I would recommend that he
statute authorize the Secretary to create such interagency bodies as he may find useful, although I recognize that statutory authority would appear to increase the likelihood of other agency participation and the needed level. There is, however, a serious objection to putting into law that the Coordinating committee will “administer the [DHS-OST] fund.” The Director of OST, on delegation from the Secretary, must be 100 percent responsible for administering the fund. He can get lots of advice, but he must be accountable and able to make decisions.

The Bill does not provide for any external advice to the Director. He will need access to the best technical advice the country can provide, especially from industry technical executives and from people with experience in emergency response by cities, counties and states. These needs are clearly identified in the last paragraph of the section by section analysis of section 104. More important, that last paragraph quite correctly identifies risk assessment, analysis of key technology areas, and a system for sharing technical knowledge as key responsibilities of the OST. The Academies Report’s highest priority institutional recommendation is the creation of the Homeland Security Institute, which would bring to the Director and the Secretary some of these key capabilities along with others defined in the Report. The Bill should explicitly provide for the contracting of the functions specified in the Report to a non-profit company working only for the DHS and reporting to the Director of OST.

Section 107 might want to leave some room for subsequent legislation which might be needed if the Congress finds that existing environmental, health and safety regulations, however well justified and needed, could adopt fast path processes or even waivers on a finding by the president of a national emergency requirement for a drug or other technology that would otherwise take too long to get into production. I appreciate, however, that the needed analysis and consultation to write such sections now may not exist on the time scale of this legislative process.

Title II is very important, for it recognizes that the homeland security function in the EOP will be even more important after the Department is created than it is now. My concern about sections 201, 202 and 301 is that no recognition of the value of OSTP and its statutory responsibilities is reflected in the bill. The president may prefer that the OHS as now constituted continue as a personal White House Assistant to the President, without a statutory basis, but although the current administration makes a big distinction between heads of statutory offices in the EOP and Assistants to the president, I note that for many years the Director of OSTP also served as Assistant to the President without difficulties of which I am aware. The statute also would ensure that the Director of the National Office for Combating Terrorism (NOCT) would be at Cabinet rank. The statute assigns that Director sufficient well-specified responsibility for the government-wide budget for counter terrorism, in preparation for its determination by OMB to ensure that the office will not become an empty “Czar” position.

However it fails to recognize that a large part of the interagency issue will be R&D, not just operational coordination. The bill as it stands would do the R&D coordination from a point inside the DSH, using the proposed Coordinating committee. This group might be useful, but it should be noted that the Executive Office of the President will need just such a group to coordinate R&D in homeland security across the whole government in order to help OMB make
an R&D component of the budget that covers all the agency and departmental R&D activities in response to the strategy.

S 2452 does not provide for this interagency coordination using the capabilities of the OSTP working through the NSTC. See infra. Thus an informal consultation mechanism bringing all the senior technical executives of relevant departments and agencies would be very useful to the Director of the Department’s OST. It would not substitute for a more objective coordination mechanism overseen by EOP offices.

Finally, I am concerned that title V does not provide for any presidentially appointed, senate-confirmed executives other than the Secretary, the Deputy Secretary of DHS and the Director of the NOCT. The heads of the three directorates and the director of the OST should have the same rank, at the undersecretary level.
Testimony of Margaret A. Hamburg, M.D.
Vice President of Biological Programs, Nuclear Threat Initiative
Senate Committee on Governmental Affairs
June 28, 2002

Mr. Chairman and members of the Committee, thank you for the invitation to participate in this hearing. My name is Margaret (Peggy) Hamburg. I am a physician and a public health professional, currently serving as Vice President for Biological Programs at NTI, a private foundation, co-chaired by Ted Turner and Sam Nunn, whose mission is to reduce the global threat from weapons of mass destruction. I have previously served in government at various levels including Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services in the last Administration, six years as New York City Health Commissioner (under both Mayor Dinkins and Mayor Giuliani), and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. I am pleased to have the opportunity to discuss issues surrounding the creation of a new Department of Homeland Security and the policy implications for public health and bioterrorism threats. Your interest in and commitment to these concerns are greatly valued.

Events this past fall – including the attacks of September 11 and the dissemination of anthrax through the postal system – demonstrated our nation’s vulnerability to terrorism, and dramatically underscored both the need and complexity of homeland defense. There is an urgent requirement to strengthen planning, coordination, implementation and oversight of efforts to improve homeland security.

I strongly applaud current efforts to give greater authority and accountability to our homeland security program, including the creation of a new federal Department of Homeland Security. There is a strong rationale for consolidating some of the many departments and agencies that share similar functions or provide various aspects of what is needed for comprehensive preparedness and response. Both the Administration’s Bill to establish a Department of Homeland Security and S. 2452 to establish a Department of Homeland Security and a National Office for Combating Terrorism as introduced by Senator Lieberman and colleagues, offer important opportunities to strengthen leadership, focus and coordination of essential programs and policies. However, they also raise a number of critical concerns that must be surfaced, discussed and addressed.

It is increasingly evident that effectively preparing our nation against the threat of terrorist attack requires well-defined authority, accountability and coordination / integration across an exceedingly broad array of agencies and activities. The existing Office of Homeland Security, despite the yeoman efforts of Governor Ridge and his staff, is clearly not structured to achieve this task. The formation of a new Department of Homeland Security, at a cabinet level, can potentially make a very real and enduring difference to efforts to plan, coordinate and integrate U.S. government activities relating to homeland security particularly in such realms of overlapping/shared activity as border security, customs procedures and aspects of emergency.
response, in order to achieve greater efficiency, effectiveness and accountability. How best to address the activities related to bioterrorism prevention, preparedness and response is a more complicated question.

In my testimony this morning, I want to briefly raise a number of issues that apply broadly to the creation of a new Department of Homeland Security, but then focus most of my attention on the issues that specifically relate to the biological threat.

DEPARTMENT OF HOMELAND SECURITY: SOME BROAD CONCERNS

With respect to a new Department of Homeland Security, we need to move forward, but do so carefully, with great thought and consideration as to what are the goals and how best can we achieve them. Several important concerns come to mind:

Need for a Strategic Framework

The creation of a new Department of Homeland Security represents an ambitious undertaking which will be enormously difficult to implement and very disruptive to many functions and activities for a considerable period of time. Realistically, even under the best of circumstances, we will lose time and forward momentum in our current programs as we undertake this effort. Thus the goals of the reorganization must be well defined before legislation enacting this Department is passed. We should be very clear about what we are doing and why. This is not the time to undertake change unless we are certain it will provide needed longer-term gains. A truly meaningful reorganization should be done in the context of an overall strategic plan or framework for action that defines goals and objectives, as well as the related roles and responsibilities of the various component partners.

Need for Balance

Current approaches require that a great many agencies and agency components be pulled into one large Department focused primarily on terrorism preparedness and response. However, this new Department of Homeland Security will still be responsible for dealing with a broad range of other activities. Many of these more routine activities will be important to the core Departmental mission because they will, on a regular basis, allow for the practice of systems that would be recruited into service in the event of an attack (e.g. disaster response and sheltering, FEMA). Similarly, routine non-terrorism activities might serve to identify unusual patterns or situations that might signal an impending terrorist event (e.g. monitoring shoreline for drug-runners or boating accident rescues, Coast Guard). However, there is serious concern that when you create a Department as diverse as this one would be, you will either lose focus on the organizing mission of countering terrorism or you will fail to effectively support those other routine functions. It is hard to imagine a Department remaining honed in on terrorism preparedness and response while responding to mudslides, hurricanes and fires, monitoring the fisheries, searching out drug traffickers, controlling hog cholera and investigating outbreaks of disease. It is also hard to imagine effective leadership for such a diverse array of tasks, requiring an equally diverse array of professional backgrounds and expertise.
Need to Address Existing Weaknesses (Not Just Move Pieces Around)

Given the above concerns about managing this complex and varied new Department, serious questions must be raised as to how known weaknesses in certain of the component agencies and activities will be systematically and effectively addressed. Merely rearranging the organizational structure will not resolve many of these deeply entrenched problems. Some of the problems may benefit from new leadership or enhanced attention and scrutiny; however, without a clear game plan and focused strategy, others may continue to foster, or worse, their continuing dysfunction may be amplified in a new and confusing bureaucracy. A host of personnel, budgetary and jurisdictional issues may add to the difficulties of providing appropriate oversight, management and operational accountability.

Need to Maintain Program Connectivity / Coherence

In several domains, but particularly with respect to bioterrorism, the creation of a new and distinct Department may serve to disconnect certain functions such as bioterrorism surveillance, laboratory networks and response from the infrastructure needed to respond to routine, non-intentional public health issues. The response to a disease outbreak, whether naturally occurring or intentionally caused, will require the same critical components. Most likely, we will not initially know the cause of an emerging epidemic. What is more, our overall infrastructure for infectious disease recognition and response is far from robust. We must be careful not to further fragment our capacity, and inadvertently undermine our own best interests. We must also avoid the unnecessary development of duplicative systems at a time of limited resources.

HOMELAND SECURITY AND THE BIOLOGICAL THREAT

As our nation prepares to respond to the looming concerns posed by bioterrorism, both the nature of the threat and the role of public health, medicine and science continue to be poorly understood and underemphasized. The threat of bioterrorism is fundamentally different from other threats we face, such as "conventional" terrorism or attack with a chemical or nuclear weapon. By its very nature, the biowarfare threat – with its close links to naturally occurring infectious agents and disease – requires a different paradigm.

Furthermore, public health has not been traditionally viewed as an element of national security. Understandably, those working on matters of national security are much less familiar with the public health system – what it is, how it works and why it is important to our overall mission of protecting the nation. For too long, public health has been neglected or overlooked. However, as the threat of bioterrorism illustrates so profoundly, public health is an essential form of public safety and must be a fundamental pillar in our national security framework.

It is not surprising that the various Commission Reports (e.g. Hart-Rudman) that have looked at national security-terrorism issues and current legislative proposals for the creation of a federal Department of Homeland Security have had trouble conceptualizing an appropriate organizational approach that includes bioterrorism preparedness and other biodefense activities. In fact, there is no clear and simple answer to the question of how best to organize the components of an effective bioterrorism prevention, preparedness and response program.
Critical Elements of a National Response

Addressing the question of organization, of course, requires definition of the tasks before us. In this time of heightened anxiety and concern, our nation has a real opportunity—and obligation—to make sure that we have in place the programs and policies necessary to better protect ourselves against this threat, and to attempt to prevent such an attack from occurring at all. While there are many challenges, we do know a great deal about what needs to be done and how to do it. A national response to bioterrorism must incorporate the following elements.

(1) **Prevention.** Every effort must be made to reduce the likelihood that dangerous pathogens will be acquired or used by those that want to do harm. This must include improving intelligence, limiting inappropriate access to certain biological agents and efforts to establish standards that will help prevent the development and spread of biological agents as weapons.

(2) **Strengthening public health.** Rapid detection and response will depend on a well-trained cadre of trained public health professionals to enhance disease surveillance and outbreak investigation, educated and alert health care providers, upgraded laboratories to support diagnosis and improved communications across all levels of government, across agencies and across the public and private sector.

(3) **Enhancing medical care capacity.** We must improve treatment for victims of an attack by enhancing local and federal emergency medical response teams, training health professionals to diagnose and treat these diseases, developing strategies to improve the ability of hospitals to rapidly increase emergency capacity and providing necessary drugs or vaccines where they are needed through the National Pharmaceutical Stockpile.

(4) **Research.** A comprehensive research agenda will serve as the foundation of future preparedness. Perhaps most urgently, we need improved detectors/diagnostics, along with better vaccines and new medications.

Some of these activities are already underway, but need to be strengthened and extended. Other programs and policies still need to be developed and implemented. Clearly these activities are all essential for homeland security. Yet it is important to note that while certain aspects of these activities are required to respond to the threat of bioterrorism specifically, these programs are just as important for the day-to-day, routine activities of public health and medical care.

**Potential Benefits of Inclusion in a New Federal Department**

There are certain real advantages that might be gained from placing these programs within a new federal Department of Homeland Security. Perhaps first and foremost, the biological threat, and the necessary programs to address it, is of profound importance to our national security. These activities require greatly enhanced priority and support. By residing within this new Department they may be more likely to command that needed attention and support. Furthermore, experts in
biological weapons threats, biodefense and public health preparedness must be full partners at the national security table, participating in strategic planning, policymaking and program design and implementation. Being part of the Department of Homeland Security might help to institutionalize this important participation.

In addition, very legitimate concerns have been raised that if not housed within this new Department, crucial public health and bioterrorism programs may be neglected, especially over time. Furthermore, important operational public health and biomedical defense functions may not be integrated with national security objectives.

Clearly, there is an urgent need for improved coordination and integration of bioterrorism programs and policies across agencies of government. The current patchwork—of programs that address bioterrorism prevention, preparedness and response, including research—is inadequate and unacceptable. These need to be brought together into a collective programmatic vision, and implemented in a manner that sets priorities, supports synergy, identifies gaps and avoids unnecessary overlap or duplication. To date, this has proved a difficult challenge. One might argue that the most effective way to address this concern is to pull these activities together under one roof.

The picture is further complicated by the fact that state and local government entities are also critical elements of bioterrorism preparedness and response. They too must be integrated into an effective vision and framework for action. Similarly the private and voluntary sector, importantly including the medical care system and the pharmaceutical industry, are significant players in a comprehensive approach to combating the threat of bioterrorism. Looking at the federal government from the outside, it can be very confusing to discern where and how best to interact with the system. Again, the creation of a unified site within a Department of Homeland Security might reduce confusion, strengthen the ability to work across levels of government and support the kinds of public-private partnerships that will prove essential to success.

Potential Disadvantages of Inclusion in a New Federal Department / Recommendations

While there may be benefits to be gained by moving certain aspects of bioterrorism and related public health issues into a consolidated new Department of Homeland Security—some profound and some more cosmetic—we must look carefully at the broader question of how best to address these threats so that our overall governmental effort is maximally effective. Certainly there are some notable concerns, at least in the form suggested by the Administration’s proposal. I want to outline a few specific examples for examination and discussion, and offer some selected recommendations.

Organization of Bioterrorism Activities

As currently envisioned, the proposed Department of Homeland Security would seek to develop a single, government-wide, comprehensive and integrated research and preparedness plan to prevent chemical, biological, radiological and nuclear (CBRN) attacks, to reduce our nation’s

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vulnerabilities to terrorism and to minimize damage and assure effective response should an
attack occur.

This approach is intrinsically troubling, because as noted earlier, the bioterrorism threat has some
very distinctive features as compared to "conventional" terrorism or other weapons of mass
destruction. Past experience tells us that many so-called bioterrorism programs failed to achieve
their potential because they were addressed within the framework of CBRN or "Chem/Bio".
There was an underlying assumption that these problems could be effectively approached with a
"one size fits all" model, but in reality, such programs simply failed to address the biological
component. This may be more of a semantic problem than a conceptual one at this time, but we
must guard against falling into that old trap.

Meaningful progress against this threat depends on understanding it in the context of infectious
and/or epidemic disease. It requires different investments and different partners. Until the true
nature of bioterrorism is fully recognized, our nation's preparedness programs will continue to be
inadequately designed: the wrong first responders will be trained and equipped; we will fail to
fully build the critical infrastructure we need to detect and respond; the wrong research agendas
will be developed; and we will never effectively grapple with the long-term consequence
management needs that such an event would entail. We may also miss critical opportunities to
prevent an attack from occurring in the first place.

Recommendations:

1. The new Department of Homeland Security will require significant expertise in public
    health, infectious disease and biodefense/terrorism. This must be seen as an important
    priority. Individuals with appropriate background and experience must be represented at
    the highest levels of leadership and decision-making.

2. The appointment of an Undersecretary for Biological Programs should be considered to
    oversee and integrate the various activities going on within the Department of Homeland
    Security that relate to the biological threat. In addition, that individual might be charged
    with liaison responsibility to the various other Departments with significant
    responsibilities and programs in the biological arena.

3. An external advisory group for biological programs might have value to ensure periodic
    review of the appropriateness and comprehensiveness of issues such as biological threat
    related programs, policies and resource allocation / budget priorities.

Emergency Response/Role of Public Health Infrastructure

As noted earlier, a bioterrorism attack would differ in fundamental ways from other forms of
terrorist assault. The requirements for effective bioterrorism preparedness and response are, for
the most part, substantially different as well. Biological terrorism is not a "lights and sirens"
kind of attack. Unless the release is announced or a fortuitous discovery occurs early on, there
will be no discrete event to signal that an attack has happened, and no site you can cordon off
while you take care of the casualties, search for clues and eventually clean up and repair the
damage. Instead, a biological terrorism event would most likely unfold as a disease epidemic, spread out in time and place before authorities even recognize that an attack has occurred. We would know we had been attacked only when people began appearing in their doctor’s office or emergency rooms with unusual symptoms or inexplicable disease. In fact, it may prove difficult to ever identify the perpetrators, the site of release, or even determine whether the disease outbreak was intentional or naturally occurring.

Under most circumstances, the “first responders” to a bioterrorism event would be public health officials and health care workers. “Ground zero” will be in hospitals, health care facilities and laboratories. The critical “battlefield” response activities for bioterrorism will unfold through disease diagnosis, outbreak investigation, treatment of the sick and public health actions required to stop continuing contagion and stem disease. How swiftly we recognize and respond to a potential attack will dramatically influence our ability to reduce casualties and control disease. All of these recognition and response functions are more closely tied to public health and medical care activities that respond to naturally occurring infectious disease threats than to the emergency response required for other types of catastrophic terrorism or even other kinds of natural disasters.

In the months since 9/11, the Bush administration — through programs developed and administered by the HHS Office of Public Health Preparedness (OPHP) and the Centers for Disease Control and Prevention (CDC) — has made some progress in building the programs necessary to strengthen public health infrastructure for bioterrorism within this broader context of infectious disease. If these programs are carved out and moved into this new Department, it will disconnect bioterrorism preparedness from other essential components of infectious disease response and control, thin out already limited expertise and enormously complicate the ability of our public health partners at the state and local level to work effectively. If the nation develops two parallel systems for infectious disease surveillance and response — one (that for bioterrorism) of which is only really activated and practiced in a crisis — the likely outcome will be to weaken and fragment our nation’s capacity to respond to infectious disease, rather than to strengthen it, whether that infectious disease threat is naturally occurring or intentionally caused.

**Recommendations:**

1. HHS and CDC should continue to have direct responsibility for programs related to the public health infrastructure for infectious disease recognition, investigation and response, including bioterrorism.

2. A public health professional with appropriate background and experience could be placed within the Department of Homeland Security with dual reporting to the DHS Secretary and the HHS Secretary. This individual could then work closely with the CDC Director to achieve mutually agreed upon public health priorities for bioterrorism preparedness and response.

3. The Department of Homeland Security should assure greater coordination, collaboration and program integration among the components of government doing infectious disease surveillance activities (e.g. DOD, USDA, Wildlife and Forestry).
Biodefense Research

Further investments must be made in biomedical research to develop new drugs, vaccines, rapid diagnostic tests and other medical weapons to add to the arsenal against bioterrorism. It is also essential that we improve technologies to rapidly detect biological agents in environmental samples and develop other technologies to protect the health of the public. We must learn more about how these organisms cause disease and how the human immune system responds so that we can develop better treatments and disease containment strategies to protect us in the future. In addition, we must also invest more focus and resources on “systems research,” in an effort to understand more about such issues as personal protective gear, environmental safety and decontamination.

Success will entail research endeavors and collaboration involving multiple agencies of government (HHS, DOD, DOE, USDA and others), academia and the private sector. Coordination of the development and budgetary support for such a comprehensive, integrated biodefense research agenda could certainly be offered under the auspices of the proposed Department of Homeland Security. This can help make sure that crucial links between national security needs and research and development priorities get made, as well as assure proper balance and integration of the bioterrorism related research activities of the various mission agencies, including threats to humans, animals and crops. Hopefully, this would help foster proper recognition and support for elements of the research enterprise which are currently undervalued/under-resourced — such as the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and the Department of Agriculture’s animal health research facility, Plum Island — as well as identify program gaps, overlap and opportunities for synergy.

However, the role of the Department of Homeland Security should be that of coordinator/ facilitator. The actual design and implementation of the research agenda and its component programs must remain at the level of the mission agencies, where the scientific and technical expertise resides. With a few possible exceptions, it would be unrealistic and inefficient to build the kind of sophisticated scientific expertise necessary to take on the direct conduct or management of research and development activities across a broad range of disciplines and technologies at the level of this new Department.

Recommendations:

(1) A research coordination office should be established within the Department of Homeland Security and charged with responsibility for assuring the development and funding support for a comprehensive, integrated biodefense research agenda. An individual with appropriate scientific background and experience would head this office. The possibility that this individual might have dual reporting to the Secretary of HHS or NIH/NIADD Director, as well as to the Secretary of the Department of Homeland Security should be considered, given the fact that HHS is the primary department with responsibility for biomedical research, and the unique role played by NIH.
This research coordination office could also help support the integration of threat and vulnerability analysis with the research priority setting process.

(2) An external advisory mechanism should be established to encourage ongoing communication and collaboration with academic and industry partners. New mechanisms must be developed to engage participation from outstanding scientists from academic and industry, and to bring new young scientists into these endeavors.

(3) Our nation faces a crisis with respect to the development and production of new vaccines and antimicrobial drugs. This is not a new concern, but the urgency to meaningfully address it is dramatically increased in light of the bioterrorism threat. High-level commitment and political will is needed. Consideration should be given to the possible role of the Department of Homeland Security, working closely with the appropriate agencies of government (e.g. FDA, NIH, DOD), industry and Congress, to provide leadership and accountability in addressing this concern and defining solutions.

CONCLUDING REMARKS

Few tasks are more important than that of effectively strengthening our nation’s security and protecting the health of the public. There are many more outstanding concerns that will need to be clarified and addressed before such important legislation is passed. I deeply respect your efforts, Mr. Chairman, and those of the members of the committee, to take on this vital but difficult challenge. I welcome the opportunity to assist you in this work and would be happy to answer any questions you may have.
HOMELAND SECURITY

New Department Could Improve Coordination but May Complicate Priority Setting

Statement of Janet Heinrich
Director, Health Care—Public Health Issues
Mr. Chairman and Members of the Committee:

I appreciate the opportunity to be here today to discuss 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.¹ 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 2002² 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 in 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.³

³These changes are primarily covered by Sections 102 and 106, respectively, in Title V of the President’s proposed legislation.
⁴These changes are primarily covered by Sections 301, 302, and 303 of the President’s proposed legislation.
In order to assist the Committee in its consideration of this extensive reorganization of our government, my remarks today will focus 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. My testimony today 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 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 federal 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.

\[\text{See "Related GAO Products" at the end of this testimony.}\]
Background

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 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). The Strategic National Stockpile, currently administered by the Centers for Disease Control and Prevention (CDC), would also be transferred, although the Secretary of HHS would still manage the stockpile and continue to determine its contents. The President's proposal would also transfer the select agent registration enforcement program from HHS to the new department. Currently administered by CDC, the program's mission is the security of

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5 In the event of an emergency, the NDMS has response teams that can provide support at the site of a disaster. These include specialized teams for bomb victims, mental health testers, teams for incidents involving weapons of mass destruction, and mortality teams that can be deployed as needed. About 1,000 civilian hospitals have pledged resources that could be marshaled in any domestic emergency under the system.

6 The MMRS is a program that provides support for local community planning and response capabilities for mass-casualty and terrorist incidents in metropolitan areas.

7 The stockpile, previously called the National Pharmaceutical Stockpile, consists of two major components. The first component is the 12-Foot Path Package, which contains pharmaceuticals, syringes, and medical supplies and can be delivered to any site in the United States within 12 hours of a federal decision to deploy assets. The second component is the Vendor Managed Inventory.
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.

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, hospital 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 threats. This would 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. For example, the Department of Energy’s (DOE) chemical and biological national-security research and some of its nuclear smuggling and homeland security activities would be transferred to the new homeland security department. The Department of Homeland Security would carry out 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 a program of basic and applied research on the detection, treatment, and prevention of...
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. We have also testified that 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.\(^5\)

The President’s proposal 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. Let me provide you with more details.

We have reported that many state and local officials have expressed concerns about the coordination of federal public health preparedness and response efforts.\(^6\) 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),

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OPF, 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 DoD; and HHS's Office of the Assistant Secretary for Public Health Emergency Preparedness, including OPF and its NDMIS and MMIS programs, along with the Strategic National Stockpile and the select agent program. 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 DoD 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 MMIS, 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 MMISs 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 this President’s proposal, CDC’s responsibilities for the stockpile would be transferred to the new department, but VA and HHS involvement would be retained, including 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 Preparedness and Response program and HHS’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 origins 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 the US Coast Guard’s 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 legislation 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

\footnote{GAO/NSIAD-98-212.}

\footnote{U.S. General Accounting Office, Chemical and Biological Defense: Coordination of Nonmilitary Chemical and Biological R&D Programs, GAO/NSIAD-93-10 (Washington, D.C.: August 13, 1993), and GAO/NSIAD-88-182.}
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 proposal would transfer parts of DOE's nonproliferation and verification research and development program to the new department, including research on systems to improve the nation's capability to prepare for and respond to chemical and biological attacks. However, the legislation is not clear whether the programmatic management and dollars only would move or the scientists carrying out the research would also move to the new department. Because the research is carried out by multiprogram laboratories that employ scientists skilled in many disciplines who serve many different missions and whose research benefits from their interactions with colleagues within the laboratory, it may not be prudent to move the scientists who are doing the research. One option would be rather than moving the scientists, the new department could contract with DOE's national laboratories to conduct the research.

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 will 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 antifungal drugs. These efforts have dual-purpose applicability: The scientific research on biologic agents that could be used by terrorists

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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 these programs 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 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 those 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.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

Contact and Acknowledgments

For further information about this testimony, please contact Janet Heinrich at (302) 515-7118. Gene Aloise, Robert Copeland, Marcia Creece, Greg Ferriero, Gary Jones, Deborah Miller, Roseanne Price, and Keith Rhodes also made key contributions to this statement.
Statement of William J. Madia  
Director, Oak Ridge National Laboratory  

Before the  
Committee on Governmental Affairs  
United States Senate  
June 28, 2002  

INTRODUCTION

Mr. Chairman, Senator Thompson, members of the Committee; my name is William Madia, and I am Director of the Department of Energy’s Oak Ridge National Laboratory and past Director of their Pacific Northwest National Laboratory. I am pleased to provide this testimony on how best to organize our nation’s science and technology capabilities to help secure our homeland against terrorist attack.

The challenge of assuring our homeland security is complex. I know the Administration and Members of this Committee have been considering the many issues involved in assuring our government is properly organized and well prepared to provide for homeland security for many months. Now Congress and this Committee face a demanding, yet critically important task as you formally take up the President’s proposal to form a Department of Homeland Security. I strongly support this proposal, and its emphasis on the critical role of science and technology in meeting our homeland security needs.

In this statement I begin with a brief review of the nature of our homeland security challenge. This is followed by four observations regarding organization of our science and technology response. I close with comments on the role of the national laboratories managed by the Office of Science and the National Nuclear Security Administration in the Department of Energy.

OUR HOMELAND SECURITY CHALLENGES

Our homeland security challenges are enduring, daunting in scope, diverse, and technically and logistically complex. The threat we face is dynamic. It changes rapidly with political and social developments around the world. It grows with the technical capacity of our adversaries, and with changes in our own economy and infrastructure. We require a science and technology response that is equally robust. We need a focused response around clear priorities. We must take into account the challenge of implementation on a national scale. We should be as flexible and adaptable as are the adversaries who would threaten us.

Our homeland security challenges are compounded by clear constraints. We cannot protect everything against every possible contingency – there are simply too many possibilities, and we will need clear priorities if we are to be effective. Our response
needs to take into account the costs and other impacts of the security measures we deploy. If we make our transportation system more secure by greatly increasing the cost of moving either people or goods we will both reduce our freedom and quality of life and disrupt our economy, the strength of which underpins our ability to meet homeland security needs in the first place. The systems we deploy should create the minimum of disruption or friction in our economy, and, where possible, should provide benefits in addition to enhanced security, such as increased robustness against natural disaster or accident. Finally, we will need appropriate standards so that the systems and technologies we deploy will communicate and work together.

Our effort since last September has been primarily focused on rapid deployment, and sometimes improvement, of the best available current technology for immediate needs, and we are making real progress. We are developing and deploying new tools for rapid detection of chemical or biological agents, for inspecting sealed containers for radioactive material, and for improving aviation security. However, for many critical problems these and other currently available technologies provide only partial solutions. As we plan and organize for the longer term we should complement our rapid development and deployment efforts with a sustained program to create better solutions and to predict and prepare for threats that are the stuff of speculation today, but may become all too real tomorrow.

I would like to recognize and support the comprehensive and thoughtful National Academy report prepared by the Committee on Science and Technology for Countering Terrorism chaired by Drs. Lewis Branscomb and Richard Klausner that was released Tuesday morning as a valuable contribution to our understanding of these issues.

SCIENCE AND TECHNOLOGY IN THE DEPARTMENT OF HOMELAND SECURITY

As both President Bush and Governor Ridge have noted, U.S. leadership in science and technology, and the broad and diverse research enterprise that provides that leadership, are among our few most powerful advantages in assuring our homeland security. I believe that science and technology are critical to the primary functions of the proposed Department of Homeland Security as laid out in the Governor’s recent statement to this Committee. We can employ our research enterprise to 1) deliver the best possible technology solutions available to the most critical threats today; 2) deliver the science and technology required for better, more complete solutions tomorrow; and 3) anticipate new threats that may emerge from advances in science and technology or the deployment of new technology in the U.S. economy.

To carry out these functions we need: clearly assigned leadership; a thorough understanding of the requirements of those responsible for different elements of our security; and understanding of the promise, limits, and costs of our technologies. We will need to rapidly bring new ideas to application and continue to make scientific advances in critical areas for homeland defense. I offer four observations for how these things can be accomplished in the context of the proposed DHS:

Statement of William J. Medley
Director, Oak Ridge National Laboratory
• We require clear leadership of our science and technology efforts in support of homeland security. Accordingly, I support the President’s proposal formally assigning the new Department the role of leading the nation’s technology development and deployment efforts as they apply to homeland security, with responsibility for coordinating across all federal agencies. A center for program coordination and management, such as has been proposed at Lawrence Livermore National Laboratory, would enable this function. I support there being a senior official in DHS, reporting to the Secretary, with crosscutting responsibility for science and technology, a role assigned to the Undersecretary for Chemical, Biological, Radiological and Nuclear Countermeasures in the President’s proposal. To assure proper coordination, the DHS should also have strong coupling to the policy setting function of the Office of Science and Technology Policy.

• Next, we should set our science and technology priorities from the best possible understanding of both our vulnerabilities, and the effectiveness and cost of proposed solutions. Therefore, to inform its leadership and planning for technology deployment, the new Department will need dedicated risk analysis and technology evaluation capabilities. The DHS’s role in assessing vulnerabilities and potential solutions should also be closely connected to the threat identification and analysis functions of our intelligence community.

• Third, in line with the President’s proposal, I support the establishment of a strong problem-directed R&D program in the new Department. Its research and technology development efforts should be organized around and responsive to the specific challenges and needs of the customers who will deploy the resulting technologies, whether these customers are located within the new Department, in other agencies, or at the state and local level — for instance improving aviation security or protecting nuclear reactors. This program should be designed to close the gap between new ideas and basic science advances and deployable solutions. In operation this program should be flexible and highly responsive. It should be judged by results, and subject to the minimum necessary procedural requirements. DARPA may be a good model in several respects, as has been suggested by Dr. Marburger. The management flexibility components of the President’s proposal are particularly important for research and development.

• To ensure our long-term capacity to respond with new and better solutions, we should provide robust support for the basic research that will underlie and inform our problem-directed R&D, with particular emphasis on information technology, modeling and simulation, biotechnology, nanoscience, advanced sensor technology and related fields. Continuing strong support for NSF, DOE Office of Science, NIH and other basic research programs in these areas is needed.

These recommendations do not imply the creation of extensive new research capabilities or wholesale transfer of large elements of our existing federal research infrastructure to
the proposed Department. Rather, and again in line with the President’s proposal, the DHS should draw broadly on our existing government, university and industrial research base, and must have ready access to the expertise and research facilities of DOE, DOD, NIH and other agencies.

ROLE OF THE NATIONAL LABORATORIES

I strongly believe that our science and technology response to our homeland security challenges must draw broadly on the talent and expertise resident in our research universities, our industry, and in the government laboratories managed by multiple agencies. The national laboratories managed by DOE’s Office of Science and National Nuclear Security Administration will play a very substantial role, particularly on weapons of mass destruction issues. These laboratories have specialized capabilities in several areas of science and technology, such as the control and detection of nuclear materials, and expertise pertinent to radiological, chemical and biological threats, that will be critical to our homeland security. The national laboratories maintain the interdisciplinary approach and scientific and engineering breadth necessary to take a broad systems view of these problems, and have the ability to deliver substantial projects in a secure environment. It is essential that the new DHS have ready access to the national laboratories, and these laboratories should be expected to give full attention to the needs of homeland security. The proposed “Centers of Excellence” in the major DOE laboratories to support DHS would be effective in obtaining the necessary focus and commitment. Single points of contact and other coordination mechanisms between the Office of Homeland Security and the future DHS with both the Office of Science and NNSA are already under development.

Let me close with some supporting examples of science and technology either developed by the national laboratories or under development. These examples illustrate both the capabilities of the laboratories and the role that I believe the laboratories should play.

- Rapid detection and characterization of the nature and distribution of harmful nuclear, chemical or biological material in the environment and inside buildings or other structures is a critical homeland security challenge. The “Sensornet” concept, in which arrays of sensors are deployed on the ubiquitous cell phone towers to detect harmful agents, with a supporting communications and alert infrastructure, is an example of the kind of extensible, integrated system that we can hope to develop and deploy over the next few years, and has recently been demonstrated in the state of Tennessee. In the PROTECT program; two national laboratories are collaborating on systems to protect against chemical attacks and support first responders in public facilities, with initial demonstration in the Washington DC Metro. A variety of promising new sensing and analytic technologies for identifying chemical and biological agents in structures or in the open environment are seeing rapid development and testing across the laboratory system.
• Methods for detecting the transport of special nuclear or other radiological materials are needed for a variety of homeland security, border control, and other threat prevention applications. National laboratories are demonstrating and deploying to industry for production a variety of new methods, including hand-held detectors for special nuclear materials and glass fiber based radionuclide detection systems.

• Similarly, methods for assuring the security of our airports, ports and other commerce facilities, and public buildings are under development. These include a millimeter wave holography system that can detect nonmetallic objects in screening applications, highly sensitive technologies for detection of explosive residue on boarding passes or persons in transit, and a variety of techniques for detecting materials or objects in sealed containers.

• Methods for extracting real information -- for "connecting the dots" -- from the flood of data that we see each day are critically needed for intelligence applications. Software that assists analysts in understanding the connections between literally thousands of documents has been developed and deployed, and research in critically needed next generation methods is ongoing.

• Modeling and simulation of both complex engineered systems such as our electrical grid and of contaminant transport in the natural environment are essential tools for assessing vulnerability, for assisting responders both in planning for and in real time reaction to terrorist incidents, and for maintaining the operation of critical infrastructure that has been attacked. This is an area of substantial historical and current emphasis at many of the laboratories, with new efforts directed specifically at critical elements of our infrastructure.

• National laboratory staff have been providing DNA/forensics expertise in support of the investigation of the 2001 anthrax releases, provided technologies to help with cleanup of anthrax-contaminated areas on Capitol Hill, and carried out additional DNA sequencing work on a number of other biopathogens. Laboratory expertise has been employed in support of the emergency response and cleanup of the World Trade Center attack. Several laboratory-developed systems have been deployed at the Olympics or other major public events, including the Biological Aerosol Sentry and Information System, providing public health officials with early warning of a potential bioterrorist attack.

• One of our principle tools for reducing the danger of weapons of mass destruction is our cooperative effort with Russia to reduce the likelihood of diversion of nuclear materials. The national laboratories provide the technical expertise for these efforts.

I very much appreciate the opportunity to provide this testimony and will be pleased to answer questions or provide any additional information that would be helpful.

Statement of William J. Madia
Director, Oak Ridge National Laboratory
Testimony of J. Leighton Read, M.D.
General Partner, Alloy Ventures, Palo Alto, California
Before the Senate Government Affairs Committee
Department of Homeland Security Role in Bioterrorism Countermeasure R&D
June 28, 2002

Mr. Chairman and Members of the Committee, it is an honor for me to testify before you today regarding the role of the Department of Homeland Security in launching, managing and sustaining an ambitious science and technology research program for new countermeasures against weapons of mass destruction. My comments will focus particularly on how the Department’s leadership role can obtain diagnostics, drugs and vaccines to protect our nation from a bioterrorist attack, but many of these observations are relevant to the other WMD threats.

The Bottom Line

As a serial entrepreneur and now a venture capitalist, let me focus on the bottom line: the Nation will only be successful in obtaining the bioterrorism countermeasures it needs if the new Department is able to engage the enthusiastic participation of the biotechnology and pharmaceutical industry. I can state unequivocally that the conditions are not in place to accomplish that goal today.

First, dramatic organizational changes must take place in the way we prioritize our needs; that is the great opportunity afforded by the creation of the Department under discussion today. The Department offers a chance to develop a fundamentally new approach for engaging the private sector in this effort. Current DOD and NIH bioterrorism countermeasure efforts are submerged in large agencies with diverse agendas. The new Department can bring a single-minded focus on development of the highest priority countermeasures and will have the stature to make sure public and Congressional interest does not flag during the long development times for many of our needed measures.

Second, the Department must signal private sector enterprises and the vast capital markets that support them that we will create a meaningful market for successful new technology that addresses our highest priority needs. While the discussion of particular incentive structures is not the topic for today, it is important that the Committee understand the fundamental difference between what drives our remarkable high-technology and biotechnology industries and the traditional defense industry. I know that some of the points will be familiar to Senator Lieberman, whose insightful S. 1764 provides for sound, innovative incentives that require serious attention.

Perhaps the Committee should direct the Department to work with appropriate experts to optimize the incentives and respective roles that will produce the public-private partnerships we need and to make legislative recommendations. I would anticipate that we need different groups of experts to address these incentive issues for biological, chemical and nuclear threats because the technical and economic challenges are different.
High-tech and Biotech Companies are not built to do Contract R&D

A recent report highlights the trillion dollar contribution to our Nation’s GDP and the 27 million jobs from venture capital-backed companies such as Apple, Microsoft, and Amgen and FedEx. Currently there are over $75 billion allocated to venture capital funds in the United States that are available for investment in companies which offer the potential for explosive growth by delivering products into large markets with clearly understood unmet needs.

Venture capitalists do not, as a rule, invest in companies with business models such as professional services firms or companies aiming to build a business based on contract R&D at 15, 20 or even 30 percent gross margins. We aim for our companies to produce products based on defensible intellectual property which have the kinds of margins seen in truly innovative software, pharmaceuticals, and electronic devices. Year in and year out, through the natural cycles of technology, this is a proven recipe for creating enormous value for consumers and investors.

That is why I am so concerned about the current shortsighted focus on getting a bunch of R&D started on bioterrorism countermeasures without giving full attention to the actual products we need to build and the market forces that will get them finished and deployed and sustained.

The Department of Homeland Security can address this problem

Centralizing the authority in the Department for setting priorities, funding solutions, and managing incentives is the first and most important step. My own experience trying to find the “go-to guy” responsible for specific bioterrorism countermeasures reinforces what you have seen in report after report (such as Hart-Rudman, Gilman, and the Defense Science Board) documenting the appalling division and duplication of responsibilities among dozens of silos in the Departments of Defense, Health and Human Services and elsewhere throughout the government. It is impossible to locate the customer for any significant, long-lead time technology that might just save our Nation from several of the highly likely attack scenarios.

First, we need a national strategy for Homeland Security and the new Department should play the central role in its creation and maintenance. I would be concerned about anything that causes confusion about who is in charge, as might happen if we create a statutory Office for this purpose in the White House. It could be seen as yet another silo, one more voice in the cacophony attempting to perform “coordination” among disparate agencies. Homeland Security is surely the most basic component of national security. Let’s make the National Security Advisor and the President accountable for ensuring that the new Secretary has the cooperation he needs. There seems to be a myriad of new panels and committees being proposed. Strategy and work groups should be broken down by the nature of the threat, not according to the government’s org chart. The technical challenges, expertise, and private-sector relationships are different for chemical, biological, nuclear and cyber threats. I can say for sure that we need one high level
decision-maker and one high level expert panel devoted exclusively to the problem of biological threat and response if we are to optimally engage the private sector. Both should reside in the Department, freed of historical institutional biases and allowed to focus on results and not process.

The Department must be able to work effectively with both HHS and DOD on science and technology related to its goals, and we should be bold in taking steps to move entire programs into the new department, especially where there is a history of poor coordination and duplication and especially where we need to engage the private sector. The Department can and should be a model for effective public-private partnerships. The Department’s leadership role should be clearly extended to include all of the research specifically addressing the bioterrorism threat conducted anywhere in the Executive Branch.

Strong engagement with the Department of Defense is essential

The failure to seriously address integration of homeland security with the Department of Defense efforts is a glaring omission in the draft legislation I have reviewed. Blue ribbon panels have been especially critical of DOD’s productivity and preparedness for bioterrorism. In our darkest reflections on the new reality, we know that the military will be required to enforce any meaningful quarantine around a bioterror attack with a transmissible agent. Think about it: protection of our warfighters engaged in a homeland defense operation is inseparable from protection of civilian responders and the general population. As we learned so clearly in the Swine Flu epidemic in the 70’s, the specification, manufacture, distribution and deployment of a biological countermeasure (the swine flu vaccine) must be integrated in a seamless policy. In retrospect, it was the right thing to stockpile the vaccine, but we should have waited with a hair trigger for more information to begin immunizations.

Homeland security and the Food and Drug Administration

Another key relationship for the new Department that is getting too little attention is that with the FDA. As a wealthy society in peacetime, with strong sense of accountability for everything related to health, we have evolved a highly conservative posture towards regulating medical products. Our society continuously engages in a constructive dialogue about how to balance risk and benefit in most settings, but there is a clear and different need for leadership regarding our risk posture for biodefense countermeasures. In the setting of moderate threat, we will likely want to offer the public vaccines or drugs that carry the benefit of full FDA approval from the perspective of this very risk-averse posture. But just as generals must make difficult trade-offs in time of war, some threat scenarios require that the Secretary commission, stockpile and be prepared to deploy biological countermeasures that carry very significant risk to individuals. We can give him the authority to have us prepared for worst-case scenarios without weakening our strong peacetime regulatory systems.
Meaningful countermeasures are definable and achievable

The new Department should reject the notion that there are so many bioterror threats imaginable that countermeasures are doomed to fail. We can identify the highest risk agents for the near and intermediate time frame, based on the biology and technical challenges faced by our attackers. Even though HIV has remained elusive, most concerted vaccine development programs against important natural agents have succeeded! Drugs and new approaches to helping the immune system offer additional opportunities.

How did these successful vaccines come into being? In almost every case, the basic science was supported at or by our extraordinary National Institutes of Health. And without exception, the applied research necessary to translate these basic findings into workable, safe, effective manufacturable biologic products was carried out by pharmaceutical and biotechnology firms that were driven to create value for their shareholders by pursuing large market opportunities for high-margin products.

We should also acknowledge that there are categories of threats that are difficult to address with long-lead time agent-specific countermeasures. An example would be novel genetically engineered pathogens for which we need novel and powerful new approaches. Senator Lieberman has pointed in S. 1764 out that we also need to stimulate creation of rapid-reaction research tools so that we might someday have the power, in the middle of the epidemic, to develop and deploy completely new countermeasures.

Are the markets too small to motivate private investment?

Some of the countermeasure priorities to be set by the new Department will have important beneficial uses against natural infections and diseases. A broad-spectrum antibiotic needed for plague or tularemia could save lives in the hospital from multiple-resistant infections. Gene chips deployed as an early warning system for bioattack could be designed to timely register the appearance of naturally occurring pandemic influenza, an inevitable phenomenon which has the potential to cause more damage to our population than many man-made epidemic scenarios. Contract R&D via the very useful SBIR process or DARPA’s remarkably enlightened procurement mechanism is an ideal way to stimulate such dual (beneficial) use technology.

But when Government is the only natural customer for products that require long-term, high-risk applied research and development, the government must find a way to effectively engage its suppliers. I am thinking of vaccines to protect against Ebola, for example. We need a new model, without the parasitic dependency fostered by current DOD procurement. A properly empowered Secretary in the new Department can engage the community of bioinnovators and they will work with him to create this model.

Compared to their primary markets in the civilian health care system, biodefense markets may look small, but I think this is due to our failure to really grapple with what is at
stake. A moderate earthquake in Taiwan on 9/21/99 shut down that country’s high tech industry for 10 days. As a direct result, dozens of our Silicon Valley companies missed their quarterly earnings because shipments of critical components were delayed. Imagine how long it will take to get those chips, motherboards and displays to build our products if five confirmed cases of smallpox occur in Taiwan next month? A requisition for two hundred million doses of smallpox vaccine is ten times too small to protect our economy from the threat of an attack on our trading partners! Our allies and trading partners have an equal stake in this deadly game and must be pressed to carry their part of the cost. The Homeland Security Department needs to be able to reach out and make this happen as well.

Background as a biomedical entrepreneur

My comments here are based on my experience as co-founder of Affymax, co-inventor of the technology underlying the Affymetrix GeneChip™, as founder of Aviron, a venture-backed vaccine discovery and development company recently acquired by MedImmune, and now a partner at Alloy Ventures, a venture capital fund investing in entrepreneurs building early-stage companies in information and communication technology and the life sciences. I have served as a member of the Executive Committee of the Biotechnology Industry Association and am currently working on a project with Business Executives for National Security focusing on policy issues discussed in these remarks.

Finally

I would like to compliment this Committee and the Chairman for vigorously and sincerely taking on the challenge of designing our new homeland security structure beginning immediately after September 11th. Your efforts here will undoubtedly have an enormous impact on our ability to carry on with our lives in spite of the new threats.

It is essential that the new Department be established, that it be forcefully led, that it have the tools it needs to be effective and that it is held accountable for preparing us for a bioterrorism attack. I am sure that the private sector will play an important role in its success.
HOMELAND SECURITY AND WEAPONS OF
MASS DESTRUCTION

HEARING BEFORE THE
Committee on Government Affairs
United States Senate
June 28, 2002

Statement of
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MEETING THE CHALLENGES OF
ESTABLISHING A NEW DEPARTMENT OF
HOMELAND SECURITY:
A CSIS WHITE PAPER
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PREFACE

On June 6, 2002, nine months after the devastating terrorist attack on the World Trade Center and the Pentagon, President Bush announced a sweeping reorganization of the U.S. federal government designed to strengthen its ability to provide homeland security. Reaction to the President’s plan—the most ambitious such reorganization in 50 years—has been both supportive of its general outlines and critical of its details.

We firmly believe that it is in the interest of all Americans for the creation of a new Department of Homeland Security to succeed. America remains vulnerable to catastrophic terrorism. Too many of the security procedures instituted since September 11, 2001 have provided too little security—often because of the lack of a central, coordinated framework for efficient government action. The President’s proposal has the promise to improve this situation enormously.

But in our view, important issues must be clarified and resolved if the initiative is to realize its full potential and America is to become more secure. We also believe the plan is missing some key pieces that need to be addressed.

Most importantly, we believe that the initial steps to implement the President’s proposal should be considered provisional. America’s security needs will evolve as America’s society, business climate, population and threat assessments change. The great burden of modern government is its lack of flexibility in adapting to change. Congress needs to institutionalize a climate of continuing assessment and evolution as our government strives to meet the demands of providing homeland security.

President Bush has shown great leadership in launching this bold initiative. Now, the Congress and all Americans have a responsibility to further the debate, with the common goal of doing what is best to protect the land we love. It is in this spirit that we offer this White Paper to the administration and the Congress.1

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1 This white paper is the product of the CSIS Task Force on Homeland Security. Members include (in alphabetical order): Philip Anderson, Kurt Campbell, Arnaud de Borchgrave, Mary DeRosa, Jay Farrar, Michèle Flournoy, John Hamre, David Heyman, Joelle Lastino, Thomas Sanderson, and Anne Solomon.
SUMMARY OF RECOMMENDATIONS

Empower the Office of the Secretary of Homeland Security

- Establish offices capable of performing four key functions (among others): threat assessment, strategic planning, program and budget review, and development of new "operational concepts."

Facilitate More Effective Intelligence Sharing and Analysis

- Establish a National Intelligence Fusion Center as part of the new Department to enhance connectivity, information sharing, and collaboration at all levels of intelligence and law enforcement.
- Establish an information "classification" system for use by domestic law enforcement and the Department of Homeland Security.
- Add analyst positions in FBI field offices and law enforcement offices in major urban centers to provide analytic input to domestic intelligence databases.
- Establish information sharing protocols so that data may be shared with third parties without case-by-case review and approval procedures.

Consider Economic Issues

- Avoid mandates in the Department’s statutory authority that would inhibit or prevent consideration of economic issues.

Forge Close Links Between the Department and Other Homeland Security Entities

- Establish in the new Department offices responsible for working closely with each of the following communities: international partners, the Department of Defense, state and local officials, and the private sector.

Establish Close Private Sector Ties

- Establish a departmental culture and policies that are informed by 21st Century global commercial operations and management realities.
- Create an Under Secretary for Acquisition comparable to the DoD Under Secretary for Acquisition, Technology and Logistics or NASA’s Assistant Administrator for Procurement.
- Enhance the flexibility of the new Department’s procurement mechanisms by moving the Chemical, Biological and Radiological Technology Alliance (CBRTA) of the National Technology Alliance (NTA) to the new Department and create an NTA-like instrument within the Department.
Enhance the Skills and Performance of Homeland Security Personnel

- Create a Homeland Security Training Academy that reports directly to the Secretary of the new Department.

Foster Better Communication with the American People

- Create an office within the new Department charged with undertaking an ongoing, national public education campaign to inform the American people about threats to the U.S. homeland and what individual citizens can do to enhance their own safety and security.

Support the Technical and Analytic Needs of the New Department

- Establish a Federally Funded Research and Development Center for Homeland Security.

Revamp Congressional Oversight of Homeland Security

- Create a Select Committee of oversight in the House, and a similar committee in the Senate.
- Relinquish responsibility in committees that exercise overly broad and, in most cases, duplicative oversight of the agencies that will be folded into the Department of Homeland Defense.
- Membership of each respective Select Committee should be made up of chairpersons and ranking members from the committees (House and Senate) and subcommittees (House) that now exercise oversight over the various agencies that will be consolidated in the new Department of Homeland Security. This criteria for membership will ensure cross-jurisdictional involvement by members, further providing comprehensive oversight.
- Terms of membership on each Select Committee should be governed by the same criteria that govern chairmanship or ranking member status on other committees.
- Each new Select Committee should have its own separate staff, not affiliated with any other committee or subcommittee.
- Within each Appropriations Committee, create new subcommittees of oversight. In conjunction with those new subcommittees, dissolve oversight responsibilities now resident in standing subcommittees.
BROAD CONSIDERATIONS FOR DECISION MAKERS

Although creating a Department of Homeland Security is an important step, it must be viewed as only one part of the answer to the management challenges of the homeland security mission. No single structural fix can resolve what is a massive, long-term strategic problem.

Six broad considerations should inform the efforts of homeland security decision makers:

Articulate a Homeland Security Strategy

The administration has not yet articulated a national strategy for homeland security that defines the mission as well as the capabilities and processes necessary to perform that mission. In the absence of a comprehensive U.S. Homeland Security Strategy, the formation of the new Department alone will not ensure greater success in protecting the American homeland. Because we cannot protect every possible target from every possible threat, it is imperative that the homeland security strategy that the White House publishes later this year conveys a clear understanding of the threats to be addressed and clarifies priorities for resource allocation – essentially, where to place emphasis and where to accept or manage a degree of risk. Completing this strategy should be the top priority of the White House Office of Homeland Security.

The strategy should identify clear objectives and a division of labor among all of the actors at the federal level, clearly identifying which agencies have lead responsibility in which homeland security areas, and which should be prepared to provide support. In short, the strategy should point the way toward well-defined roles and responsibilities, coordination processes, and operational procedures for enhancing the accountability and performance of the U.S. government across the homeland security domain – key elements that reorganization alone will not fully address. The strategy should also serve as the basis for allocating federal resources for homeland security – creating a foundation for unifying the efforts of the federal government and establishing the conditions for effective cooperation and coordination with state and local governments and the private sector. In order to ensure that it remains a living and relevant document, the Homeland Security Strategy should be tied to the budget process and reviewed, updated and submitted to Congress on an annual basis.

Conduct a Comprehensive Threat and Vulnerability Assessment

The foundation of any homeland security strategy must be an informed, thorough assessment of the threats we face and the vulnerabilities of our society. Such an assessment is critical to developing a risk-management mechanism for determining priorities, reconciling competing interests, and applying resources. If we try to protect equally against all possible threats, we will protect adequately against none of them.
Although there has been significant discussion of threats and vulnerabilities, no one in government has yet conducted the kind of creative, comprehensive analysis that is necessary to determine which should be accorded the highest priority—and which should be accorded the least. Most attention so far has focused on very high consequence/low probability threats, such as weapons of mass destruction—nuclear, biological or chemical devices—or a successful attack on a nuclear power plant. A comprehensive assessment would certainly include such threats, but would also look at threats at the other extreme of the consequence/probability spectrum, such as individual suicide bombers—and, crucially, at everything in between.

Threats in the middle of the consequence/probability spectrum merit greater alarm and attention than they have received to date. In retrospect, this middle space is where September 11 fell, and it is the space in which future terrorists will likely operate. Terrorist attack options in this category include "dirty bombs," well-coordinated attacks involving multiple near-simultaneous suicide bombings nationwide, and attacks on "soft" energy targets like oil refineries, petroleum or liquid natural gas terminals.

Without a comprehensive threat and vulnerability assessment process that considers both the probability of various types of attacks and the severity of their consequences, decision makers will have little analytic basis for making tough strategy choices about where to place emphasis, where to accept or manage a degree of risk, and how best to allocate resources to improve America's security. Like the strategy development process, the threat and vulnerability assessment process must be an ongoing one, tied to the budget, if it is to inform our national priorities for and investment in homeland security.

**Strengthen White House Coordination**

Many critics fear the administration's proposal for a Department of Homeland Security will not solve the inter-agency turf and coordination problems that have come to light in the wake of the September 11 attack. Some have lamented that major players, such as the FBI and the CIA, are not included in the proposed Department, and have suggested that those entities or parts of them should be transferred. But transferring an agency because it has a homeland security mission is not necessarily the answer. Even if parts of the FBI and CIA were transferred to the new Department, a host of other agencies would still retain some homeland security role. The Department of Defense will always be a major player. The Departments of Justice and the Treasury will have significant roles, even after some of their entities are transferred. And to differing degrees, the Departments of State, Commerce, Transportation, Energy, and Health and Human Services will all retain pieces of the homeland security mission. It is simply not practicable or wise to transfer all elements of the bureaucracy that have a role in homeland security.

As the administration and Congress continue to look for ways to address the inevitable and significant coordination challenges that will remain a part of homeland security, one critical step should be to ensure strong central authority in the White House.
The administration envisions a continued and critical role for a White House Office of Homeland Security, as do most proposals from Congress. The essential coordinating role of this office should be elevated and enhanced. The Office of Homeland Security, its leader and staff must be to this mission what the National Security Council Advisor and staff are to the foreign policy/national security mission – with the authority and ability to coordinate policy decisions, resolve operational disputes, and force timely cooperation among agencies.

The administration must also act to clarify the relationship between the Homeland Security Council and the National Security Council. In this new security environment, international and domestic security are inextricably intertwined, and the success of U.S. strategy may well depend on our ability to integrate our efforts abroad and at home. At present, however, there is no mechanism in place to ensure that the necessary integration takes place. It is imperative that the administration create such a mechanism on a priority basis.

Craft an Effective Implementation Strategy

Beyond developing an organizational structure for the Department of Homeland Security, how policy makers choose to implement the reorganization is another important challenge – one that will shape how well we protect our way of life in the future.

Two key considerations should be reflected in any implementation strategy:

- *Adaptive, Flexible Bureaucracy.* We can assume that when the administration releases its Homeland Security Strategy in the next few months, the homeland security structure that the White House has proposed will fit that strategy. But given the dynamic nature of threats and rapid changes in society, the homeland security mission will require an ongoing reevaluation of strategy. Just as the threats we face will change, so must our manner of addressing them. Obviously, we cannot create or realign government agencies every time our strategy changes. That is why it is important to create a government structure that is more adaptive, flexible, and able to work across organizations than those of the past.

More specifically, it is imperative that the new Secretary of Homeland Security be given the authorities and resources he or she needs to rapidly stand up an adaptive, flexible organization with a culture that places a premium on accountability and performance. In practice, this may require providing the Secretary with some rather extraordinary tools on a provisional basis, such as the ability to hire, fire and reassign employees more easily for a certain period of time, the ability to waive some procurement restrictions in order to facilitate more rapid acquisition of high priority goods and services, and the ability to reform and reorganize offices within the Department with appropriate notice to Congress. Creating this kind of flexibility will also require, among other things, a thorough review of the procurement, ethics, fiscal and privacy laws that too often interfere with agencies working together and reaching out to the private
sector. We cannot accomplish this transition immediately, but at the very least we must start it.

- **Phased Implementation.** In 1947, President Truman implemented one of the nation’s largest governmental reforms through the National Security Act that established the Department of Defense and the Central Intelligence Agency. The Truman Administration had the luxury of implementing these dramatic reforms during a time of peace. Today, we are in the midst of ongoing hostilities – and many of the institutions and individuals responsible for carrying out current homeland security operations are the very ones who would be uprooted in a reorganization. A transition to a new bureaucracy entails a massive transfer of resources (169,000 people and more than 20 agencies) and raises numerous practical considerations, from logistical concerns regarding new office locations to bureaucratic concerns regarding reporting structures and roles. To ensure all possible continuity in prosecuting the war on terrorism, we will need a phased approach – conceivably over several years – to integrate the new Department, as well as innovative uses of technology and management practices to create “virtual” organizations with a shared sense of mission and culture in the interim. The goal must be to strike the right balance between moving expeditiously on clear near-term needs and deliberately on long-term structural reforms.

**Balance Other Critical Concerns**

Security is our nation’s greatest challenge and must be the government’s highest priority. But the American people will suffer if actions taken to further security consistently trump other important interests and values.

- **Preexisting Missions.** Many of the entities that will become part of the Department of Homeland Security have important missions in addition to homeland security. The Customs Service, for example, has a significant economic mission; the Coast Guard is responsible for maritime safety, maritime mobility, drug and alien interdiction, and protection of natural resources; FEMA deals with natural disasters; and the Animal Plant Health Inspection Service lists animal welfare, agriculture trade, aquaculture, and several other non-homeland security matters among its functions. Some of these unrelated functions might be left behind in the transfer of these entities to the Department, but most will not. Although its primary mission will be homeland security, the Department must be flexible enough to promote these other missions as well, all of which remain extremely important.

- **Civil Liberties.** Perhaps the greatest challenge for those in the government pursuing the homeland security mission will be addressing the balance between security and civil liberties. Among the issues that will test this balance are proposals to:
• eliminate the separation between foreign and domestic intelligence collection;
• relax restrictions on surveillance;
• allow greater access by the government to data collected by the private sector and local and state governments;
• use data mining and profiling techniques;
• institute a national identification system; and
• use biometric technology for identification documents.

All of these actions would involve lifting some restrictions that are designed to protect the privacy or other liberties of American citizens.

The government must not rush to judgment when considering these and other inherently controversial proposals. To the maximum extent possible, they must be fully and publicly debated. While public airing of views will sometimes make speedy action more difficult, it will also strengthen the legitimacy of whatever measures are finally agreed upon. Conversely, if the American people perceive that steps to limit their liberties are being taken secretly or without careful thought, their trust in government will erode.

Before lifting any restriction that is designed to protect privacy or other civil liberties, the government must consider the following set of questions:

• What is the history and purpose of the restriction? What liberty is it designed to protect and what are the risks if it is lifted?
• What, precisely, is achieved by lifting the restriction? What new information will it bring? Do we need the information? All of it? Will we be able to use it? Are there other ways to get it?
• Are there less onerous ways to protect liberties than the existing restriction?
• How can the government oversee the new information collection or sharing in a way that is robust enough to ensure that abuses will be detected? Is the oversight authority sufficiently detached to be effective?
• What measures have been taken to ensure strict accountability for abuses?

Seize an Historic Opportunity to Reform Government

Understandably, much of the discussion about the new Department has focused on what it needs – what functions or entities could be added to improve the government’s ability to protect the U.S. homeland. At the same time, Congress should seize this historic opportunity to rationalize the federal government and render it more effective, both within the new Department and in other agencies with homeland security functions. The consolidation of many homeland security functions under one roof should be accompanied by careful scrutiny of each component being transferred to identify internal reforms that could enhance performance and efficiency. Nor should this effort to eliminate unnecessary redundancies, streamline the bureaucracy, and increase effectiveness be restricted to the new Department. Every agency that is responsible for
part of the homeland security mission should be scrutinized. Are there offices that should be disestablished, reconfigured or absorbed into others?

At the same time, Congress has an historic opportunity to accelerate (and in some cases leapfrog) recent government management initiatives (e.g., e-governance) and dramatically reform the way we organize and operate government institutions. The current organizational structure and decision-making apparatus of the U.S. Executive Branch is based on an architecture designed over sixty years ago – and was predicated on the technology that existed at that time. Today’s technologies have driven major changes to business models – significantly decreasing the effectiveness of traditionally vertically-integrated hierarchies and replacing them with flatter, more horizontal and distributed working environments that can respond to changes more rapidly and more effectively than in the past. This evolution must be incorporated by our government agencies as well to create organizations that are more adaptive, flexible and efficient in marshalling resources to secure our borders. Decision-makers can capitalize on the urgency of completing the current homeland security legislation to make some tough organizational decisions and innovations that will improve the way our government works.
RECOMMENDATIONS

Empower the Office of the Secretary of Homeland Security

- Establish offices capable of performing four key functions (among others): threat assessment, strategic planning, program and budget review, and development of new “operational concepts.”

The Secretary's office should include a small threat assessment unit specifically charged with “thinking like a terrorist” and researching ways in which U.S. security could be breached in the future. In contrast to the near-term, operational focus of the more substantial information analysis branch, this small analytical staff would focus on the mid- to longer-term, and would undertake disciplined reviews of evolving terrorist objectives, doctrine, and techniques in an effort to inform the development of strategy and program priorities for the Department. This office should draw widely on the research community in both the United States and other countries.

The Secretary’s office should also include a strategic planning office whose mission would be to define and prioritize objectives for the Department, articulate a Department-wide strategy to meet those objectives, and develop a division of labor that clearly assigns responsibility for various aspects of the strategy to specific departmental actors. This planning process should build on the threat assessment work described above and include a companion assessment of the capabilities resident within the Department to deal with priority threats to the U.S. homeland. The objective should be to help the Secretary provide clear policy guidance and develop a multi-year action plan for the Department. This plan should provide the blueprint for developing the Department’s budget, identifying and prioritizing capability shortfalls that need to be addressed, specifying short-term actions to be taken on a priority basis, and highlighting long-term investments to be made to enhance performance in critical areas. This plan should be issued over the Secretary’s signature to guide resource allocation across the Department. It should also be a living document that is reviewed and revised on an annual basis. The process of developing this plan should include all stakeholders within the Department, as well as close consultations with the White House Office of Homeland Security. The development of such a strategy-based, integrated action plan will be critical to ensuring that the new Department — and the USG more broadly — gets the highest possible returns on what is likely to be tens, if not hundreds, of billions of dollars invested in homeland security over the next several years.

In order to ensure this plan is implemented, the Secretary’s office should also include an office responsible for conducting a rigorous program and budget review, whereby the activities and expenditures of the Department are reviewed annually in light of the requirements of the multi-year plan. This review process would provide a mechanism for ensuring that the actions of various components accord with the Secretary’s guidance,
and would provide the Secretary with a critical mechanism for enforcing his or her priorities and those of the President.

Finally, the Secretary’s office should include an advanced concepts office chartered to develop new approaches to government operations that would bridge the discontinuities and address the shortfalls identified in strategic planning and simulations. It would utilize current operations research techniques to identify new ways of doing business, and help the Secretary provide guidance to the Department’s various bureaus to develop new capabilities to meet priority requirements. An excellent model for such an office is the Advanced Systems Concepts Office in DoD’s Defense Threat Reduction Agency.

Facilitate More Effective Intelligence Sharing and Analysis

- Establish a National Intelligence Fusion Center as part of the new Department to enhance connectivity, information sharing, and collaboration at all levels of intelligence and law enforcement.

The President’s proposed reorganization does not address the central problem of missed warnings due, to a large extent, to the fragmented, territorial and risk-averse cultures of the entities that collect and analyze intelligence. There is an urgent need to dismantle information stovetubes and share security data more effectively across the federal government and with states, localities, and need-to-know private sector entities. Establishing a National Intelligence Fusion Center would help to create a more collaborative relationship between U.S. intelligence agencies, U.S. domestic law enforcement, and, when warranted, foreign law enforcement agencies, with a view to closing fissures that terrorist groups could exploit. Such a fusion center would collate intelligence and information for all sources, foreign and domestic, down to the level of local law enforcement.

The Center should also: a) provide common, controlled access to relevant information and analysis for cleared government officials; b) use existing joint terrorism task forces (JITF) as a model for law enforcement and intelligence collaboration; and c) embed a strong “ombudsmen” or internal watchdog capacity to guard against civil rights abuses. The Center would require integrated databases with technology now in research and development for data mining, data fusion and data visualization. The Center would directly support the work of the analytic offices of the new Department and others across the U.S. government.

- Establish an information “classification” system for use by domestic law enforcement and the Department of Homeland Security.

Over the years, the Defense Department and the Intelligence Community have developed a comprehensive system for classifying and disseminating information to
individuals with appropriate clearances. The lack of a comparable system for law enforcement at any level has become a substantial barrier to sharing information among those who have a need to know. One of the Homeland Security Secretary’s first assignments to the Department should be the creation of such a system. First steps should be to establish classification guidelines and a Department-wide clearance process so that all individuals with the appropriate clearance (SECRET, for example) would be eligible to see appropriately classified information. This classification system should be interoperable with existing systems for handling national security information.

- Add analyst positions in FBI field offices and law enforcement offices in major urban centers to provide analytic input to domestic intelligence databases.

Though the law enforcement community currently develops useful facts that might provide important insights for terrorism prevention and detection, these facts are contained in isolated case files and are not routinely developed into “knowledge” that can be transmitted through a cleared community to improve terrorism prevention efforts. One of the reasons such data is not disseminated is the lack of interoperable information systems in the law enforcement community. But an equally important reason is the absence of analysts at the local level who can turn these isolated facts into larger observations and knowledge for use by counter-intelligence and counter-terrorism experts at higher headquarters. The FBI and law enforcement agencies in major American cities should devote the resources needed to create adequate analytic capabilities in field offices. Semi-finished intelligence reports could then be provided to the larger community.

- Establish information sharing protocols so that data may be shared with third parties without case-by-case review and approval procedures.

One of the great impediments to information sharing is the absence of protocols that might guide the subsequent release of information shared between two agencies. A common practice in government is for two agencies to develop sharing procedures through which they exchange information needed to do their respective jobs. Such sharing procedures rarely permit a receiving agency to pass on the information to a third party without returning to the originating agency for permission. Such case-by-case review and approval procedures are a serious impediment to timely data coordination, analysis and assessment.

The new Department of Homeland Security should develop a model data sharing protocol that would govern the subsequent release of information provided by liaison organizations to third parties. Such data sharing protocols would require appropriate procedures to protect the original “sources and methods” used to gain the information. The information sharing protocols currently used in the Intelligence Community might provide a model for early action in this area.
Consider Economic Issues

- Avoid mandates in the Department’s statutory authority that would inhibit or prevent consideration of economic issues.

There is no question that security is now our nation’s greatest challenge and must be the government’s highest priority. But the United States will suffer if actions are taken to further security without adequate regard to their economic consequences. Security and economic vitality are not necessarily incompatible. A Department whose sole mission is security, however, may not only fail to recognize when its policies may cause economic harm, but may also view the consideration of economic consequences to be “soft on security” or even unpatriotic. The functions of the Department of Homeland Security – particularly those of the Customs Service, the transportation and border security offices, and the offices devoted to critical infrastructure protection – will have significant impact on the economy. If the Department’s statutory authority requires it to take only security into account, it will prevent attempts to find flexible solutions that further both the security and the economic health of the nation.


Almost every government agency sees its own mission as paramount and discounts or ignores other policy priorities. At least in theory, the White House, through its coordinating offices, provides the necessary policy balance. With the creation of a massive Department of Homeland Security whose functions can have significant impact on the economy, this natural agency tunnel vision could result in a dangerous imbalance of priorities – toward security and away from economic health and efficiency – that would be difficult for the White House to realign. Therefore, both the White House Office of Homeland Security and the Department of Homeland Security must have a formal part of their structure dedicated to economic concerns. While we do not propose a specific structural solution here, one possibility for the Department would be a separate office reporting to the Secretary whose mission is to review the impact of policies on the economy. While there is no guarantee that this office would have significant day-to-day influence in the Department, if it exists by statute it would have some voice.

Forge Close Links Between the Department and Other Homeland Security Entities

- Establish in the new Department offices responsible for working closely with each of the following communities: international partners, the Department of Defense, state and local officials, and the private sector.

Protecting the American homeland will require the new Department to work in close partnership with a number of outside entities. At the international level, the Department
will need to build relationships with counterpart agencies in other countries in an effort to help strengthen aspects of their security that have a direct impact on ours and to identify international resources—such as cutting-edge products, services or practices—that could be imported or adapted to enhance the security of the United States.

The new Department should also seek close links to the Department of Defense’s new Northern Command, which will become the single focal point for all DoD support to civil authorities. Specifically, DoD should, as an urgent near-term step, establish a permanent Northern Command liaison office in close proximity to (preferably in the same building as) the Secretary of Homeland Security. This liaison office should have full capability to link the command center of the new Department with the command center of Northern Command.

The new Department will also need to create mechanisms for ensuring close communication and coordination with state and local officials involved in homeland security. The kind of mechanisms pioneered by FEMA for federal-state-local cooperation in the area of natural disasters may be a model that can be applied more broadly across the four pillars of the new Department. Working with state and local officials must be a central element of the Department’s day-to-day operations.

Similarly, the private sector will be a critical partner in almost every dimension of the new Department’s work, and the Department should be structured so as to enable maximum communication and cooperation with those private sector entities that will be critical to achieving its mission (see recommendations below).

Establish Close Private Sector Ties

- Establish a departmental culture and policies that are informed by 21st Century global commercial operations and management realities.

The Department will depend on private sector entities for two essential needs:

- first, to provide counter terrorism-related products, systems and services; and
- second, to safeguard critical transportation, energy, water and other systems that are privately owned or managed.

To establish effective private sector ties, the structure, policies and procedures of the new Department must be informed by an understanding of a commercial environment transformed during the post-Cold War era. During the 1990s, both U.S. and foreign firms established partnerships with competitors outside national borders and developed markets, R&D and manufacturing facilities abroad. For example, many biologics manufacturing facilities that may be relevant to U.S. acquisition of bioterrorism countermeasures are located abroad. Similarly, many critical infrastructure facilities within U.S. borders are foreign-owned or operated. Leveraging such private sector
activities to achieve public sector objectives will require sector-specific analysis of these realities and a Department equipped to deal with them.

- **Create an Under Secretary for Acquisition comparable to the DoD Under Secretary for Acquisition, Technology and Logistics or NASA’s Assistant Administrator for Procurement.**

A streamlined acquisition infrastructure with senior, experienced leadership is essential to develop and implement critical private sector partnerships. Acquisition officials in the new Department must be cognizant of sector-specific industrial cultures and considerations that will influence firms’ capacity to respond to national needs, and must develop policies and incentives accordingly.

Corporate concerns include risk management and liability, patent, tax, and anti-trust issues, among others. For example, in the area of risk management and liability, existing statutes such as Public Law No. 85-804 and the Price Anderson Act should be reviewed to assess their usefulness across sectors. Such a review should consider the range of potential customers to be served, including state and local governments and private sector entities. New indemnification legislation and liability exposure protection may be required. Other issues will require similar sector-specific analysis and policy approaches. These steps should be taken to disperse the “clouds of uncertainty” that darken private sector trust in stable government regulation, legislation and contracts.

- **Enhance the flexibility of the new Department’s procurement mechanisms by moving the Chemical, Biological and Radiological Technology Alliance (CBRTA) of the National Technology Alliance (NTA) to the new Department and create an NTA-like instrument within the Department.**

The Department of Homeland Security should benefit from innovative instruments such as the National Technology Alliance (NTA) whose mission is to influence commercial and dual-use technology development to meet national needs. The National Imagery and Mapping Agency (NIMA) currently serves as the NTA Executive Agent. Several steps should be considered. One is to move the Chemical, Biological and Radiological Technology Alliance, part of the NTA, from NIMA to the new Department. A second step is to establish within the Department an NTA-like entity based on Section 845 of the National Defense Authorization Act, Public Law No. 103-160.

**Enhance the Skills and Performance of Homeland Security Personnel**

- **Create a Homeland Security Training Academy that reports directly to the Secretary of the new Department.**
In designing the new Department of Homeland Security, Congress should establish a new training academy charged with conducting an extensive program of exercises and training for U.S. government personnel involved in homeland security. This academy should focus on two primary objectives: creating a more proactive, analytically based counterintelligence culture, and improving national capabilities for crisis response and consequence management.

At present, the U.S. Government’s considerable counter-intelligence capabilities are largely reactive in nature, using a “case file” approach aimed primarily at prosecuting suspected spies and terrorists. Counterintelligence officers have considerable skill when tipped off about a potential spy or terrorist, but virtually no analytic experience proactively anticipating where and how terrorists might next try to attack America – a skill that is critical to prevention. The President has said that he wants a proactive, analytically grounded approach to counterterrorism to be a hallmark of the new Department. We believe that establishing a training academy to develop these new analytic skills and create a more prevention-oriented culture in the counterintelligence community is critical to the success of the new Department.

The second focus of a homeland security-training academy should be a rigorous program of homeland security exercises allowing key decision makers from across government (and in collaboration with state and local governments) to refine approaches to incident management for various types of attacks. Such exercises can serve several valuable purposes. They can: uncover discontinuities in planning for future events; reveal insights into the complexity of problems that cannot be developed through other means of analysis; establish operational working relationships among participants in “peacetime” that become crucial for communication and trust in crisis; help organizations to surmount turf battles and recognize what they can and cannot do as well as what other organizations bring to the table; and reveal critical shortfalls in processes and capabilities that need to be addressed. A comprehensive homeland security exercise and training program should include periodic sessions for not only senior officials in the Department but also key players in other federal agencies involved in homeland security as well as state, local, and private sector officials.

Foster Better Communication with the American People

- Create an office within the new Department charged with undertaking an ongoing, national public education campaign to inform the American people about threats to the U.S. homeland and what individual citizens can do to enhance their own safety and security.

Since September 11, 2001, Americans have heard a great deal about potential threats to the U.S. homeland, but very little about what they, as citizens, can do to enhance their own safety and security. For example, few Americans know how best to respond to a terrorist attack involving biological agents – yet how they respond in the first hours of such a scenario could mean the difference between life and death, and between a
continued number of casualites and much more catastrophic effects for the nation. Public education is a critical element of any effective national strategy of homeland security, yet no senior official or agency has been designated and resourced to be responsible for this vital function. Building on the lessons learned from past civil defense efforts, Congress should create an office in the Department of Homeland Security responsible for leading the development and implementation of a nation-wide campaign aimed at educating Americans about the nature of potential threats to the U.S. homeland, what individual citizens can do to help law enforcement agencies prevent attacks, and what they should do in response to specific kinds of attacks to reduce the risks to their health and safety.

Support the Technical and Analytic Needs of a New Homeland Security Department

- Establish a Federally Funded Research and Development Center for Homeland Security.

There are numerous technical and analytic needs required to stand up and operate the proposed Homeland Security Department. They include (among others): developing new tools and techniques for integration and analysis of intelligence; assessing the balance of the homeland security research portfolio and establishing priorities for investments; developing recommendations for counterterrorism technology standards; establishing a risk-based management system for evaluating threats and allocating resources; and determining optimal ways to deploy WMD countermeasures. An existing mechanism that can support these needs is the use of a Federally Funded Research and Development Center or FFRDC. No such institution, however, is currently dedicated to these critical homeland security functions.

The use of FFRDCs is a common practice in government for agencies that seek the best expertise the country can offer and independent, objective advice. FFRDCs have flexible hiring and firing authority that allows for comparatively easy recruitment and retention of experts relative to the federal government. FFRDCs are also not allowed to make a profit or compete for follow-up work in which their analysis guided the parent agency. Consequently, decision-makers can be more confident that the advice that comes from an FFRDC is independent and objective. In the past, such research centers have played a critical role in enabling federal agencies to grapple with new security challenges. Given the scope and importance of the challenges associated with homeland security, establishing a new FFRDC for this purpose would provide the new Department with a powerful tool.

Revamp Congressional Oversight of Homeland Security

- Create a Select Committee of oversight in the House, and a similar committee in the Senate.
Congressional leadership should create new select committees in order to streamline the reporting process, eliminate fragmentation of authority, and ensure efficient and effective oversight of the new Homeland Security Department.

- Relinquish responsibility in committees that exercise overly broad and, in most cases, duplicative oversight of the agencies that will be folded into the Department of Homeland Defense.

Today, far too many Congressional committees and subcommittees have been given, or have taken, oversight responsibility for various aspects of homeland security. To ensure effective oversight of homeland security, Congress must rein in the number of committees and subcommittees that exercise authority over the new Department.

Specifically, the scope of jurisdiction of the House Government Reform Committee should be narrowed and its functions redefined to eliminate duplicate oversight over the many defense and homeland security functions already under the jurisdiction of other committees.

The Senate Government Affairs Committee should revise its charter and divest itself of the International Security and Proliferation function of the Subcommittee on International Security, Proliferation and Federal Services. This oversight role is adequately exercised in other standing Senate committees.

- Membership of each respective Select Committee should be made up of chairpersons and ranking members from the committees (House and Senate) and subcommittees (House) that now exercise oversight over the various agencies that will be consolidated in the new Department of Homeland Security. This criteria for membership will ensure cross-jurisdictional involvement by members, further providing comprehensive oversight.

The relevant Senate committees include: Agriculture; Appropriations; Armed Services; Banking, Housing and Urban Affairs; Commerce, Science and Transportation; Energy and Natural Resources; Judiciary; and Intelligence.

The relevant House committees (and attendant subcommittees) include: Agriculture (Specialty Crops and Foreign Agriculture); Appropriations (Agriculture; Commerce, Justice, State; Defense; Energy and Water; Transportation; Treasury, Postal Service and General Government); Armed Services (Military Readiness; Military Research and Development); Energy and Commerce (Environment and Hazardous Materials; Health; Telecommunications and the Internet); Financial Services (Financial Institutions and Consumer Credit); Judiciary (Courts, the Internet and Intellectual Property; Crime, Immigration and Claims); Science (Energy; Research); Transportation (Aviation; Coast Guard and Maritime Transportation; Highways; Railroads); and Intelligence (Human Intelligence, Analysis and Counterintelligence; Intelligence Policy and National Security; Terrorism and Homeland Security).
• **Terms of membership on each Select Committee should be governed by the same criteria that govern chairmanship or ranking member status on other committees.**

Term limits on membership ensure fresh perspectives, while maintaining more than adequate understanding of the issues because of members’ other committee assignments.

• **Each new Select Committee should have its own separate staff, not affiliated with any other committee or subcommittee.**

Separate staff will ensure independence and limit cross-jurisdictional turf battles. Further, a separate staff provides focused and expert insight to members of each Select Committee.

• **Within each Appropriations Committee, create new subcommittees of oversight. In conjunction with those new subcommittees, dissolve oversight responsibilities now resident in standing subcommittees.**

Unless separate new subcommittees are created, and oversight within current subcommittees is dissolved, the new Department will be whipsawed by competing demands and lines of authority within the Appropriations Committees.
Testimony of the
American Society for Microbiology
Submitted for the record of the
Senate Committee on Governmental Affairs
on the

Hearing to Examine How a Department of Homeland Security Should Add Weapons of Mass Destruction and Relevant Science and Technology, Research, Development and Public Health Issues

June 28, 2002
INTRODUCTION

The American Society for Microbiology (ASM) wishes to submit the following statement for the record to the Senate Committee on Governmental Affairs for the hearing to examine how a Department of Homeland Security should add weapons of mass destruction and relevant science and technology, research development, and public health 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
biodiversity 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 terrorism. In the months since September 11, 2001, the NIAID has rapidly accelerated work to protect the nation against the threat of terrorism. 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 activities. 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 present this testimony. 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.
Responses to Questions for the Record Submitted to Dr. Margaret Hamburg
by Senator Daniel K. Akaka
Senate Committee on Governmental Affairs

"Preparing for Reality: Protecting Against Weapons of Mass Destruction"

June 28, 2002

1. According to the Domestic Preparedness Plan released by the Centers for Disease Control and Prevention, there are six elements of response to a public health crisis:

1) medical surveillance to detect an event;
2) making quick, rapid and appropriate decisions;
3) implementing pre-existing response plans;
4) rapid and appropriate distribution of vaccines and medicines;
5) ability to keep up with the flow of sick and "worried well"; and
6) ability of response system to receive and rapidly utilize outside help.

Which of these elements do you feel poses the most significant problem, and which causes you most concern because of funding deficits?

The Domestic Preparedness Helpline refers to a non-emergency resource available for use by emergency responders across the United States. The State and Local Domestic Preparedness Hotline is 1-800-368-6498. The Helpline provides general information on all of the Office for Domestic Preparedness (within the Department of Justice) programs and information on the characteristics and control of WMD materials, defensive equipment, mitigation techniques, and available federal assets. The Helpline provides "customer intelligence" that will aid state and local jurisdictions in building capacity in their communities to respond to a WMD terrorism incident.

To answer the second part of this question, the six elements listed form a subset of those required for a public health system. There is a need for a robust public health system that is intrinsically linked to health care providers throughout the nation and the world. Public health funding deficits affect a broad array of programs and priorities that are fundamental to ensuring the health of the nation, particularly in a crisis. Requirements for such a system include the development of response strategies before a crisis occurs, and address such issues as the rapid and appropriate distribution of vaccines and medicines, mass casualty care, and infection control measures.

Although we have seen some funding directed toward training efforts in the domestic preparedness arena (e.g. the Nunz-Lugar-Domenici Domestic Preparedness Program), the vast majority has been directed towards the first responder community and has utilized a
chemical terrorism paradigm which does not directly apply to biological terrorism incidents. It is imperative that plans that are developed be practiced with the diverse response requirements for different agents of terrorism in mind. Additionally, practice must occur through a number of means, including tabletop exercises, meetings, terrorism related disaster drills, etc.

In addition, it is essential that we emplace mechanisms for ongoing communication, planning, and practice between and among all critical preparedness and response partners, both within and without the government. Such communication should be included in the list of critical elements of response to a public health crisis.

2. At the Governmental Affairs Subcommittee on International Security, Proliferation, and Federal Services July 2001 hearing on bioterrorism, an expert on emergency medicine and preparedness testified that because our nation's hospitals, private practices, and clinics do not have a federal counterpart, emergency preparedness and response plans are often made without their input. How should the health care community be included in Department of Homeland Security activities and planning?

Along with public health, the inclusion of the health care community in activities and planning regarding the proposed Department of Homeland Security will be essential to success. A new Department of Homeland Security should have in-house expertise (medical and public health professionals on staff at the senior levels). Additionally, related policy should be informed by an external advisory committee oriented solely towards public health and medical homeland security needs.
Responses to Questions for the Record
Submitted to Janet Henrich
by Senator Daniel K. Akaka
Senate Committee on Governmental Affairs

“Preparing for Reality: Protecting Against Weapons of Mass Destruction”

June 28, 2002

1. According to the Domestic Preparedness Helpline Plan released by the Centers for Disease Control and Prevention, there are six elements of response to a public health crisis:

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6) ability of response system to receive and rapidly utilize outside help.

Which of these elements do you feel poses the most significant problem, and which causes you most concern because of funding deficits?

Response: All six of these elements are vital to minimizing the risk to any public health emergency, and we have previously reported weaknesses in many of these areas. Improving infectious disease surveillance may be the most crucial of these elements because of the importance in managing the incident of recognizing an emerging crisis as soon as possible. Early and accurate detection and identification of an agent can greatly reduce the risk of illness and even death during an outbreak by allowing public health officials to identify and treat those at risk, and to take steps to reduce the potential for transmission to others. However, improving the infectious disease surveillance system is a difficult and complex task because it requires the cooperation and collaboration of public health officials, hospitals, private providers, and laboratories and updating the paper-based systems that are used in many areas with new technology to speed and simplify information sharing.

The ability to adequately manage the incoming flow of patients in an emergency causes great concern because it depends on partners in the private sector, mainly hospitals, who are reluctant to maintain surge capacity because of the associated costs in such a competitive industry. Many hospitals may also need capital improvements, such as expanding isolation facilities and installing air handling and filtration systems, which are expensive. This is a particularly pressing issue because significant funding for hospitals and state public health departments to begin addressing these issues is very new and
remains to be seen how effectively the money will be distributed and used by communities to improve preparedness for large numbers of illnesses in a public health emergency.

2. At the Governmental Affairs Subcommittee on International Security, Proliferation, and Federal Services July 2001 hearing on bioterrorism, an expert on emergency medicine and preparedness testified that because our nation's hospitals, private practices, and clinics do not have a federal counterpart, emergency preparedness and response plans are often made without their input. How should the health care community be included in Department of Homeland Security activities and planning?

Response: As you know Senator, our world has changed significantly since September 11, 2001. Hospitals and other health care providers have become significantly more involved in community planning for emergencies in many areas. They have also become more active in preparedness planning at the state level because of new federal initiatives and funding that I mentioned earlier. Hospital and healthcare representatives can serve important roles in helping to plan for emergencies at the state and local level, and at the federal level as well through participation in advisory committees and through their traditional relationships with policy makers. Officials at the Department of Health and Human Services, as well as the Department of Homeland Security, will have to continue to consider ways to gather meaningful input from the healthcare community on policies and programs. However, these activities must be carefully coordinated so that hospitals and healthcare providers continue to be important resources for both responding to terrorism and for the day-to-day care of patients.