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WORLD AT RISK: THE WEAPONS OF MASS DESTRUCTION PREVENTION AND PREPAREDNESS ACT OF 2009

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

OF THE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 22, 2009

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WORLD AT RISK: THE WEAPONS OF MASS DESTRUCTION PREVENTION AND PREPAREDNESS ACT OF 2009

TUESDAY, SEPTEMBER 22, 2009

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:07 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.

Present: Senators Lieberman, Akaka, Pryor, McCaskill, Bennet, and Collins.

OPENING STATEMENT OF CHAIRMAN LIEBERMAN

Chairman LIEBERMAN. Good morning and the hearing will come to order. Today, we are going to hear testimony on legislation that Senator Collins and I introduced earlier this month to prevent and prepare to respond to attacks against our homeland by weapons of mass destruction (WMD), particularly biological weapons.

Our legislation has a focus on heightening security at laboratories that handle the world's most dangerous pathogens, dangerous because they are those that can most easily be weaponized. But, of course, the legislation is more comprehensive. It is as comprehensive as the Commission report was and as our own Committee's deliberations on this subject warrant.

In December of last year, then-Director of National Intelligence (DNI) Mike McConnell publicly stated his conclusion that a WMD terrorist attack is more likely than not to occur somewhere in the world between now and 2013—that is obviously within the next 4 years—and that a biological attack is much more likely than a nuclear or chemical attack.

The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, chaired by our former colleagues, Senators Bob Graham and Jim Talent, reached a similar conclusion and went well beyond in what I believe was an extraordinary piece of work documenting the problem and making very significant recommendations.

The fact is from all this that it is hard not to conclude that we are still not properly prepared to counter the threat of a weapons of mass destruction attack against the United States and particularly the bioterrorist threat, despite measures taken after the 2001

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anthrax attacks. In sum, and as the Graham-Talent Commission concluded, we are a Nation and world at risk.

For anyone who thinks that in the work of this Committee and in discussions that go on in our homeland security community that we are being overly zealous, that we are perhaps imagining threats to America that don't really exist, one need only follow the media coverage over the last several days of the investigation and now apprehension of these people here in this country. People who apparently were directly connected to al-Qaeda and apparently were planning very significant attacks within our country again, apparently within the greater New York City area.

So the threat is real. It goes back to, if there is a capital of world Islamist terrorism, it is in the mountainous areas between Afghanistan and Pakistan and spreads in different cells throughout Pakistan. They continue to want to do us harm.

What the Commission's report convinced me again is that if they want to do us harm, one way they can manage to do it with devastation is through a biological attack, and that is why the legislation that Senator Collins and I have introduced based on the Commission report, we think is so critically important to the homeland security of the people of the United States of America.

This legislation, which we call the Weapons of Mass Destruction Prevention and Preparedness Act of 2009, S. 1649, would provide a multi-layered approach across the full spectrum of prevention, preparedness, and response to this threat. Our legislation, as I mentioned, implements the Commission's recommendations and our Committee's conclusions from our ongoing investigation into the Nation's defense against a WMD attack.

I want to briefly describe some key elements of the legislation and their origin in the Graham-Talent Commission report and our Committee's work.

First, this bill would identify and categorize the most dangerous pathogens, that is, those that are easiest, that have the greatest potential to be turned into weapons to be used in a biological terrorist attack, and that therefore require improved security, a heightened level of security at the laboratories that handle them. We think that our approach ensures that we focus our security efforts where they are needed most and not burden the wider range of scientific research unnecessarily.

Our Committee's interest in laboratory security was informed greatly by the Commission's report and the commissioners' testimony before our Committee last December. The report cited findings on inadequate security at our Nation's laboratories and concluded, "when it comes to materials of bioterrorism, America's vulnerability may well begin at home." Through this legislation, we seek to close this vulnerability.

Second, our bill would build the culture of preparedness as called for by the Commission by requiring a national strategy for dispensing antibiotics and other medicines to the public to respond to a biological attack. We would also expand the use of the Postal Service in the distribution of these countermeasures. Right now, we are spending billions of dollars to stockpile these supplies, and those are very important investments, but our Committee has found that we lack an adequate plan for distributing those supplies

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and countermeasures, quickly and efficiently if an attack occurs. The bill would also provide medical kits to emergency responders so that they can protect themselves in order to be able to protect us in responding quickly to a WMD attack.

Third, our bill acts on the Commission's call for improved public information. It would put in place specific communication plans to inform the public of what to do during the critical moments after an attack, and we have learned from testimony before the Committee that communications to the public can have an extraordinary effect on diminishing the number of victims of a WMD attack.

Our bill also requires the development of pre-scripted, adaptable messages, as recommended by the Commission, so that appropriate information can be disseminated swiftly. Such information would include the direction of a deadly radioactive or biological plume and instructions about whether it is better to shelter in place, stay in your home, stay in your worksite, or to evacuate quickly, and we think that kind of information could save thousands of lives.

Fourth, the legislation would direct the Secretary of State to build an international biosecurity coalition by providing training and assistance to other countries in laboratory security and global disease surveillance.

Finally, the legislation would also require the Director of National Intelligence to improve intelligence on WMD and terrorism, particularly by increasing his hiring of scientists and improving foreign language capabilities.

Senator Graham, Senator Talent, you and your fellow commissioners and your staff have done a great service for our country in this report and that is why we look forward so much to hearing your views regarding the legislation that has resulted from it.

I am also pleased to welcome again a return appearance by Greg Kutz, Managing Director for Forensic Audits and Special Investigations at the Government Accountability Office (GAO). Mr. Kutz and his team have spent the past 2 years investigating the state of security at our Nation's five most elite laboratories, that is, the laboratories that handle the world's most dangerous pathogens. In a 2008 report, and then in a follow-up report released a couple of months ago, GAO draws a disconcerting picture of the poor security regulations governing these laboratories and of the state of physical security at these laboratories, which Mr. Kutz will describe for us and which energize even more our consideration of this legislation and remedial action.

Bottom line, we have to be direct and honest with the American people about the risk facing this country from a weapon of mass destruction attack by a terrorist organization. As the Graham-Talent Commission noted, "America's margin of safety is shrinking, not growing."

Senator Collins and I are hopeful and believe that our Weapons of Mass Destruction Prevention and Preparedness Act of 2009, S. 1649, will close many of the existing gaps and thereby grow our margin of safety.

Senator Collins.

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OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

As the Chairman has indicated, the recent arrest of a terrorism suspect in Colorado is a sobering reminder of the continued threat to our Nation. Al-Qaeda and other terrorist organizations have publicly declared their intention to acquire and use weapons of mass destruction against the United States.

Just last week, another media report highlighted how terrorists might join forces with global drug traffickers in order to take advantage of the traffickers' vast networks of tunnels, black markets, technology, and human intelligence. The terrorists have noted the ease with which traffickers smuggle illegal drugs across our borders. In the words of a former U.S. Embassy official in Afghanistan, "When you get to the point where you can smuggle tons of drugs through one border, then you certainly have the capacity to smuggle in weapons of mass destruction or agents."

Clearly, this threat is real, urgent, and evolving. On September 8, the Chairman and I introduced legislation to help counter this threat. Our bill would improve our Nation's ability to prevent and respond to WMD attacks. It would enact many of the recommendations of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, the Commission that the Chairman and I helped to establish in 2007.

I am certainly pleased to see once again the leaders of that Commission, our former colleagues, Senators Bob Graham and Jim Talent, here today. Their report warns us that it is more likely than not that a weapons of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013. We have repeated that warning a lot in our public statements, but I think we cannot say it often enough to convey to the public how urgent action is. The Commission's report is a call to action. Our bill is the answer.

The Commission's findings reinforce the urgency felt by this Committee during our many hearings regarding the terrorist threat to our Nation. We have examined many deadly threats targeting the American people, and to respond to these threats, our Committee has led numerous reform efforts since the terrorist attacks of September 11, 2001. Our work has strengthened intelligence gathering efforts, tightened security at our ports and chemical facilities, and vastly improved our emergency preparedness.

Nevertheless, the Commission's report provides a chilling reminder that the terrorists have been active, too. Nuclear proliferation and advances in biotechnology are giving terrorists new methods and new means to commit mass murder, so we, in turn, must continue our efforts to identify risks and to increase security.

As the Commission's report explains, the most likely WMD threat to the United States is a biological weapon. It is easier to develop and disseminate bioweapons and gain access to lethal pathogens. Furthermore, terrorists know that a bioweapon can be a stealth attack. We may not immediately recognize that such an attack has even occurred until hundreds of people have been sickened or even died.

Despite this threat, some of the world's most dangerous pathogens are not secure, and that includes pathogens housed in biologi-

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cal laboratories right here in the United States. The GAO's alarming report shows that there are deficiencies in basic perimeter security at facilities that house the world's most dangerous biological agents, diseases such as the Ebola virus and smallpox. The GAO also pointed out that lab regulation, for the most part, relies on self-policing.

The fact is that thousands of people right here in our country have access to the most dangerous pathogens. More than 400 research facilities and nearly 15,000 individuals are on the Select Agent List, an authorization to handle the most deadly pathogens. We needn't look far. The Federal Bureau of Investigation (FBI) has determined that a cleared scientist at a regulated research lab most likely carried out the 2001 anthrax attacks.

To counter this threat, we must increase the security at biological laboratories, and our bill seeks to accomplish that goal by identifying those pathogens that terrorists are most likely to use and increasing the security standards at the labs that handle them. A negotiated rulemaking with Federal agencies and research institutions at the table would develop these standards. This collaboration would ensure that the regulations that make our Nation's biological labs more secure do not have the unintended consequence of deterring legitimate research. In addition, we provide a 4-year grant program to help fund the security enhancements.

Let me just mention one other part of our bill that I think is very important, and then since the Chairman has outlined the rest, I will just submit the remainder of my statement.

The Commission also found that the Federal Government is unaware of some research facilities that handle less strictly controlled but still dangerous pathogens. To close that gap, our bill would require registration of those labs and facility security requirements that would be tiered based on the risk that terrorists might use a particular pathogen from a biological lab. That is the kind of approach that we used successfully in our chemical facility law, where we had a tiered approach with greater mandates for security to apply to the most high-risk facilities.

Again, I look forward to hearing the testimony of our witnesses today and I am eager for us to move forward and advance this bill to the full Senate. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you very much, Senator Collins.

Senator Graham, Senator Talent, thank you. I am very pleased that your Commission, in some sense, took a good lesson from the 9/11 Commission—and to some extent so did Congress because we provided appropriations to continue your work because in some ways this is the most important chapter because unless something is done with your report, it is not going to matter much. So your capacity and that of your staff to continue to be involved in informing and advocating about this problem and a solution to it is gratefully appreciated.

Senator Graham, welcome back. Good to see you.

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TESTIMONY OF HON. BOB GRAHAM,[1] CHAIRMAN, COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM

Mr. GRAHAM. Thank you very much, Chairman Lieberman, Senator Collins, other Members of the Committee. We very much appreciate this opportunity to discuss a critically important dimension of our report, securing against a biological weapon of mass destruction.

I wish to say to all the Members of this Committee that it is our intent to issue an interim progress report next month as to how far we have proceeded. There are some critical words in that 2013 statement, which is that if we continue at the same pace, it is more likely than not that a WMD attack will occur somewhere in the world by the end of 2013, and that attack will be biological rather than nuclear. We have the opportunity to change the probabilities based on action. The reality is, our report was issued approximately 10 months ago. Ten months of our limited time to reach a position where we can reduce the vulnerability of the American people have now passed and we will be reporting as to whether we think we have used those 10 months prudently. We expect to have a final report early in 2010, prior to the ending of this Commission, which will be in February 2010.

I can give you, I hope, the happy news that we anticipate that this Committee is going to get very good grades in our progress report. In fact, by far, you have been the most energetic Committee in the Congress relative to dealing with this critical and urgent issue, for which we are deeply appreciative.

I would also like to thank Senator Akaka for his recent introduction of the Energy Development Program Implementation Act of 2009, which puts in place an Alternative Energy Peace Corps as was called for 31 years ago by the Nuclear Nonproliferation Act of 1978. We wish to also alert Senator Akaka that he is likely to get a good grade in our interim progress report.

As we review our recommendations, while we feel positive about what is happening in this Committee, one of our major concerns continues to be, as it was with the 9/11 Commission and other previous commissions, the question of congressional reform. "A World At Risk" offers a recommendation which reads, "Congress should reform its oversight, both structurally and substantively, to better address intelligence, homeland security, and cross-cutting 21st Century national security missions."

Today is a good example of why we made that recommendation. Today, in addition to this Committee, there are two other committees of Congress holding hearings on this very subject of laboratory security. When the Department of Homeland Security was formed, there were 86 different committees and subcommittees overseeing the new Department. Today, that number has been reduced from 86 to 82. There are signs of the continued dysfunction of congressional oversight identified not only by our Commission, but by a series of citizens' commissions. Congress has been appropriately

[1] The joint prepared statement of Mr. Graham and Mr. Talent appears in the Appendix on page 39.

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forceful in demanding reform in the Executive Branch. We believe it is time to include the House and Senate in this process.

And you should be pleased that our action plan, one of our action steps under congressional reform is that the Senate and House Homeland Security Committees should be empowered as the sole authorizing oversight committees for the Department of Homeland Security and all agencies under that Department's jurisdiction. I would hope that objective would be achieved and thus place the full responsibility where we believe it should be, with this Committee and your counterpart in the House.

I use the word "urgency." We think there are three clocks ticking. One, the Chairman has already discussed, and that is the 2013 clock. In addition to that preface, that assuming things stay as they are, that it is more likely than not that there will be a weapon of mass destruction used on earth before 2013, but that probability, which we found in December 2008 to be somewhat greater than 50–50, can go up if time is wasted and is not followed by effective action.

As Senator Collins said, our adversaries are not sitting in the stands waiting to see what we do. The reason that we have been falling behind is because as much effort as we have made to increase our security, it has not been as great as the effort our adversaries have made in order to penetrate that security. We think that relationship continues, and therefore, the probability of a weapon of mass destruction may be greater today than it was 10 months ago.

But 2013 is not the only clock. There also is a 2010 clock. It is a nuclear clock. Every 5 years, the signatories to the Nuclear Nonproliferation Agreement meet to review what has happened in the last 5 years and to plan for the next 5 years. We think that the meeting that is going to occur in 2010 is of special importance. We have made a number of recommendations to improve our security against a nuclear attack. Most of those recommendations require executive action. The Congress has devoted a great deal of attention through things such as the Nunn-Lugar Cooperative Threat Reduction Program to increasing our security on the nuclear side.

The other clock, the third clock, is the 2011 clock. There will be a similar meeting in 2011 reviewing the 1972 Biological Weapons Convention. We have made recommendations of what the United States should be prepared to do at that conference. One of our action items is the United States should reaffirm the critical importance of the 1972 Biological Weapons Convention to international peace and security by proposing a new action plan for achieving universal adherence and effective national implementation to be adopted at the next review conference in 2011.

The relevance of that to this Committee's action is that if the United States is going to present itself as being the world leader on issues of control of biological weapons, we need to be the gold standard of such actions on a universal basis. This legislation and appropriate implementation, we believe, would give us that status. So we think it is critical that this legislation be passed and then a sufficient amount of time provided for implementation, so that when we get to the 2011 conference, we will hold the moral, legal,

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and policy high ground to encourage other countries to follow our example.

So those are the three clocks that we think dominate this discussion.

Now turning specifically to the biological threat, we see our adversary as having a continued energized will to use biological weapons and increasing capabilities to do so. These characteristics of the biological threat include, first, the fact that the development and dispersing of biological weapons is not expensive. In fact, it is getting cheaper and scientifically easier.

Second, a biological weapon could rival or exceed the damage caused by an improvised nuclear device (IED).

And third, there are fewer hurdles to creating an effective bioweapon than a nuclear device. Virtually all dangerous pathogens are available in nature. The equipment needed to produce a large quantity from a small seedstock and then weaponize the materials is readily available today on the Internet. The most effective delivery methods are well known in the pharmaceutical, agriculture, and insect control industries.

This is not speculation. Al-Qaeda was well down the road to producing such weapons prior to September 11, 2001. Due to the ease in creating a clandestine production capability, our intelligence community had no knowledge of two such facilities in Afghanistan prior to their capture by U.S. troops. Facilities with more sophisticated equipment than those found could be in operation today, again without our knowledge.

I would like today to focus on two of the titles in your legislation, Title I and V. Senator Talent will discuss the other titles. Title I, Enhanced Biosecurity Measures in U.S. Laboratories, responds to our recommendation in "World at Risk." Certain principles animated the section of our report dealing with laboratory security. We are concerned about the proliferation of high containment labs, which were not only unregulated, but often unknown to the government. And just this week, the Government Accountability Office has issued yet another report entitled, "High Containment Laboratories: National Strategy for Oversight Is Needed." We have been at this business at least since the anthrax attack in October 2001, 8 years ago, and still a national strategy is not available.

The fragmentation of government oversight among agencies, the need for a thorough review and update of the Select Agent programs, and the importance of regulating labs in a way that did not discourage robust scientific research in the United States are all reasons why we give the issue that you have labeled as Title I such primacy.

Enhanced biosecurity measures should improve security, streamline oversight, and focus our resources on the real risks. By correctly applying risk management principles, the United States can increase security without impeding science or critical U.S. industries.

The legislation calls for the establishment of Tier I pathogens, which would be those that could be most readily weaponized and which would receive the most rigorous level of review. We would also recommend that there be a Tier II and III, each of which

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would represent a somewhat declining level of risk with an appropriate level of regulation relating to that risk.

Title V of the legislation deals with the issue of citizen involvement. We believe that it is critically important that the American people feel a greater sense of engagement in this issue. We strongly believe that a well informed, organized, and mobilized citizenry has long been one of our Nation's greatest resources. An engaged citizenry, in fact, is the foundation for national resilience in the event of a natural disaster or a WMD attack.

I recently visited with intelligence, military, law enforcement, and parliamentary officials in the United Kingdom and they unanimously said there had never been a WMD or other terrorist plot in the United Kingdom which had been broken without significant citizen involvement. We believe there are models to be followed.

I will present for the record a letter from the Business Executives for National Security (BENS),[1] a nonpartisan organization with a 27-year history of facilitating public-private collaboration. This includes 7 years of building security and resilience-focused partnerships at the State and local level. This organization has been active in many places in the country. It has been particularly effective in its work in Iowa, which occurred approximately 18 months before the very devastating floods of last year, and while that was natural, not a manmade disaster, the benefits of having developed such a private-public partnership were in evidence.

In conclusion, we commend you for introducing this extremely important piece of legislation and we look forward to participating in a robust discussion on Capitol Hill and with the Administration and the stakeholders as we move towards passage and implementation.

We stand ready to help where we can to promote this very important stride for our national security. Thank you.

Chairman LIEBERMAN. Thanks very much, Senator Graham. That was very helpful testimony. I particularly appreciate the three clocks that are ticking because you help us put our work on this in the context of ongoing events that have dates that are associated with them.

I don't want to take a lot of time on this, but I also appreciate your going back to the question of congressional reform of the handling of homeland security issues. Senator Collins and I, and this Committee, are proud of the work that we did with the House on the 9/11 Commission Report because we really put into legislation almost every one of the recommendations that the 9/11 Commission made to do everything we could to avoid another September 11, 2001.

But the one that we suffered a total and embarrassing failure on was the attempt to reform us. We are very good at reforming the Executive Branch, but this gets into turf battles here. I appreciate your mentioning it. At some point, you and Senator Talent and Members of the Committee ought to talk about how we could try this again.

We appreciate that you say that the Homeland Security Committee should clearly have jurisdiction here, but it is really the

[1] The letter submitted by Mr. Graham appears in the Appendix on page 66.

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question that Tom Ridge first raised, which was he was spending too much of his time as Secretary of Homeland Security going to too many committees and subcommittees and they were redundant. It wasn't that he was avoiding oversight.

So, anyway, I appreciate your mentioning it. Hope springs eternal. Senator Collins and I are both very stubborn people and we are not going to give up on this, so you encourage us to be even more stubborn.

Senator Talent, thanks for being here. Thanks for all your work, and we welcome your testimony now.

TESTIMONY OF HON. JIM TALENT,[1] VICE CHAIRMAN, COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM

Mr. TALENT. Thank you, Mr. Chairman, and just a follow-up on that. Not only does the redundant oversight consume too much of the executive's time, but as we point out in the report, oversight done properly can be hugely helpful. This Committee is a perfect example of that. But you can't do it properly when you have dozens and dozens of different committees doing it. So we would not only stop doing something that is interfering with the Executive Branch, but Congress could really play an even more effective role if we got the oversight correct.

I have a written statement which I will submit for the record and then just make a few comments.

Chairman LIEBERMAN. Good.

Mr. TALENT. I have to echo and want to echo what Senator Graham said about this Committee's work. The biggest enemy I think we confront in this is inertia, and to defeat inertia, it takes tremendous leadership and perseverance—stubbornness I think you just called it—and this Committee has shown that kind of perseverance from the day we issued the report. And really, in fairness, although everybody has been supportive—I don't think anybody on the Hill has not supported our report—but you are the only ones who have done that, which is the reason why we are here with this bill today. So I want to congratulate you on that.

I think part of the reason is that the Committee understands and keeps in front of it the strategic nature of this threat. I find in the public and even within government, it is just so easy to slip into the idea that because the enemy, or the people that we are opposing in this, don't represent a first world economy, don't even have a nation-state, that therefore they can't really be that dangerous.

But I think they have a more accurate strategic view of the world than we do. They understand that the world is a matrix of systems that are very important to not just the quality of life, but the ability of the average American, and person throughout the world to live, and that those systems are easy to attack particularly using asymmetric weapons. They understand the concept of asymmetric weapons very well.

That is one of the reasons why what the intelligence community was telling us, what the expert opinions, the actual evidence we

[1] The joint prepared statement of Mr. Talent and Mr. Graham appears in the Appendix on page 39.

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saw, the development of this threat to me was so plausible because it is logical for them to be trying to get weapons of mass destruction given their strategic view of the world. I would be, in a way, surprised if they weren't trying to do so. And you all know we have evidence that they think it is a priority for them.

So this Committee gets that. I think part of our job is to try and make certain everybody else does.

The other thing that is so important is to understand that we have to do something, even at the risk that doing something may produce some side effects that we didn't intend, rather than do nothing out of fear of the side effects. We have to move forward. If we don't do something—I mean, the current trajectory of risk does not favor us, so we have to disturb the inertia and move forward, and you all understand that. And also, it is across a broad front. It isn't any one thing. It is a series of incremental things that need to be done at the same time, and I think the bill represents that and I am very strongly supportive of it and appreciative of your leadership.

Just a few individual comments with the time that I have, and this is reflected in my statement. The bill addresses the issue of how we distribute medical countermeasures, which is hugely important. I think the bill is going to help achieve progress in that area. But I just want to remind the Committee, we have to have the medical countermeasures to distribute, as well. In essence, we have to have the vaccines and the antibiotics to distribute or the distribution system doesn't do us any good.

There are a couple of programs that have been established to accomplish that, Biomedical Advanced Research and Development Authority (BARDA) and Project BioShield, to encourage investment or to provide for government investment in the development of these vaccines. We want to point out that the Office of Management and Budget (OPM) seems to have gotten it into its institutional head to try and cut those programs. I understand that they are there to watch the budget, and that is a good thing, but those programs are hugely necessary and I would ask the Committee to watch for it, and those of you who are also appropriators to particularly watch for that.

And I will just add one thing. There is a pretty direct and proven connection between funding development of vaccines and actual vaccines. The scientific community knows how to produce vaccines for these kinds of pathogens if they have the money to do it. So we really will get something for this investment. We will get the vaccines and anthrax and the medical countermeasures, etc.

Second, I really want to applaud the Committee for taking on the workforce issue in the bill, how we can plus-up the personnel we have who have language skills, who have knowledge of nuclear issues and biological issues. We found all throughout the government people sounding the warning that we don't have enough of those people already. Unfortunately, there is a cohort of people in the government about 5 years away from retirement who possess a lot of the knowledge that we have, and we really have got to find people to take their place and we are not replacing them.

And again, I think a big part of the problem, Mr. Chairman, is the fear of doing something because we have these security regula-

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tions in place so that we are so worried about hiring somebody who might be off in some respect that we don't hire anybody. We have to—particularly with language skills. It takes years and years in many cases to process people through security so that we can hire someone. Well, people aren't going to wait around necessarily for years to get hired. So this is an issue that needs to be addressed and the bill addresses that.

I am particularly pleased at how the bill addresses the issue of citizen awareness and response, which I think is a huge untapped resource in this whole field, though not completely untapped. You all, I am sure, have talked with the authorities in New York City, for example, where they do a much better job of this. There is a lot of awareness there. The public is cooperating. That just adds to our ability to deal with this.

I really like the medical kits idea that you have put in here and I hope there is a way, and believe there is a way, to work with that so the general public can begin accessing it, as well. I think it is a hugely important idea that you have.

And finally, I will just close with one thing. The Chairman mentioned that there are people who tend to discount the danger of a biological attack. The Department of Defense, as you all know, had biological weapons programs in the 1950s and 1960s. I think it ended in the Nixon Administration. President Nixon just decided we weren't going to pursue them anymore. And they did a number of important tests on the efficacy of bioweapons, and this is using 1950s and 1960s technology. I just suggest if the Committee has not had a brief on those, ask the Department of Defense—I don't think they have ever studied them and put it all together in one brief, but it is a real eye-opener.

It was effective even then. And people who think that this is not a weapon that this will be effective against civilian populations just need to look at those studies and what we ourselves were doing. Now, as a battlefield weapon, it is questionable, because a lot of them don't take effect quickly enough in battlefield terms. But as a way of attacking civilian populations, it is extremely plausible and very effective, and I am grateful that you have a strong omnibus bill to deal with it.

Chairman LIEBERMAN. Thanks very much, Senator Talent. Very helpful testimony.

Mr. Kutz, welcome back. Thanks for all your service. A somewhat different look at this problem, but directly relevant, and we welcome your testimony now.

TESTIMONY OF GREGORY D. KUTZ,[1] MANAGING DIRECTOR, FORENSIC AUDITS AND SPECIAL INVESTIGATIONS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. KUTZ. Mr. Chairman and Members of the Committee, thank you for the opportunity to discuss biosafety laboratories. Today's testimony highlights the results of our assessment of perimeter security for Level 4 labs. My testimony has two parts. First, I will discuss our findings, and second, I will discuss our recommendation.

[1] The prepared statement of Mr. Kutz appears in the Appendix on page 50.

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First, we found significant differences in perimeter security at the Nation's five Level 4 labs. These labs handle the world's most dangerous agents and toxins that cause incurable and deadly disease. As requested by the Centers for Disease Control and Prevention (CDC), our report and my testimony do not specifically name these labs.

The poster board which is on my right,[1] and for Senator Bennet, you should have this in your packet since you can't see, if you have got it——

Senator BENNET. I have it. Thank you.

Mr. KUTZ. The poster board here on my right shows the results of our assessment of controls at these five labs. The black circles indicate the controls in place during our 2008 assessment. As you can see, three of these five labs had all or nearly all of the 15 key controls that we evaluated. Specifically, what we refer to as Lab B had all 15 controls in place, while Lab A had 14 and Lab D had 13.

The presence of multiple layers of security at these three labs reduces the risk of unauthorized access to the labs. Examples of controls in place at all three of the labs include: A blast stand-off area between the labs and perimeter barriers; barriers to prevent vehicles from approaching; a command and control center; roving arm guard patrols; and x-ray screening at building entrances.

The poster board also shows that in stark contrast to these three labs, the other two labs had little to no perimeter security. Specifically, what is shown as Lab C had only three of the 15 controls in place, while Lab E had four. Examples of controls that these two labs did not have in place include: A blast stand-off area between the lab and perimeter barriers; barriers to prevent vehicles from approaching; a command and control center; x-ray screening at building entrances; and vehicle screening.

Moving on to my second point, based on our 2008 assessment, we recommended that CDC take actions to enhance perimeter security at these Level 4 labs. CDC agreed that perimeter security was important, but noted that the differences you see in security here were the result of risk-based planning. They also questioned whether the 15 controls that we looked at were relevant and appropriate for these labs. One year later, in response to our second report, CDC told us that they will consider our recommendations in developing future security plans.

We understand the perimeter security is only one piece of the overall security picture and that a comprehensive approach to Select Agent security should be taken. However, it is discouraging that CDC would question the relevance of basic controls, such as blast stand-off areas, intrusion detection systems, x-ray screening at building entrances, and visitor and vehicle screening.

Despite CDC's limited actions in the last year, three of these labs have enhanced their perimeter security. For example, as shown by the red circles on the poster board, Lab C now has a command and control center, camera coverage of exterior lab entrances, and visitor screening. Other initiatives underway at this lab would leave

[1] The chart referenced by Mr. Kutz appears in the Appendix on page 66.

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them with eight of the 15 controls in place and two others partially in place.

Also, as you can see, Lab E made improvements and now has six of the 15 controls in place. Further, Lab D recently informed us that they have made improvements and have all 15 of the controls in place.

In conclusion, we are encouraged that three of these labs have made improvements in perimeter security in the last year. We believe that an active and layered system of security can prevent unauthorized access to these labs. This is particularly important as several new Level 4 labs are either operating today or will be in the near future.

Mr. Chairman, this ends my statement and I look forward to your questions.

Chairman LIEBERMAN. Thanks, Mr. Kutz. That was your normal good job from you. We will do 7-minute rounds of questions.

Let me start with you, just to follow up what you have said. This is very disappointing, that two of the five labs with the most dangerous pathogens, meaning that they are the most likely to be weaponized, even on their own, still have great gaps in their security. I am particularly disappointed in what you say is the nonchalant attitude—I am characterizing it that way—of the Centers for Disease Control about this. First, how do you explain that reaction by CDC?

Mr. KUTZ. I can't explain the reaction by CDC with respect to perimeter security because I believe that these controls we are talking about are fairly basic and I think most security experts would agree that they would reduce the risk of unauthorized attacks on these labs So I can't explain that.

I can explain the differences, to some extent. If you look at, for example, I think Lab B there, they have additional requirements outside of the CDC for security at those labs. So the actual base requirements that all three met, look at that, all three met the baseline requirements, which is hard to believe. But actually, these other labs, like Lab A and B, had other requirements from the Department of Defense (DOD), the National Institutes of Health (NIH), and the Department of Health and Human Services (HHS). So what you saw there were more stringent requirements from other parts of the Federal Government than for the Select Agent program.

Chairman LIEBERMAN. So Lab C and Lab E were the only two of the five that were only part of the Select Agent program under CDC?

Mr. KUTZ. Yes, Lab C and Lab E.

Chairman LIEBERMAN. And those were the ones that are really lacking. Well, I will state my own intention, and maybe the Committee can do it, to express our displeasure to CDC about this state of affairs, because these two labs, which have very dangerous pathogens in them, are at risk, and when they are at risk, so are we.

Let me go to Senator Graham and Senator Talent and ask a few baseline questions. We are particularly focusing, and I think for good reason, based on your report, on security at the laboratories. But let me step back and ask you to answer a question I know you

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considered. Accepting your premise that a WMD attack is probable somewhere in the world in the next 4 years and that it is more likely to be biological than nuclear, I am going to mention three ways in which the components for such an attack against the United States could be brought together.

One obviously is to manufacture the actual biological agent for attack elsewhere in the world. As you said, Senator Graham, we know that there were two active laboratories in Afghanistan that al-Qaeda was running.

A second, I suppose, would be to, going to Mr. Kutz's point, to steal pathogens from an existing laboratory supervised by the government, well or not so well, and take it somewhere else, to a secret location, and develop it into a weapon.

And the third—of course, this is the case we had with anthrax, where the Department of Justice determined in 2008 that Army biological researcher Bruce Ivins was the sole perpetrator of the 2001 anthrax attacks—is for somebody within the labs to be compromised, I mean, basically to be doing conversion to weapons within the labs.

We are focused here on the security of the labs. I want you to talk a little bit about your evaluation and the Commission's of the probabilities here, or is it impossible to do that? From which of the three courses I have mentioned is it most likely that a terrorist intending to do a biological attack against the United States would get the biological materials?

Mr. GRAHAM. The Commission did not attempt to make such an assessment. I will be sufficiently either indiscrete or courageous to try to do so. I would suggest it is the third option. That is the only one to which we have been exposed. That is, a scientist inside the lab——

Chairman LIEBERMAN. Right.

Mr. GRAHAM [continuing]. Who had passed a plethora of security background checks and then takes this material. He weaponized them in a crude manner such that they could be sent through the mail and ended up killing five people and creating significant disruption in our lives, including those of us who worked in these buildings.

Chairman LIEBERMAN. Right.

Mr. GRAHAM. So I think, while all three of those are potentials that need to be protected against, of the three, the more likely is the one that has already occurred, which is the rogue scientist.

Chairman LIEBERMAN. I appreciate your directness in that, and that is the evidence we have. So not to say that there is any sole path to this. Obviously, better perimeter security would not impact that individual or would not stop that individual. And, of course, in the case of Mr. Ivins, presumably, he went through all the personal security checks. What more can we do to deter or discover that kind of exploitation of the system for anti-American purposes?

Mr. GRAHAM. Well, as you know, the Department of Homeland Security has a program which is specifically targeted at the rogue scientist. That in itself has been a source of some controversy because it has resulted in what many would describe as an overly bureaucratic and delayed process to get people cleared to work in our scientific laboratories.

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While security is our principal concern, we are not unaware of the fact that the vast majority of what goes on in these laboratories is very positive, contributing to our health. Therefore, we don't want to make these centers of creativity and innovation so entangled with restraints that they can't carry out their basic mission.

I wish, Mr. Chairman, I could give you five specific things that we could do to increase the confidence in the individuals who are working in the laboratories. I can't do so, but I think the kind of recommendations that you are making for comprehensive oversight of these facilities, while this report focuses on the physical aspect, that comprehensiveness of oversight is also needed for the personnel issues, that would lead us to some thoughtful and constructive proposals to avoid another Bruce Ivins.

Chairman LIEBERMAN. I appreciate that answer. Senator Talent.

Mr. TALENT. Yes. I would add a couple things, Mr. Chairman. I agree with Senator Graham, by the way, that if I had to guess, that they would get it from a lab, because as we emphasized in the report, they will likely try to recruit bioscientists, life scientists, and the people that they are going to try and recruit are going to be the people who are active in the field, which means they are working someplace. And it just seems to me logical that the first thing such a person would try and do is to see if they could get the material from the lab where they are working. So I think that is a string of assumptions, but I think they are reasonably plausible.

I would say three things that we can do, agreeing with what Senator Graham said—but what the bill is doing is hugely important. I mean, for the first time, we are going to have comprehensive rulemaking in which all the various agencies are involved.

Chairman LIEBERMAN. Right.

Mr. TALENT. That is going to promote, I hope—I think this is very important—a culture of cooperation within the private scientific community and the agencies who are responsible for this. So they are going to begin talking, not that they are not now, there is a task force, I know, but more systematically and formally really talking about this, and you are going to see better regulation and better procedures growing out of that, almost in an evolutionary way. I think it is one of the geniuses of the bill.

And I hope what that does, then, is create within the scientific community a real acceptance of the need for an enhanced culture of security. I think there is still resistance——

Chairman LIEBERMAN. Sure.

Mr. TALENT [continuing]. But a sense of, look, we really do have to be aware about what the person next to us is doing because that is how you get somebody like Ivins. If somebody is next to him saying—now, it is hard, because as they pointed out, you can just put your pencil down and get a pathogen, and this is hard, but I think these are incremental steps that will help.

And then I do want to point out again the importance of having an effective system for producing and distributing countermeasures, because the better we are at responding, the more we tend to deter an attack. The Chairman and I made a decision when we started up the Commission that we would focus on prevention rather than remediation because you can't do everything, but this

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is an area where the two are linked because the better you remediate, the more likely you are to prevent.

Chairman LIEBERMAN. Correct. That is a form of deterrence. I appreciate your answer. It seems to me, also, in this matter, we are dealing again with a tension that we have dealt with from the beginning of America, which is between security and liberty. This is in a very specific way. Obviously, we don't want to discourage the extraordinary advances that come from the liberty of research and innovation, but on the other hand, we have got to create surveillance monitoring and measures to try to ferret out anybody who has gone astray and gone wild.

I do think that the idea that we share, and it is in the bill, of tiering the regulation is important and perhaps sends a message to the scientific community, too. We are trying to isolate here for the most intense scrutiny the relatively small number of labs where the highest risk pathogens are, the ones that can be turned most easily into the most devastating weapons, and, frankly, to let up a little on surveillance at a lot of the other labs where the experts judge that the risk of conversion to weapons is less serious, and I think that may be a good balance as we go forward.

Yes, Mr. Graham.

Mr. GRAHAM. Mr. Chairman, if I could just offer a couple of rays of hope, there has been a fairly distinct divide between the nuclear scientists and the biological scientists. The nuclear scientists largely came in existence after the first two nuclear weapons were actually utilized and, therefore, there has been from the beginning this culture of security. It was clear that the mushroom cloud was a potential outgrowth of nuclear technology and, therefore, security was an assumed part of the scientific community. We have had no similar iconic figure for the biological side. So we can take some lessons from how the nuclear scientists have managed this joint issue of innovation and creativity versus appropriate security and maybe apply those lessons to the biological.

Chairman LIEBERMAN. Good point.

Mr. GRAHAM. A second thing, some of the most scientifically committed universities in this country, over 20, have now formed a coalition to work precisely on this issue of the culture of security within our university setting, and I commend those institutions for their initiative. I hope that what they are doing will not only be successful in the member institutions, but will help set a standard for other higher education institutions that are engaged in this work, as we have seen recently, sadly, from your alma mater——

Chairman LIEBERMAN. Yes.

Mr. GRAHAM [continuing]. The potential of consequences of inappropriate action by people in these laboratories.

Chairman LIEBERMAN. Thank you, Senator Graham. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Kutz, Senator Graham's last comment is actually a good lead-in to a series of questions that I want to ask you because he talks about that nuclear scientists have a culture of security. That is their focus and that has not always been the case with scientists who are dealing with biological agents.

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I suspect that the cultural differences are also reflected in the regulators. I don't think that it is a coincidence that labs that were doing work for DOD had higher security than labs that were under the sole jurisdiction of the CDC. Did you find in dealing with the CDC that there was more focus on biosafety than on security?

Mr. KUTZ. Yes, there was more of a focus on safety, which isn't a bad focus, by the way, but there were no people that had actual security backgrounds that were doing the oversight and that were going out and approving the actual plans for security at these five Level 4 labs. So that clearly was something that we noted.

Senator COLLINS. And indeed, it is my understanding that the 15 standards that you used as an assessment were developed by the GAO, is that correct? In other words, did the CDC have a similar set of mandatory standards that needed to be met?

Mr. KUTZ. No. Theirs were more guidelines and they were much easier to meet. Ours were more stringent, more specific, and ours were more consistent with what you saw from DOD, for example.

Senator COLLINS. And when your report was issued a year ago and found such serious deficiencies in two of the labs that answered to the CDC, did the CDC order security improvements at the two labs?

Mr. KUTZ. No. They tried to explain that what we saw was actually part of a plan that was resulted from risk-based analysis. So they tried to actually rationalize or justify it rather than say that something needed to be done.

So as I mentioned, the three labs that have made improvements since then, they did it all on their own. There was no government assistance with respect to that. It was the labs themselves.

Senator COLLINS. That is really worrisome to me. It seems to me that when you went to the CDC a year ago and showed such glaring deficiencies in just basic security measures, that the agency should have acted immediately. And are you telling us that the improvements that were made, such as they are, were initiated by the labs themselves, not as a result of any order or even direction by the CDC?

Mr. KUTZ. Correct. The six red dots you see on that board were all self-initiated by Labs C and E, and as I mentioned, Lab D also went from having 13 to 15, and that was on their own.

Senator COLLINS. And I think that demonstrates why it is so important that the Department of Homeland Security be involved in the regulation, because that Department, as one of the Commissioners, Robin Cleveland, mentioned to us previously, has as a focus and a mission of homeland security. It is startling to me that you could present the regulator with the report showing such serious problems and no action was taken, but that is what happened.

Mr. KUTZ. That is correct. That is what happened.

Senator COLLINS. Thank you.

Senator Talent and Senator Graham, I want you both to respond to this issue. We have talked a lot this morning about the worry that terrorists could gain access to pathogens at these biolabs and we have talked about the possibility of the rogue scientist. But isn't there also a concern that these labs may contain specialized equipment and technology that could be valuable to terrorists in weaponizing a pathogen? In other words, it is not just the people.

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It is not just the biological agents. It is the specialized equipment, as well, is it not? Senator Graham.

Mr. GRAHAM. It is, and one of the many strengths of your legislation is to recognize that and begin the process of registering and providing some control over this equipment. It goes beyond equipment which is capable of weaponizing. It also relates to equipment which can actually be used to produce pathogens. Most of these high-risk pathogens occur in nature. Anthrax, for instance, is the product of decaying cattle, primarily. The word "anthrax" is a Russian word that means Siberian boil, because the first place anthrax was discovered was dead cows in Siberia. But there are other pathogens which are now being man-created and the equipment to do so is also a security risk. Your legislation would provide for some registration and control over who has access to that equipment.

Senator COLLINS. Thank you. Mr. Talent.

Mr. TALENT. I really agree. I think it is one of the major steps forward in the bill, is the provision of the registration authority and the focus not just on the pathogen, but on the equipment that could be misused. Right now, if the lab is not handling something on the Select Agent list, then the government just does not know anything about them. We do not know who is out there, and that, to me, is irresponsible.

And I think it should be done in a way—and this is very important, we believe—that whoever is directing that lab who is now going to have to register because of the equipment doesn't think of it as this is another dumb government thing I have to do. I will just fill this out as quickly as I can, send it in, and hope they never contact me again and hope I never have to do anything ever again having to do with this subject.

I hope that this is done in such a way—and you all, by providing for negotiated kind of rulemaking, I hope will achieve that—where that person says, you know what? Maybe this is something I need to not just comply with in the most bare minimum way possible but take an interest in. Maybe I need to start reading some industry things about this and be a little more concerned and circulate something to my employees about this because this is something I need to care about. That is the attitude we want out there, and the way to get it is the cooperative kind of rulemaking which you provide for in the legislation.

Senator COLLINS. Thank you. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks very much, Senator Collins.

Senator Akaka, and then Senator McCaskill.

OPENING STATEMENT OF SENATOR AKAKA

Senator AKAKA. Thank you very much, Mr. Chairman. I want to thank you very much for holding this hearing and I want to add my welcome to Senator Graham, Senator Talent, and Mr. Kutz as you give your testimony and commitment to increasing our ability to counter WMD threats to our national security.

I am pleased that President Obama has implemented some of the Commission's recommendations. He has appointed a coordinator for WMD Terrorism and Proliferation, and mandated greater integration between the National Security Council and the Homeland Se-

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curity Council. And still more can be done. It is important that we continue to focus on the greatest threats to our national security. We should remember that the Commission warned that the terrorists' use of WMD somewhere in the world is more likely than not by the end of 2013.

All levels of government, along with the private sector and individual citizens, really need to work in concert to provide capabilities and readiness to prevent catastrophic attacks and to limit the consequences if such attacks occur. Senators Lieberman and Collins have taken a strong leadership role in introducing the Weapons of Mass Destruction Prevention and Preparedness Act and I look forward to working with them on this bill.

Senator Graham, I recently introduced the Energy Development Program Implementation Act, which would put in place a mechanism to implement Title V of the Nuclear Nonproliferation Act of 1978. Under my bill, the United States would work with developing nations to foster non-nuclear alternative energy sources, which would provide economic and environmental benefits and also reduce the risk of nuclear technology ending up in the wrong hands.

Your Commission's World at Risk report recommended implementing this program. You also recommend actions by the Executive Branch. Are there other recommendations about nuclear proliferation and terrorism from your report that this Committee should consider?

Mr. GRAHAM. Yes. We are in what has been referred to as a nuclear renaissance. After 30 or 40 years in which there was relatively little development of new nuclear capabilities, particularly for civilian purposes, suddenly, a number of countries, including the United States, are either considering expanding our current base of nuclear capability and some countries which have never had nuclear before are expressing interest.

The fact that the Congress is now considering a number of what are referred to as 1-2-3 agreements, which are the agreements required by the Atomic Energy Act for the United States to cooperate in civilian nuclear with a foreign country, is itself illustrative of this nuclear renaissance.

It does pose some significant challenges. Let me just mention a few. One, the countries that have never had nuclear power before, therefore, have no system of regulatory standards or enforcement capabilities, either for safety or security. It is going to be a particular responsibility of the international community, particularly the International Atomic Energy Agency (IAEA), which is the regulating institution for the Nonproliferation Treaty, to see that those new entrants into the nuclear club do so under safe and secure circumstances. We have a number of recommendations for strengthening the authorities of the IAEA for this and other purposes.

Second, in our report, we suggest that the United States should be economically neutral on the expansion of nuclear power for civilian purposes, specifically, that we should not subsidize nuclear expansion in foreign countries. If a foreign country decides based on its own analysis that nuclear is an appropriate part of its energy construct, we should honor that, but we shouldn't subsidize it, thereby creating incentives for further expansion of nuclear with

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the almost inevitable expansion of the potential of diversion of that nuclear to military purposes.

Senator AKAKA. For too long, the Federal Government has not invested enough in supporting foreign language competency, as was mentioned earlier. This week, the Government Accountability Office will be releasing a report about serious proficiency gaps in languages critical to our national security at the State Department.

Earlier this year, I introduced the National Foreign Language Coordination Act to put in place a national strategy for foreign languages because Americans need to understand other languages and cultures to ensure our national and economic security. I am encouraged that the bill we are considering today has a provision for an intelligence community language capability strategy.

Do you believe this provision is sufficient, or is a broader national strategy for foreign languages needed?

Mr. TALENT. I think the provision in the bill is a really good step, Senator, and this is one of these areas where I think there is a limit to what Congress can do. This really requires vigor and energy in the executive, somebody taking this and running with it and taking the responsibility for making certain decisions.

Part of it is that we don't have the skills out there. Part of it is that we are not vigorously pursuing the people who have the language skills. And part of it is that we have set up requirements that really discourage those people from joining up. I mean, somebody who has the kind of language skills and cultural knowledge, for example, of Iran probably has had some connection to Iran. So if that is a disqualifier from a security standpoint, then you are never going to be able to recruit anybody.

And so there are huge, national communities around the country that want to help out, that have people who know how to help out, and we are not letting them help out. I just think it is going to take somebody high enough up to make a decision to say, look, we are going to start accessing these people. If there is some fallout or some baggage, I will bear it. Let us just go and do it. I don't think that decision has yet been made, but I don't know what you all can do other than what you are doing in this bill. They are going to have to take it up and run with it. You can do oversight and keep pushing, but this is an executive thing, I believe.

Mr. GRAHAM. Yesterday, I attended a briefing and the conditions of the briefing are such that I can't say who was the principal presenter, but I can say it was a very high person in our U.S. military, and he made the observation that in dealing with the kind of warfare that we are engaged in in Afghanistan, that intelligence is the very pointy end of the spear. You are trying to isolate the bad people from the civilians, because if you don't, you will end up harming civilians and therefore severely damaging your ability to carry out the mission. Intelligence is the key to being able to make that and a set of other good judgments.

He went on to say that good intelligence is predicated on knowledge, that you can't provide good intelligence if you don't have a knowledge of the history and culture of the area in which you are operating, if you don't have a knowledge of the language that the people speak, or if you don't have some understanding of the demographic composition of the area in which you are operating.

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So I think what you are pointing to is we are going to build up the knowledge base which will then make it possible to have superior intelligence capabilities. So I commend you for your prescience in identifying this as an important national security issue.

Senator AKAKA. Mr. Chairman, my time has expired.

Chairman LIEBERMAN. Thanks, Senator Akaka. Thanks for those thoughtful questions. Thanks for the legislation you introduced.

Senator McCaskill, let me thank you for two things. First, for deciding to cosponsor the legislation that Senator Collins and I have introduced to prevent a WMD attack, and second, thank you for the work you did in 2006 to free up Jim Talent so he could do the great service he has done for our country as Co-Chair of this Commission. [Laughter.]

Mr. TALENT. I retain a few mixed emotions about that. [Laughter.]

Chairman LIEBERMAN. You look pretty good. You look pretty happy.

Mr. TALENT. I am grateful for Senator McCaskill's presence here and wonder if she took the late flight in. I didn't see you on it——

Senator MCCASKILL. No. Actually, I did the 4:30 alarm this morning. I rolled in on the early flight.

Mr. TALENT. Yes. Your two choices of coming in from Missouri to make a Tuesday morning hearing are not either one of them very palatable.

Chairman LIEBERMAN. So there are opportunities for service after the Senate and you have done that in an exemplary fashion. Senator McCaskill.

Senator MCCASKILL. And Senator Lieberman, let me just say, to follow up on your comments, I think he is doing such great work there, I think it is very important he continue in that work for the long haul. [Laughter.]

Chairman LIEBERMAN. Got it.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. I want to thank both Senator Graham and Senator Talent for their work in this area. I think that both of you understand this place very well and you understand what works and what does not. I think you are being very kind to use the word "inertia," Senator Talent, because I think it is a little worse than inertia. We don't have a whole lot of people at the press table over there today. We don't have the best attendance that we would hope for in this Committee hearing this morning.

And partially that is about the attention span of this place and what drives it. Right now, we are in the midst of a very heated and drawn battle over health care reform, and in those moments, it is really hard to get people's attention around here on anything else.

I think the bill that has been introduced, which I am pleased to be able to cosponsor with Senator Collins and Senator Lieberman is incredibly important to the security of this Nation and I stand ready to do whatever I can to fight the fact that no one is giving it much attention right now, talking about this important topic. If this hearing had occurred in 2002, we would have had a line outside. But now, it has drifted away from the front of people's consideration and therefore we are going to have more difficulty getting

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it across the finish line. But I know with the leadership of this Committee, particularly our Chairman and Ranking Member, we can do it.

Let me ask you, Mr. Kutz, without going into specifically where the labs are located, was there any connection between the perimeter security that GAO found, between those labs that were government-owned and those that were privately-owned?

Mr. KUTZ. The two labs that had the weakest security were not-for-profit and university, so they were private. Two of the best were government operated and owned.

Senator MCCASKILL. And is the sixth biosafety Level 4 lab that has just recently become operational, is that a private or is that a government? Do you guys know?

Mr. KUTZ. I know it is in Montana. I don't know which.

Senator MCCASKILL. The reason I ask that is it seems to me that, as much as I don't like it in some instances, it would be fairly simple, maybe, to amend our bill to talk about funding from the government being contingent upon this perimeter security being present——

Chairman LIEBERMAN. That is a good idea.

Senator MCCASKILL [continuing]. And any other—because I am sure all of these labs, whether it is in the efforts that you all referred to in terms of government funding, of trying to get the BARDA and the BioShield that Senator Talent referred to in terms of investment in the vaccination, that we ought to be able to hook up the contingency of public money with the requirement of these securities, and I will try to follow up for that.

It is interesting that you both agree that our most likely problem is going to be with a rogue scientist and, therefore, that would seem to dictate incredibly aggressive screening procedures and an incredibly aggressive mental health screening and all of that. On the other hand, Senator Talent, you said that part of our problem is our fear in taking that risk is paralyzing our ability to get good people in the door that we desperately need for their scientific acumen and backgrounds. And you said just, I think, a few minutes ago that the Executive Branch is going to need to take the lead on this.

Do you think there is anything else that we can do in Congress or you can do in your Committee to give the Executive Branch cover, because if it is about a political risk——

Mr. TALENT. Yes. It is interesting that you said that word, because I was just thinking that one of the things that Congress could do, and almost informally, is approach the key decision makers and say, look, if you feel you need to take some responsibility for saying, we are going to hire somebody who has language skills and complete the security review—hire them on a preliminary basis and complete the security review so we can get them in the door, we are going to protect you. We are not going to hang you up for making that kind of a decision. I think that might happen.

The key here, though, is that the bill is designed to get everybody at the same table and talking about this so what will emerge from there is the right balance that I don't think you can prescriptively in a bill say. And you can go wrong in either direction.

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I mean, Fort Detrick, in response to the Ivins case, imposed such strong security measures that they have stopped doing any research.

Senator MCCASKILL. Right.

Mr. TALENT. Well, that is not a good result, and neither is a good result to have labs that are saying, well, we are going to ignore what the GAO is telling us. We don't want to have x-ray machines. I mean, I don't get why you couldn't have x-ray machines.

So I think what the bill is aiming at is to create a cooperative process where reasonable people are getting together and recognizing that even if they come from the scientific community, security is important. Even if they come from the security community, science is important.

It gives me a chance to just propose—you had an addition you suggested, Senator. I think if you created some kind of a council on lab security and said you want the representatives from the key nonprofits and the agencies, and they have to get together on a regular basis and they have to talk, and then you all oversaw that, I think that would be useful as an integrator, as a way of creating that kind of community of interest across institutional lines that we are trying to get at. That, I think, would be helpful, Senator.

Senator MCCASKILL. Is there anything else, Senator Graham or Senator Talent, that we have not included in this bill that you think needs to be included?

Mr. GRAHAM. Well, I think the basic structure of this bill is not to fall in the trap of being overly prescriptive. This is a rapidly evolving area of science. The issues that are probably going to be our biggest challenge 20 years from now, we can't even conceptualize today. What you are doing is you are setting in place a series of institutions that will have the capacity over time to respond to emerging threats. There may be some details that we could discuss, but I think the basic approach of this as a matter of good public administration is sound and therefore we give it our strong support.

Mr. TALENT. The model is what you did in this Committee with the intelligence community. That, to me, is the model, where you set in motion forces within the intelligence community that have caused them to work together, and, in fact, that is one of the really good news stories of the last 3 or 4 years. The increase in our intelligence capabilities is, I think, directly as a result of what you all did in that bill.

Senator MCCASKILL. If I could, we are going to have a hearing on another topic that you all have obviously talked about in your assignment, and I know that, Senator Talent, you have written about it. We are going to have a hearing, I think, in the Armed Services Committee on Thursday on missile defense. I would like, Senator Talent, just to ask you your reaction to Secretary Gates's recommendation that we rely on the SM-3s in the short run with switching our emphasis in the long run to improved technology that would not be reflected in what had been planned by the Bush Administration——

Mr. TALENT. For Czech Republic and Poland.

Senator MCCASKILL [continuing]. For Czech Republic and Poland.

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Mr. TALENT. And I am happy to do that, Senator. I think we should both say this is—we are taking off our hats now, our Commission hats, because this is something we didn't feel was part of our mandate, missile defense, and we didn't get into it, and deliberately so. And Senator Graham and I have talked a lot about this individually. He may have slightly or greatly different views.

I didn't like it, the decision, for a number of reasons. Part of it is missile defense, I think, the ground-based interceptors, we know will work. We were far along in that process. It is the less expensive and the quicker way of doing it. The intelligence assessment that the Iranians may be moving more slowly than we think, I think is questionable, and in any event, I don't want to take that chance. And this is a subject where I would like to see redundancy rather than choosing one from another. And then there are serious foreign policy implications, as well.

So it was not something I liked to see happen, but I say that as a private individual and maybe as a commentator on foreign policy in general, not as the vice chairman of the Commission.

Senator MCCASKILL. Thank you.

Mr. GRAHAM. As Senator Talent has said, we are taking off our Commission hats, where we were very collegial and our report had the unanimous support of all of the nine members of the Commission. I have had some concerns about the concept of missile defense in the context that our stated national policy is that if a country uses a nuclear weapon against the United States or an ally, the result of that will be massive retaliation. If a reasonable country feels that we are serious about that, you would think that they would be extremely reticent to use such a weapon against the United States, particularly reticent to use it in a form that has their signature all over it.

I have sat in a signals intelligence facility thousands of miles away from the site and seen a foreign government launch its missiles. We have the capability of monitoring missiles all over the world and would know within seconds of launch who was responsible. There are many other ways today that a state which wanted to deliver a nuclear weapon against the United States could do so without putting its signature on it, such as delivering it in a cargo container. That is why I think seaport security is, among other reasons, such an important element. So I think it is a defense against an increasingly unlikely event.

Second, we state in our report the importance of the U.S.-Russian relationship. Between us, we control about 95 percent of the nuclear weapons in the world. There is no relationship that is more important to restraining the proliferation of nuclear weapons than that between the United States and Russia. We are two big, powerful countries and we will periodically have disagreements, but we need to try to manage our relationship in the context of the primacy of avoiding contributing to a nuclear conflagration.

So the fact that this was such a sensitive thing to the Russians, and understandably so—if they had facilities like this located in Cuba, we know how we would react—we knew what, in fact, we did do back in the early 1960s—were the benefits to us in terms of our defense against nuclear weapons worth the risk to our relationship with the Russians that the sites in the Czech Republic and Poland

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represented? I personally think not, so I believe that we have made a wise decision and that the overall security of the country is heightened.

Some of the test of that will be what do we do now with this new approach that Secretary Gates is discussing of a different way to defend ourselves against missiles and how we use maybe some of the resources that we would have spent there to do a better job of defending those places such as our seaports, which I think are much more likely to be the gateway to get a nuclear weapon into the United States than by launching it with a missile that has your name written on the side of it.

Senator MCCASKILL. Well, I am glad I was able to get this bipartisan agreement to divide opinion here before we finished. [Laughter.]

Thank you very much for your indulgence on that question. They are both very knowledgeable and I wanted to get both of their takes on it. Thank you.

Chairman LIEBERMAN. I am glad you did. It was helpful. Thank you.

We are going to do a second round, quickly, of 5 minutes. We have got a vote at noon.

Let me focus here on another part of your Commission report and of the bill. I think you have done a great service in focusing on the development of a robust response capability to a bioterrorist attack as one of the best things we can do to deter such attack, as we said before.

I would also say, parenthetically, as we are geared up now to deal with the H1N1 pandemic and its potential spread in our country that whatever we do to set up systems to respond to a bioterrorist attack will also enable us to use those same systems to respond to an epidemic or a pandemic or an outbreak of disease of one kind or another.

Let me ask you a baseline question as to where we are now, which is whether you think any of our major metropolitan areas today are ready to get antibiotics or countermeasures out to people at risk within a reasonable amount of time, or really a necessary amount of time, after a biological weapon attack. I gather some people have the standard of 48 hours. Of course, that seems like a long time to me, 2 days. So the question is, are any of our major metropolitan areas really ready to dispense the countermeasures that people will need to minimize the impact of a biological attack?

Mr. GRAHAM. Probably not, at least, I am not aware of any. And it is a more complicated problem than the act of dispersing the medications. One is knowing that you are under attack.

Chairman LIEBERMAN. Right.

Mr. GRAHAM. There are probably, within a 50-mile radius of where we sit today, 75 hospitals. If each one of those 75 had three people show up with symptoms that might be associated with a lethal pathogen, they might conclude that it was an aberration. It is only when you aggregate three times 75 that you begin to appreciate that this is not just a random incident, that we are under attack, and then begin the processes that are necessary.

I am, frankly, not aware of anyplace that has a fully coordinated means by which that could be done within the time frame nec-

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essary to then start the process of getting medications out to people.

The reason that we think that in the area of biological that prevention equals preparation to respond to the attack is that there, you do have the potential of making biological—they are still a weapon of destruction, but you might be able to eliminate the middle word, "mass." If you are able to respond sufficiently, you can contain the effect of a biological attack. With a nuclear attack, tens or hundreds of thousands of people are going to be killed and there is no way to reduce that number.

We also, in some discussions with our intelligence agencies, in their assessment of the mentality of our adversary, that our adversary, once they come into possession of the capability of a biological attack, are probably going to use that fairly quickly. They are not in the business of stockpiling materials for some future attack, like maybe the North Koreans are trying to do with their nuclear capability. So they will want to use it quickly.

They will assess a range of targets, both in the United States and worldwide, and are likely to use it against the target that they think will result in the highest kill rate. So if you have prepared yourself and your adversary is aware of the preparation that you have done, you are probably going to be down the pecking order in the likelihood that you will be the site selected to target that to be used soon after acquisition of a biological weapon. So that is why we think that one of the most important deterrents in the biological area is how well you are prepared to deal with the event itself.

Mr. TALENT. Mr. Chairman, I should say I just snuck around and asked the staff, and they tell me that there are models out there that are pretty far advanced. I don't think anybody feels like they are as prepared as they want to be, but the Postal Service with its model has been working with localities. I think our statement says Seattle, Philadelphia, and Boston. They have been pleased about the tests that they have run there. So I think we are making progress——

Chairman LIEBERMAN. This is on the ability of those communities to respond quickly.

Mr. TALENT. The overwhelming point that we kept getting, and it makes great sense, is that whatever the Federal Government does, it has to adopt an attitude of working with the local authorities and let them adjust to what they think they need to do. And this is, of course, how first responders are—they have all these kinds of sharing and partnership agreements locally and mutual support agreements and we have to make that work for us rather than DHS saying, this is how you will do it everywhere, because that won't work.

Chairman LIEBERMAN. Thanks to both of you. That is why we have a separate title on what the Federal Government can do to incentivize and support, rather than demand that response capability, because that ultimately, as you said, both of you, very convincingly, is the best deterrent we can have. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Just following up on that point, we have done a lot of work with State and local governments, and with our private sector partners to improve the response because obviously if you are a terrorist and

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you think a community is unable to respond, that gives you even more of an incentive to choose a particular method of attack.

But there is also some discouraging news in that area. Earlier this month, the Inspector General (IG) for the Department of Health and Human Services released a report that looked at the ability of local communities to effectively and efficiently distribute medical countermeasures in the event of a pandemic flu. Well, obviously that possibility is here right now.

The IG examined 10 localities and found that most of them had not completed planning for countermeasures distribution and dispensing. They found, for example, that there weren't formal agreements that had been worked out between the local hospitals and the communities, and that they failed to identify alternative sources of staffing to cope with the absentee rate that would be associated with a pandemic.

That really concerns me, that this many years have passed and we still don't have the measures and the planning in place. Could you both comment a little more on what specifically you think that we need to be doing in this area? I will start with you, Senator Talent, since you addressed this in your opening comments.

Mr. TALENT. Sure. What you said doesn't surprise me, and I think it is consistent with what Senator Graham and I were saying. I am not confident that any place in the country is where it needs to be or really close to where it needs to be. Now, there are some areas that are ahead of others and I think we can look at what they are doing and try and model.

But what you said and what the IG said is perfectly consistent with what we found, that we are not ready in this area. It is, I don't want to say inviting attack, but it is an avenue of deterrence of which we are not taking advantage. And I think it goes back to what Senator Lieberman opened up the hearing with, which is how do you create an ongoing sense of urgency within this government and local governments, as well.

Senator Graham has talked about the fact that we, as a Commission are looking at doing this, providing a citizen check-list—you may want to talk about this, Senator Graham—for how folks can check up on what their local government is doing. What are the 10 things your local government should be doing? And I think that will be helpful.

But everything that we can continue to do to raise the awareness that this is really a possibility and, in fact, will become a probability—it is the insidious nature of terrorism. It is one of the reasons it is an effective form of conflict against first world countries. It is shadowy, it is beneath the surface, and so we just tend to forget that it is there until they jump up and attack us, and how do you promote that in a society where people are doing what we want them to do? They are off with their families and their jobs and doing good things and they are not waking up every morning worrying about this, and I really don't want them to, but I do want a stronger sense of urgency, and I think you put your finger on one of the real difficulties.

Senator COLLINS. Thank you. Senator Graham.

Mr. GRAHAM. Just to pick up on what Senator Talent said, one of the things that our Commission has done during this second

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phase of our life, the post-report phase, is we have commissioned various studies. One of those has been with Texas A&M University, which has a Center for Homeland Security, to develop a Guide for Citizens. If, let us say, you are a citizen of Camden, Maine, and you want to know how well prepared is Camden in the event of either a natural or a terrorist-caused biological incident in your community, how would you as a citizen find out? Well, what we hope to give to citizens is a list of the right questions to answer and some idea of the metrics to be used in evaluating the answers that you get so that there can be an informed citizenry, if necessary, pushing its governmental agencies to higher standards of action in order to protect the people of that specific community.

Senator COLLINS. Thank you. Thank you all for your testimony.

Chairman LIEBERMAN. Thank you, Senator Collins. Senator Akaka.

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

Senator Graham, in March, you testified at a hearing I held to examine the creation of a National Security Service Workforce. It seems that personnel plays a huge part in what we are trying to do. You articulated the Commission's findings and recommendations regarding workforce challenges in the area of national security, particularly in the intelligence community.

I have been considering legislation alongside other Members of this Committee to strengthen the national security workforce. My question to you is, how might this Committee encourage the development of national security professionals government-wide?

Mr. GRAHAM. Well, if I could focus, as I did in March, on the specific area of the intelligence community, although I believe the principles are applicable elsewhere, in my judgment, one of the most effective role models of developing human capital is the military's Reserve Officer Training Corps (ROTC) program. Over half the commissioned officers in every branch of the United States military comes through a ROTC program.

The program has the opportunity that, let us say, if the Navy is looking 10 years down the road and they say, anticipating some new technology, we are going to need more officers with a particular set of scientific knowledge, they can begin to adjust their selection process of persons who will be entering the Navy ROTC to prioritize students who are going to be studying in the areas where they will acquire that knowledge. So it has a flexibility and a responsiveness to both current and anticipated conditions.

Second, it has the requirement that people commit to a certain number of years of service as a consequence of receiving the Federal assistance in securing their education. So there is a reliability that you can depend on the fact that you will have a certain number of years of service from these individuals.

Third, it tends to promote a concept that the military has been emphasizing and which we believe our intelligence agencies need to further emphasize, and that is jointness, that people who get to know each other as students, whether they end up in the Army infantry or the armor or other specific area of the Army, they are going to have had a common shared experience during their ROTC years.

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So I think that is a model, and let me say, there is a provision in the intelligence authorization bill that will move towards establishing such a program for the intelligence agencies. I would recommend it to your attention, and at such time, I hope that as you consider and vote on the future intelligence authorization bill with that provision, that you will be supportive.

Senator AKAKA. Before my time runs out, this question goes to either Senator Graham or Senator Talent. I took a particular interest in the Commission's recommendations to strengthen United States public diplomacy efforts. Last September, I held a hearing on public diplomacy reform and found that despite the existence of a strategic plan, there was little support for it across the government. This is an area where improvement is needed.

Would you please elaborate on the Commission's recommendations for developing a new public diplomacy strategy and how it could reduce the risks associated with bioterrorism and the misuse of technology? Senator Talent.

Mr. TALENT. It is the last question and you have introduced a really important subject, and I am grateful to you for your leadership on this. Senator Graham and I have talked a lot about this. We talked a lot about it at the Commission, particularly in the context of our recommendations regarding Pakistan.

We could not agree with you more. I mean, it is obvious. We have now seen this across a number of administrations. We saw it in Bosnia, saw it in Iraq, and we are seeing it now in Afghanistan, that our government needs the capability to do what you call public diplomacy, what Secretary of Defense Robert Gates has called smart power or soft power, a range of capabilities that are primarily civilian in nature that will assist us, either assist the military or operate outside the military context, and they include the ability to effectively communicate America's intentions.

And we have a President who is popular abroad. He goes and gives speeches. That is a very good thing. But we have all run in campaigns here. You can't just give a speech and then expect that the message is going to—you have to follow it up with a kind of campaign that effectively communicates your intentions. We don't have that capability organically as a government. We just don't, not to mention the ability to systematically build local economic and democratic grassroots institutions that we have seen we need that ability over and over and over again and we don't have it. And all that is connected up with the public diplomacy piece.

So I will just say I think we need an effort across the civilian agencies, led by the Secretary of State—we say this in the report—similar to what the military did over a generation ago with the Goldwater-Nichols Act, what you all are causing the intelligence community to do, where they canvas what the requirements are for this community as a whole, inventory the capabilities they have, and then have a concerted plan for developing the necessary capabilities, and it will mean working together and sharing culture.

But I agree with you. They haven't really started, and I don't—it would be a great subject—I guess you need the Foreign Affairs Committee and some of the others to do it, but this is an area where Congress, I think, if you really show an interest over time, they will have to respond, and otherwise, I am concerned that it

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isn't going to happen. But kudos to you for continuing to push it, Senator.

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

Chairman LIEBERMAN. Thanks, Senator Akaka.

I agree with you, Senator Talent, for the kudos to Senator Akaka. He has been really noble in this pursuit.

I will say, and I appreciate the reference to the intelligence community. In the briefings that we have received on this ongoing terrorist plot here in the United States, Colorado, New York, apart from being unsettled by the clearest evidence we have received in a long time of an attempt that is at least connected to al-Qaeda and Afghanistan and Pakistan, but the remarkable cooperation among law enforcement agencies of the United States and intelligence agencies, both global and domestic has been really quite reassuring.

This has been a very productive morning for our Committee. I thank you very much for your continuing efforts, Senator Graham, Senator Talent, and Mr. Kutz.

This Committee has a sense of urgency about this. We take this legislation that we have introduced very seriously. Incidentally, not only Senator McCaskill has joined, but Senator Bob Bennet of Utah has come on as a cosponsor. Senator Collins and I intend to mark this bill up at a business meeting of our Committee next month. So we are going to really move it quickly. I suppose that is a notice to anybody out there who has any input they want to give our Committee before we go to markup that we intend to move this with speed, because that is what the reality of our world requires.

We will keep the record of this hearing open for 10 days for any additional statements or questions that anybody might have.

Senator Collins, would you like to say anything in conclusion?

Senator COLLINS. Thank you, Mr. Chairman. I just again want to thank our witnesses for all of their work—they have all been working on it for quite some time—and to assure you of our determination to get the kinds of reforms that we all believe are needed signed into law.

Chairman LIEBERMAN. Thank you very much.

The hearing is adjourned.

[Whereupon, at 12:04 p.m., the Committee was adjourned.]

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APPENDIX

"A World at Risk: The Weapons of Mass Destruction Prevention and Preparedness Act of 2009"
Homeland Security and Governmental Affairs Committee
Chairman Joseph Lieberman
September 22, 2009

Good morning. Today we will hear testimony on legislation that Senator Collins and I introduced this month to prevent and prepare for attacks against our homeland that involve weapons of mass destruction (WMD). Our legislation has a particular focus on heightening security at laboratories that handle the world's most dangerous pathogens.

In December of last year, then-Director of National Intelligence Mike McConnell publicly stated his chilling conclusion that a WMD terrorist attack is more likely than not to occur somewhere in the world between now and 2013 – the next four years -- and that a biological attack is much more likely than a nuclear or chemical attack.

The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, chaired by Senators Bob Graham and Jim Talent, reached a similar conclusion and went well beyond, documenting their work and making recommendations. It is hard not to conclude that we are still not properly prepared to counter the threat of WMD – and particularly the bioterrorist threat, despite measures taken after the 2001 anthrax attacks. In sum, and as the Graham-Talent Commission concluded, we are a Nation and world at risk.

And for anyone who thinks we are being overly zealous, imagining threats that don't really exist, one only has to follow media coverage over the past few days of the arrest of men right here in this country with direct ties to al Qaeda, who were planning a significant attack in the New York area, to know the threat is real. There are people who want to do us great harm and one way is through a biological attack.

The WMD Prevention and Preparedness Act of 2009 would provide a multi-layered approach – across the full spectrum of prevention, preparedness, and response – to this threat. Our legislation would implement the Graham-Talent Commission's recommendations and our Committee's conclusions from its ongoing investigation into our Nation's defenses against WMD attack.

Let me briefly describe the key elements of the legislation and their origin in the Graham-Talent Commission report and our Committee's work.

First, this bill would identify and categorize the most dangerous pathogens – those with the greatest potential to be used in a biological attack – and require improved security at the laboratories that handle them. Our approach ensures that we focus our security efforts where they are needed most and not burden the wider range of scientific research unnecessarily. Our Committee's interest in laboratory security was informed by the Commission's report and Commissioners' testimony this past December. The report

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cited findings on inadequate security at our nation's laboratories and concluded, and I quote, "when it comes to materials of bioterrorism, America's vulnerability may well begin at home." Through this legislation, we seek to close that vulnerability.

Second, our bill would build the "culture of preparedness," as called for by the Commission, by requiring a national strategy for dispensing antibiotics and other medicines to the public to respond to a biological attack. We would also expand the use of the Postal Service for distributing countermeasures. We are spending billions of dollars to stockpile these supplies, but our Committee has found that we lack a plan for distributing them quickly and efficiently after an attack or outbreak. The bill would also provide medical kits to emergency responders so they can protect themselves as they protect us.

Third, our bill acts on the Commission's call for improved public information. It would put in place specific communications plans to inform the public of what to do during the critical moments after an attack. And, as called for by the Commission, our bill requires the development of pre-scripted, adaptable messages so that appropriate information can be disseminated swiftly. Such information would include the direction of a deadly radioactive or biological plume and instructions about whether it is better to shelter in place or evacuate. That kind of information could save thousands of lives.

Fourth, the legislation would direct the Secretary of State to build an international biosecurity coalition by providing training and assistance to other countries in laboratory security and global disease surveillance.

Finally, the legislation would also require the Director of National Intelligence to improve intelligence on WMD and terrorism, particularly by increasing his hiring scientists and improving foreign language capabilities. The Commission praised the progress of reform in the Intelligence Community, but it specifically cited these gaps as requiring immediate attention.

Senator Graham and Senator Talent, you and your fellow Commissioners have done a great service to the country by assessing the WMD threat and proposing actionable solutions. We look forward to hearing your views regarding this legislation.

I am also pleased to welcome Gregory Kutz, Managing Director for Forensic Audits and Special Investigations at the Government Accountability Office. Mr. Kutz and his team have spent the past two years investigating the state of security at our Nation's five most elite laboratories – the laboratories with the highest biosafety rating and that handle the world's most dangerous pathogens. In a 2008 report and a follow-up report released this year, they draw a disconcerting picture of the security regulations governing these laboratories and of the state of physical security at these laboratories, which Mr. Kutz will describe for us and which energizes even more our consideration of this legislation and remedial action.

We must be direct and honest with the American people about the risks facing this country from WMD. As the Graham-Talent Commission noted, "America's margin of safety is shrinking, not growing." Senator Collins and I hope that our WMD Prevention and Preparedness Act of 2009 would provide a comprehensive framework for closing many of the gaps in our security against WMD and grown our margin of safety. Senator Collins.

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Statement of
Senator Susan M. Collins

A World at Risk: The Weapons of Mass Destruction Prevention and Preparedness Act of 2009

September 22, 2009

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The recent arrest of a terrorism suspect in Colorado is a sobering reminder of the continued threat to our nation. Al-Qaeda and other terrorist organizations have publicly declared their intention to acquire and use weapons of mass destruction against the United States.

Just last week, another media report highlighted how terrorists might join forces with global drug traffickers in order to take advantage of the traffickers' vast networks of tunnels, black markets, technology, and human intelligence. The terrorists have noted the ease with which traffickers smuggle illegal drugs across our nation's borders.

In the words of a former U.S. Embassy official in Afghanistan, "When you get to the point where you can smuggle tons of drugs through one border…then you certainly have the capacity to smuggle in weapons of mass destruction or agents."

Clearly, this threat is real, urgent and evolving.

On September 8, Chairman Lieberman and I introduced the Weapons of Mass Destruction Prevention and Preparedness Act of 2009 to help counter this threat.

The bill would improve our nation's ability to prevent and respond to WMD attacks. It would enact many of the recommendations of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism – a commission the Chairman and I helped establish in 2007.

I am certainly pleased to see the leaders of the commission and our former colleagues, Senators Bob Graham and Jim Talent, here today. Their report warns us that it is "more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013."

The Commission's report is a call to action.

Its findings reinforce the urgency felt by the Homeland Security and Governmental Affairs Committee during our many hearings regarding the terrorist threat to our nation.

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We have examined many deadly threats targeting the American people – from terrorists dispersing anthrax spores to the detonation of a nuclear device in a major city.

To respond to these threats, this Committee has led numerous reform efforts since the terrorist attacks of September 11, 2001. Our work has strengthened intelligence-gathering efforts, tightened security at our ports and chemical facilities, and vastly improved our emergency preparedness.

Nevertheless, the Commission's report provides a chilling reminder that "the terrorists have been active, too."

Nuclear proliferation and advances in biotechnology are giving terrorists new methods to commit mass murder. We must continue our efforts to identify risks and to increase security.

As the Commission explained, the most likely WMD threat to the United States is a biological weapon. It is easier to develop and disseminate bio-weapons and gain access to lethal pathogens. Furthermore, terrorists know that a bio-weapon can be a stealth attack. We may not immediately recognize such an attack until hundreds of people have died.

Despite this threat, some of the world's most dangerous pathogens are not secure. Within the United States, the Commission found serious flaws in the security of biological labs. Reinforcing these findings, the GAO recently reported alarming deficiencies in perimeter security at facilities that house the world's most dangerous biological agents – diseases such as the Ebola virus and smallpox. The GAO also found that laboratory regulation "for the most part relies on self-policing."

Thousands of people in the United States have access to dangerous pathogens. More than 400 research facilities and nearly 15,000 individuals are on the "Select Agent List" – an authorization to handle the most deadly pathogens. The FBI determined that a cleared scientist at a regulated research lab likely carried out the 2001 Anthrax attacks on the Senate and the U.S. postal system.

To counter this threat, the WMD Commission recommends increasing lab security. Our bill seeks to accomplish that goal by identifying those pathogens that terrorists are most likely to utilize and increasing the security standards at the biolabs that handle them. A negotiated rulemaking – with federal agencies and research institutions at the table – would develop these standards. This collaboration would ensure that the regulations that make our nation's biological labs more secure do not have the unintended consequence of deterring legitimate research. To help fund these enhancements, the bill would create a four-year grant program.

The Commission also found that the federal government is unaware of many research facilities that handle less strictly controlled, yet still dangerous, pathogens. To that end, our bill would require registration of these labs, and facility security

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requirements would be tiered based on the risk that terrorists might use a particular pathogen in a biological attack.

The bill would improve our ability to quickly distribute medical countermeasures and provide reliable, ongoing emergency response information to the public in the event of a WMD attack.

Finally, the bill also addresses international biosecurity threats, requiring the Director of National Intelligence to identify the security measures in place at those countries' high-risk labs.

I look forward to discussing this important legislation with our witnesses today. We must move swiftly to strengthen and improve our nation's biological defenses and security systems.

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Prepared Statement of Senator Michael Bennet
Committee on Homeland Security and Governmental Affairs
September 22, 2009

Senators Graham and Talent, I would like to thank you for joining us this morning and for your commission's diligence. Mr. Kutz, thank you for your work on this issue as well. Preventing a biological attack and the threat of weapons of mass destruction is of critical importance as we seek to ensure an effective and smart national security. It has been nearly 8 years since September 11th, yet we all know that the threat to our security persists -- the FBI's apparent disruption of this terror cell that we are learning more about each day is just the latest example of the obvious – this Committee, this Congress and our nation must not let our guard down when it comes to the real possibility of a biological attack somewhere in the United States.

We face serious challenges to our security from global and domestic threats. These threats we are confronting will require broad-based responses and significant flexibility in order to respond to evolving risks. It is of utmost importance, therefore, that we secure our critical infrastructure and put in place smart policies that leave no room for those who seek to attack us to fulfill their desires. While law enforcement must have the tools they need to respond to threats and emergency responders must have the resources, structure and communications systems in place to assist communities, we must take all necessary precautions for securing our nation. This means preparedness, and it means prevention.

The prospect of a WMD attack on our soil is a sobering reality. As noted in the findings of the Graham-Talent Commission, there are still a number of things that must be done to curb nuclear proliferation and secure nuclear materials. This is a challenge we are well aware what the consequence of inaction is and the President is taking commendable steps to address the issue. We must also make biosecurity a priority. As the Commission notes, there is insufficient attention to the threat posed in spite of the catastrophe of inaction.

There are tangible places to start. We know for instance that we need to implement uniform standards for securing the perimeters of our nation's BSL-4 laboratories. These facilities hold deadly materials, and they must be thoroughly secured. Where the GAO reported in 2008 that basic security standards have not been met, one would expect a greater sense of urgency to not only meet the prescribed measures, but to exceed these safeguards where possible. CDC should formulate a detailed plan to address this perimeter security or security at large. We know that there are threats out there, and we know of the devastating consequences of inaction.

Bureaucratic inaction and foot dragging should not be tolerated. We should hold ourselves to the highest standards. This Committee is here to find out what role Congress can play to help. Where more resources are necessary or authority needs to be conferred, Congress must act. We are here to listen, to learn, and then to act.

I would like to thank Chairman Lieberman and Ranking Member Collins for their leadership on the WMD Prevention and Preparedness Act and their commitment toward our national security.

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U.S. Senate Homeland Security and Governmental Affairs Committee
Hearing on the WMD Prevention and Preparedness Act of 2009
September 22, 2009

Statement from Chairman Bob Graham and Vice Chairman Jim Talent, Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism

Mr. Chairman, Senator Collins, and distinguished Members of the Committee:

Thank you for the opportunity for us to speak to you today on behalf of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. Congress created our Commission early in 2008, based on the recommendation of the 9/11 Commission, assigning us the task of assessing the risk of WMD terrorism and recommending steps that could be taken to prevent a successful attack on the United States. Our Commission interviewed hundreds of experts and reviewed thousands of pages of information. We want to thank those Commissioners -- Graham Allison, Robin Cleveland, Stephen Rademaker, Timothy Roemer, Wendy Sherman, Henry Sokolski, and Rich Verma -- who worked tirelessly to produce our Report, *World at Risk.*

The Commission's Report assessed both nuclear and biological threats, and provided 13 recommendations and 49 action items. Most of our comments today, however, will focus on the biological threat we identified, a very real and growing threat to America and the world, and also the focus of the legislation you recently introduced: *The Weapons of Mass Destruction Prevention and Preparedness Act of 2009.*

The Commissioners unanimously concluded that unless we act urgently and decisively, it was more likely than not that terrorists would attack a major city somewhere in the world with a weapon of mass destruction by 2013. And we determined that terrorists are more likely to obtain and use a biological weapon than a nuclear weapon. This conclusion was publicly affirmed by then Director of National Intelligence (DNI) Mike McConnell.

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Three primary reasons stand out in support of our conclusion. First, developing and dispersing a biological weapon would not be expensive -- and it will only get cheaper and easier. Second, the lethality of an effectively dispersed biological weapon could rival or exceed that of an improvised nuclear device. Third, the constraints that a bioterrorist would confront in making an effective bioweapon are significantly fewer than those facing nuclear terrorists. Virtually all pathogens suitable for use in a biological weapon are readily available in nature. The equipment required to produce a large quantity from a small seed stock, and then "weaponize" the material – that is, to make it into a form that could be effectively dispersed -- are of a dual-use nature and are readily available on the internet. The most effective delivery methods are well known in the pharmaceutical, agricultural, and insect-control industries.

This is not speculation. Al Qaeda was well down the road to producing such weapons prior to 9/11. Due to the ease in creating a clandestine production capability, our intelligence community had no knowledge of two such facilities in Afghanistan prior to their capture by U.S. troops. Facilities with more sophisticated equipment than those found could be in operation today without our knowledge.

First, Mr. Chairman, we want to thank you and Senator Collins for the extraordinary leadership you have shown in response to our Report. The biggest internal enemy we face in dealing with this threat is the natural inertia of government. The only way to overcome this inertia is for our top political leaders to make guarding against this threat a personal priority and to persist over time in demanding action. Our Report has received support everywhere, but only this Committee under your leadership has stepped forward to turn our Commission's recommendations into action. As nothing else could have done, your determination has produced a concentration of will and energy in the Congress to produce real action, including confronting and resolving the good faith points of conflict about how best to accomplish certain tasks.

- Title I of the legislation is in direct response to recommendation 1-2: "The Department of Homeland Security (DHS) should take the lead in developing a national strategy for advancing microbial forensics capabilities." (page 28), and recommendation 1-3: "The

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Department of Health and Human Services (HHS), in coordination with the Department of Homeland Security, should lead an interagency effort to tighten government oversight of high-containment laboratories." (page 29)

- Title II is in direct response to recommendation 1-5: "The Department of Health and Human Services, in coordination with the Department of Homeland Security, should take steps to enhance the nation's capacity for rapid response to prevent an anthrax attack from inflicting mass casualties." (page 32)

- Title III is in direct response to recommendation 2-3: "The Department of Health and Human Services (primarily through the Centers for Disease Control and Prevention) should work to strengthen global disease surveillance networks." (page 40)

- Title IV is in direct response to recommendation 10: "The intelligence community should address its weakening science and technology base in nuclear science and biotechnology and enhance collaboration on WMD issues with specialists outside the intelligence community, including nongovernmental and foreign experts." (page 100), and "The intelligence community should expedite efforts to recruit people with critical language capabilities and cultural backgrounds. In conjunction with this effort, the intelligence community should streamline the hiring process, especially for applicants with critical language capabilities." (page 99)

- Title V is in direct response to recommendation 13: "The next administration must work to openly and honestly engage the American citizen, encouraging a participatory approach to meeting the challenges of the new century. The federal government should practice greater openness of public information so that citizens better understand the threat and the risk this threat poses to them." (page 109)

We appear here today to offer our specific comments on these five titles.

Enhanced Biosecurity Measures in U.S. Laboratories, in Title I:

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Certain principles animated the section of our Report dealing with laboratory security. We were concerned about (1) the proliferation of high-containment labs, which were not only unregulated but often unknown to the government, (2) the fragmentation of government oversight among several agencies, (3) the need for a thorough review and update of the Select Agent Program, and (4) the importance of regulating labs in a way that did not discourage robust scientific research in the United States.

Enhanced biosecurity measures should improve security, streamline oversight, and focus our resources on the real risks. By correctly applying risk management principles, the United States can increase security without impeding science or critical U.S. industries. Scientists are, after all, our key line of defense against biological weapons. Without their work, we would not have the drugs, vaccines, and diagnostic tests needed to protect the American people in the event of a biological attack. The work of developing medicines is difficult, takes a long time, and is fraught with challenges. We still do not, for example, have drugs or vaccines for many of the biological agents weaponized by the Soviet Union. Therefore, it is in our national security interest to make sure that our laboratories continue to develop medical countermeasures, while still operating safely and securely.

We believe that the legislation implements many of the provisions of our Report, and in certain respects improves on our recommendations. For example, the bill introduces into the Select Agent Program the idea of stratifying risks, which we think is a real advance in achieving the right regulatory balance. *Stratification of risks into tiers allows for more realistic assessments of risk, and will benefit public health investigations.* The bill calls for the Secretary of Health and Human Services to designate as "Tier I" agents the most dangerous subset of the pathogens included in the Select Agent Program that have clear potential for use as biological weapons. Stratifying the Select Agent list will allow us to focus increased security on genuine risks, and will allow public health-related research involving non-Tier I agents to proceed without excessive regulation.

Multiple studies were conducted as a result of our Report. Virtually all of them, from both the public and private sectors, have called or will call for the stratification of agents. The

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overwhelming recommendation from the scientific community is that any legislation employ a tiered approach.

Accordingly, although our Report does not deal with the stratification issue, we recommend that the legislation go further, requiring the HHS Secretary to stratify the current Select Agent list into Tiers I, II and III. This would be the best means for securing the most dangerous pathogens while causing the fewest impediments to scientific research. Tier I should include deadly pathogens that can be weaponized. Tier II should include pathogens that are dangerous but cannot feasibly be used as bioweapons. Tier III should include the majority of biological agents that are of lesser security and public health concerns. These agents would require only facility registration, as described in Section 103 of the Bill. Our primary objective, again, is to distinguish those pathogens that pose great danger from those that do not.

Today, 82 Select Agents receive the highest level of security focus and regulation. We believe the correct number of top-tier agents is closer to 8 than 80. A three-tiered system would allow us to place the greatest security emphasis on those agents that can most feasibly be weaponized, and thus have the highest probability of being used for bioterrorism. Under the current system, smallpox and anthrax, the two most feared pathogens that could be used for a large-scale bioattack, are in the same category as the herpes B virus, which virtually no expert considers to be suitable for use as a bioweapon -- unless you want to kill monkeys.

We should note that our recommendation to stratify biological agents for *security* purposes is distinct from the measures that scientists need to take for *safety*. Many pathogens, including those that cause tuberculosis, HIV, and herpes B, require special safety precautions, though most experts do not consider them to be feasible for use as bioweapons. We encourage the further refinement of safety systems and procedures for all types of biological research, so that research can be conducted with the highest level of safety.

Fragmentation of oversight should be eliminated in pathogen security. In our Report, we concluded that the fragmentation of government oversight of laboratories was a national security problem. We determined that there should be *one* set of requirements concerning pathogens for

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the scientific community to follow, instead of having separate regulatory programs from multiple departments. The authority to oversee and enforce these requirements must be vested in one lead agency so that the regulated community has a single coherent, consolidated and streamlined set of regulations to follow.

Currently, under the Select Agent Rule, as defined by 42 CFR 73, 7 CFR 331 and 9 CFR 121, HHS and the Department of Agriculture (USDA) regulate select agents. Human pathogens are regulated by HHS; plant and animal pathogens are regulated by USDA, and facilities that house pathogens that are a concern for humans and livestock are inspected jointly. Accounts of this process suggest that HHS and USDA cooperate well in meeting their regulatory responsibilities. Given the distinct expertise on these pathogens in USDA and HHS, it is appropriate that USDA's expertise be brought to bear on livestock and crops, and that of HHS for human pathogens. However, it is our belief that in constructing a regulatory system for pathogens that can infect humans, *one* cabinet secretary should be in charge. As Commissioner Robin Cleveland stated before this committee last December, we "have too many agencies, too many turf fights, and unclear oversight entities." That must end.

We recognize that the bill you recently introduced would assign overall oversight authority to the Secretary of the Department of Homeland Security. In our Report, we recommended that HHS "lead an interagency review." This recommendation was implemented by Executive Order in January. The review called for will soon be completed. The Report also called for HHS "to lead an interagency effort to tighten government oversight on high-containment laboratories." Based on what we have learned from several recent studies, numerous meetings with representatives from the executive and legislative branches, and the scientific community, we continue to recommend that overall oversight authority and responsibility for lab security be assigned to the Secretary of Health and Human Services, with recommendations on scientific matters from USDA and security matters from DHS. The Secretary should solicit, possibly through the creation of an advisory council, the recommendations from the scientific community with a view towards constantly improving the regulatory model given all the concerns of the communities involved.

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To sum up, we applaud your efforts on Title I of the bill. We suggest taking the tiered approach even further than the current draft. On the question of the lead agency, our Commissioners recommended that HHS take the lead. We continue to take that position, and believe that it will lead to the improved regulatory process that we all seek.

Response to a Weapon of Mass Destruction Attack, Title II:

A national strategy is sorely needed to establish effective and timely distribution of emergency medical countermeasures (MCMs). Countermeasures could serve to blunt the impact of an attack, save lives, and thwart the terrorists' objectives—but only if they are delivered when and where they are needed.

We recommend that the legislation not imply a federal-centric approach, but emphasize the need for cooperation among, and the strides that need to be taken by, state and local government, and non-governmental organizations. Based on the work already accomplished by the U.S. Postal Service (USPS) during the past four years, it is important to understand that this capability requires a national strategy that includes federal, state and local involvement. But a national strategy should not imply federal control. In the cities where USPS has run pilot programs (Seattle, Philadelphia, and Boston), we have seen the importance of a fully integrated partnership in the planning and execution of distribution efforts. For instance, even if USPS is perfectly prepared to deliver MCMs to households in a metropolitan area, it has no hope of succeeding without the complete preparedness and cooperation of state and local law enforcement.

We praise USPS for their extraordinary efforts during the past four years. This is the way government programs should work: first, a series of low-cost pilot programs should be created to test procedures that identify strengths and weaknesses; second, a national strategy should be designed based on the lessons learned from pilot programs; and, third, appropriate funding should be provided for full-scale development. This third step is lacking. If we expect USPS to complete this large-scale, life-saving effort, they must be provided with adequate funding.

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It is also important to note that the postal service be considered as one option for local communities under the ongoing Cities Readiness Initiative. It is not the sole option. Some jurisdictions have looked closely at whether USPS could successfully deliver medical countermeasures in their communities and have decided against it. Local leaders know their jurisdictions; they know what will and what won't work. Their knowledge of their community and their residents must be heeded if we are to respond in a timely and effective way.

We also feel obligated to comment on a key issue regarding medical countermeasures not addressed in this bill. Yes, we must have a system capable of rapidly dispensing MCMs during a crisis, but we must first have the required items to dispense. A world-class delivery system that does not have the appropriate products is of no value. Several months ago the Obama Administration attempted to raid the BioShield Reserve Fund to pay for H1N1 flu preparedness—certainly an important program, but one that needed funding on its own merits. Thankfully, this raid was not successful because leaders in Congress, who understand the importance of BioShield to our biodefense program, prevented it. Unfortunately, the story on funding for the Biomedical Advanced Research and Development Act (BARDA) does not have a similar good ending -- at least not yet. There is, however, still time to correct this funding shortfall. The current funding request for FY 2010 is $305 million. The needed funding level is $1.7 billion per fiscal year.

America must develop the capability to produce vaccines and therapeutics rapidly and inexpensively. Both the BioShield Reserve Fund and BARDA will be key elements in reaching this goal, but only if they receive proper support and funding. Developing this capability over the long-term will lead us to a security environment where biological weapons can be removed from the category of WMD. That must be the long-term biodefense strategy for America, but it will be unattainable if we do not properly fund these key programs.

International Measures to Prevent Biological Terrorism, Title III:

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The bill rightly supports international measures that contribute to effective cooperation on the shared, global biological threat. We know that a terrorist attack will not happen in a vacuum and an attack in another part of the world can—and will—affect the United States.

We suggest that care be taken in this legislation to avoid duplicating the unintended negative consequences, which resulted from the Select Agent regulations. Security restrictions must not preclude international cooperation, which is necessary for public health, infectious disease surveillance, as well as our national security. We do not want to "close our windows," so to speak, into the activities of other nations' laboratories.

Of course, the cornerstone of international efforts to prevent biological weapons and terrorism is the 1972 Biological Weapons Convention (BWC). This agreement was the first to declare an entire class of weapons to be off limits. While the treaty has some inevitable limitations—particularly the difficulty in detecting violators—it remains a powerful norm: no nation brags about their biological weapons capability.

It is our obligation to strengthen this norm, internationally. Right now, the clock is ticking on the BWC—the next BWC review conference, in which every article of the entire treaty is reviewed, takes place in 2011. We must propose a new action plan for achieving universal adherence to the BWC, so that all nations of the world are signatories to this pact. We also need to promote new ideas for how the BWC may be implemented on a national level. This conference presents the United States with an opportunity to showcase the progress we have made here at home in both lab safety and lab security. We will have the opportunity to set the global standards of success.

Government organization, Title IV

We commend the provision calling for the DNI to develop a strategy to strengthen our WMD-related intelligence capabilities. Increased attention in this area is of vital importance and, we understand, would underscore the DNI's own initiatives. We also strongly support the provisions of this bill that would strengthen the intelligence community's expertise in the nuclear

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and biological fields; prioritize pre-service and in-service training and retention of people with critical scientific, language, and foreign area skills; and ensure that the threat posed by biological weapons remains among the highest national intelligence priorities for collection and analysis.

Additionally, we recommend that the bill include a provision directing the Secretary of Defense to provide a classified report to the committees with primary oversight of the Department of Defense, Intelligence Community and Department of Homeland Security on the efficacy of the biological weapons tests conducted by the United States during the 1950s and 1960s. Some commentators assert that bioweapons are not of concern, primarily because they have not been used on a widespread basis. We are entirely confident that the report we call for, if properly done, would dispel any doubts about the threat that bioweapons pose to the safety and security of our society and our allies.

Emergency Management and Citizen Engagement, Title V

We strongly believe that a well-informed, organized and mobilized citizenry has long been one of the United States' greatest resources. An engaged citizenry is, in fact, the foundation for national resilience in the event of a natural disaster or a WMD attack.

Consistent with the Commission's Report, we must create a culture of preparedness and resilience across our nation. The most important statement we could offer to our colleagues concerning preparedness and emergency management is that there are a vast array of capabilities found across our society that can and must be organized and, when needed, mobilized in the event of a natural disaster or WMD attack. These capabilities are primarily the combined assets of state and local governments, our diverse business communities, nongovernmental organizations, professional and service organizations and all citizens. The federal government cannot hope to possess the capabilities needed in the event of a major disaster – but it can lend vital support if local and regional actors have organized beforehand.

For example, a few years ago, officials in Iowa asked BENS, or Business Executives for National Security, to assist them in building a public-private partnership to strengthen disaster

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preparedness. After extended discussions with a growing number of local and regional stakeholders, both in government and the private sector, the Safeguard Iowa Partnership was launched – a formal working partnership involving state and local governments and private organizations that understood the benefits of collaborating. When historic floods struck the state 18 months later, the trusted relationships, communication and coordination from this partnership demonstrated an improved emergency management capability that the federal government could not have prescribed or created. Moreover, such an entity can and should be established in every state and region to meet the particular needs of that area. We commend the work of BENS in helping to create an innovative approach to emergency response, preparedness, and resilience. We believe that the model they have established can and should be emulated elsewhere across the country and is applicable to both natural disasters and WMD attacks.

Finally, we would like to extend our appreciation to Senator Akaka for recently introducing the *Energy Development Program Implementation Act of 2009*. This bill will create an alternative energy peace corps, as called for 31 years ago by the *Nuclear Nonproliferation Act of 1978*. As our Report recommended, this bill would help reduce the further spread of nuclear technologies ostensibly for civilian purposes. It deserves bipartisan support.

Conclusion

We commend Senator Lieberman and Senator Collins for introducing a very important piece of legislation. We look forward to participating in a robust discussion on Capitol Hill and with the Administration and stakeholders as the *WMD Prevention and Preparedness Act of 2009* makes its way through the legislative process, and stand ready to help where we can, to promote important strides for our national security.

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United States Government Accountability Office

GAO

Testimony
Before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

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BIOSAFETY LABORATORIES

BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC

Statement of Gregory D. Kutz, Managing Director
Forensic Audits and Special Investigations

GAO
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September 2009

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Highlights

Highlights of GAO-09-1038T, a testimony before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

BIOSAFETY LABORATORIES

BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC

Why GAO Did This Study

Biosafety laboratories are primarily regulated by either the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA), depending on whether the substances they handle pose a threat to the health of humans or plants, animals, and related products, respectively. Currently, all operational biosafety level 4 (BSL-4) labs are overseen by HHS's Centers for Disease Control and Prevention (CDC). BSL-4 labs handle the world's most dangerous agents and toxins that cause incurable and deadly diseases.

This testimony summarizes GAO's previously issued reports on perimeter security at the nation's BSL-4 laboratories that were issued in September 2008 (GAO-08-1092) and July 2009 (GAO-09-851). Specifically, this testimony describes (1) the findings and recommendation on key perimeter security controls at five of the nation's operational BSL-4 labs, (2) CDC efforts to address our recommendation, (3) improvements that have been made to the perimeter security controls at the two labs found to be deficient, and (4) other observations about the BSL-4 labs GAO assessed.

What GAO Found

Significant perimeter security differences continue to exist among the nation's five BSL-4 laboratories operational at the time of GAO's assessment. In September 2008, GAO reported that three of the five labs had all or nearly all of the 15 key controls GAO evaluated. Two labs, however, demonstrated a significant lack of these controls, such as camera coverage for all exterior lab entrances and vehicle screening. As a result, GAO recommended that CDC work with USDA to require specific perimeter security controls at high-containment facilities. However, as we reported in July 2009, CDC has taken limited action on the GAO recommendation.

In July 2009, GAO reported that the two deficient labs made progress on their own despite CDC's limited action. One made a significant number of improvements, thus reducing the likelihood of intrusion. The second made a few changes and formed a committee to consider and prioritize other improvements. The following table shows progress on 9 of the 15 controls GAO initially assessed for these two labs.

Progress on Perimeter Security Controls at Two BSL-4 Labs as of March 2009

Security controls	Lab C	Lab E
Visitor screening	√	Previously in place
Command and control center	√	Not in place
Camera coverage for all exterior entrances	√	Not in place
Closed-circuit television (CCTV) monitored by command and control center	In progress	Not in place
Active intrusion detection system integrated with CCTV	In progress	Not in place
Visible armed guard presence at all public entrances	Partially addressed	Not in place
Loading docks located outside the footprint of the main building	Partially addressed	Previously in place
Barriers to prevent vehicles from approaching lab	Not in place	√
Blast stand-off area (e.g., buffer zone) between lab and perimeter barriers	Not in place	√

Source: GAO.

Note: √ This symbol signifies control in place after GAO's 2008 report was issued.

Two additional observations about BSL-4 labs concern the significant perimeter security differences among the five labs GAO originally assessed for our September 2008 report. First, labs with stronger perimeter controls had additional security requirements mandated by other federal agencies. For example, one lab is a military facility subject to far stricter Department of Defense physical security requirements. Second, CDC inspection officials stated their training and experience has been focused on safety. CDC officials said they are developing a comprehensive strategy for safety and security of labs and will adjust the training and inspection process to match this strategy.

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Mr. Chairman and Members of the Committee:

I appreciate the opportunity to participate in today's hearing to discuss perimeter security at the nation's biosafety[1] level 4 (BSL-4) laboratories, which handle substances that cause incurable and deadly diseases. Labs that work with infectious microorganisms or hazardous biological materials are classified into four ascending levels of containment, based on origin, risk of infection, severity of disease, and other factors.[2] BSL-4 labs handle the world's most dangerous substances—those that are exotic in origin and easily transmit life-threatening diseases for which no treatment exists, such as the Ebola and smallpox viruses. Federal law gives regulatory control for pathogens and toxins to either the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA), depending on whether these substances pose a threat to humans or to plants, animals, and products made from them, respectively.[3] The law requires HHS and USDA to review and publish a list of these substances, called select agents and toxins. All labs handling select agents must be registered with either HHS or USDA. The nation's operational BSL-4 labs are currently all overseen by HHS's Centers for Disease Control and Prevention (CDC). Regulations for select agents[4] require labs to conduct a site-specific risk assessment and develop a plan

[1]Biosafety is the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The principles of biosafety are containment and risk assessment. Containment includes the practices, equipment, and facility safeguards that protect personnel, the environment, and the public from exposure to substances handled and stored in the lab. Risk assessment is the process that enables the appropriate selection of practices, equipment, and facility safeguards that can prevent lab-associated infections.

[2]HHS, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: 2007).

[3]Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107–188, § 201, 116 Stat. 594, 637 (codified at 42 U.S.C. § 262a) (June 12, 2002), HHS is required to establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act is known as the Agricultural Bioterrorism Protection Act of 2002. Section 212, 116 Stat. 594, 647 (codified at 7 U.S.C. § 8401) of this act requires USDA to establish and maintain a list of biological agents that have the potential to pose a severe threat to animal health and safety, plant health and safety, or to the safety of animal or plant products. The departments share responsibility for some agents because they potentially threaten both humans and animals.

[4]42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121.

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to guard against unauthorized access, theft, loss, or release,[5] but they do not mandate specific perimeter security controls be put in place.

This testimony summarizes our recent investigations of perimeter security at the nation's BSL-4 laboratories. Specifically, our testimony describes (1) the findings and recommendation on key perimeter security controls at five of the nation's operational[6] BSL-4 labs,[7] (2) CDC efforts to address our recommendation, (3) improvements that have been made to the perimeter security controls at the two labs found to be deficient, and (4) other observations about the BSL-4 labs we assessed.

This testimony is based on our previous reports issued in September 2008 and July 2009.[8] We conducted our work in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency. More detailed information on our scope and methodology appears in our published work.

[5]Additional requirements include a written biosafety plan that describes safety and containment procedures and an incident response plan that includes procedures for theft, loss, or release of an agent or toxin; inventory discrepancies; security breaches; natural disasters; violence; and other emergencies.

[6]CDC informed us in June 2009 that a sixth BSL-4 lab has become operational. However, we are excluding it from the scope of this testimony due to its recently becoming operational.

[7]For the purposes of this testimony, we defined physical security as the combination of equipment, personnel, and operational procedures used to protect facilities, information, documents, or material against theft, sabotage, diversion, or other criminal acts. Our definition of physical security excludes, and we did not evaluate, intelligence gathering, cyber security, and human capital training and effectiveness. We did not assess the overall security of the labs or the threat of an insider attack, but focused on perimeter security leading up to each building's points of entry. Additionally, we did not test perimeter security controls to determine whether they function as intended. Perimeter security is just one aspect of overall security provisions under the Select Agent Regulations, which include personnel training and inventory control. Select Agent Regulations also require additional security measures inside the labs themselves, such as locks and other forms of physical control.

[8]GAO, *Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories*, GAO-08-1092 (Washington, D.C.: Sept. 17, 2008); and *Biosafety Laboratories: BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC*, GAO-09-851 (Washington, D.C.: July 7, 2009).

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Security Assessment from September 2008 Report

Select agent regulations do not mandate that specific perimeter security controls be present at BSL-4 labs, resulting in a significant difference in perimeter security between the nation's five labs. According to the regulations, each lab must implement a security plan that is sufficient to safeguard select agents against unauthorized access, theft, loss, or release. However, there are no specific perimeter security controls that must be in place at every BSL-4 lab. Although BSL-4 labs may have different levels of inherent risk, we determined that these 15 controls (discussed in more detail in app. I) represent a baseline for strong perimeter security. While three labs had all or nearly all of the key security controls we assessed, our September 2008 report demonstrated that two labs (Labs C and E) had a significant lack of these controls. See table 1 below.

Table 1: Results of Perimeter Physical Security Assessment

No.	Security controls	Lab A	Lab B	Lab C	Lab D	Lab E
1	Outer/tiered perimeter boundary	√	√		√	√
2	Blast stand-off area (e.g., buffer zone) between lab and perimeter barriers	√	√		√	
3	Barriers to prevent vehicles from approaching lab	√	√		√	
4	Loading docks located outside the footprint of the main building	√	√		√	√
5	Exterior windows do not provide direct access to the lab	√	√	√	√	
6	Command and control center	√	√		√	
7	Closed-circuit television (CCTV) monitored by the command and control center	√	√		√	
8	Active intrusion detection system integrated with CCTV		√		√	
9	Camera coverage for all exterior lab building entrances	√	√		√	
10	Perimeter lighting of the complex[a]	√	√	√	√	√
11	Visible armed guard presence at all public entrances to lab	√	√			
12	Roving armed guard patrols of perimeter	√	√	√	√	
13	X-ray magnetometer machines in operation at building entrances	√	√		√	
14	Vehicle screening	√	√			
15	Visitor screening	√	√		√	√

Source: GAO.

[a]We did not perform our assessment at night, so for this category we relied on the lab security officials to provide this information.

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Lab C: Lab C had in place only 3 of the 15 key security controls we assessed. The lab was in an urban environment and publicly accessible, with only limited perimeter barriers. During our assessment, we saw a pedestrian access the building housing the lab through the unguarded loading dock entrance. In addition to lacking any perimeter barriers to prevent unauthorized individuals from approaching the lab, Lab C also lacked an active integrated security system. By not having a command and control center or an integrated security system with real-time camera monitoring, the possibility that security officers could detect an intruder entering the perimeter and respond to such an intrusion is greatly reduced.

Lab E: Lab E was one of the weakest labs we assessed, with 4 out of the 15 key controls in place. It had only limited camera coverage of the outer perimeter of the facility and the only vehicular barrier consisted of an arm gate that swung across the road. Although the guard houses controlling access to the facility were manned, they appeared antiquated and thus did not portray a strong, professional security infrastructure. The security force charged with protecting the lab was unarmed.[9] Of all the BSL-4 labs we assessed, this was the only lab with an exterior window that could provide direct access to the lab. In lieu of a command and control center, Lab E contracts with an outside company to monitor its alarm in an off-site facility. This potentially impedes response time by emergency responders with an unnecessary layer that would not exist with a command and control center. Since the contracted company is not physically present at the facility, it is not able to ascertain the nature of alarm activation. Furthermore, there is no interfaced security system between alarms and cameras and a lack of real-time monitoring of cameras.

Although the presence of the controls we assessed does not automatically ensure a secure perimeter, having most of these controls in place and operating effectively reduces the likelihood of intrusion. As such, we recommended in the September 2008 report that the Director of CDC take action to implement specific perimeter controls for all BSL-4 labs to provide assurance that each lab has a strong perimeter security system in place. As part of this recommendation, we stated that CDC should work with USDA to coordinate its efforts, given that both agencies have the authority to regulate select agents. In its response to the September 2008

[9]Although the security force was unarmed, there was one armed security supervisor patrolling the facility.

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report, HHS agreed that perimeter security is an important deterrent against theft of select agents. HHS indicated that the difference in perimeter security at the five labs was the result of risk-based planning; however, they did not comment on the specific vulnerabilities we identified and whether these should be addressed. In regard to requiring specific perimeter controls for all BSL-4 labs, HHS stated that it would perform further study and outreach to determine whether additional federal regulations are needed.

CDC Has Taken Limited Action to Require Specific Perimeter Security Controls

Significant perimeter security differences continue to exist among the nation's five BSL-4 labs operational at the time of our most recent assessment. In our July 2009 report, we stated that CDC has taken limited steps to address our recommendation that it should take action to implement specific perimeter security controls for all BSL-4 labs. CDC stated that the following actions have been taken as of May 2009:

- In late 2007, CDC, along with other federal agencies, established a U.S. Government Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. The task force was formed to assess the current framework for local and federal oversight of high-containment laboratory research activities and facilities, including the identification and assessment of pertinent laws, regulations, policies, guidelines, and examination of the current state of biosafety oversight systems. The task force held a public consultation meeting in December 2008. According to CDC, the task force will communicate specific recommendations about the nation's lab safety and security issues to the Secretaries of both HHS and USDA.

- CDC and USDA hosted a workshop series in Greenbelt, Maryland, in December 2008 for all of their registered entities and partners. CDC stated that it included several safety and security topics, including discussion of physical security and operational security.

- In January 2009, in response to Executive Order 13486, a federal working group (WG) was convened to review current laws, regulations, and guidelines in place to prevent theft, misuse, or diversion to unlawful activity of select agents and toxins. The WG is chaired by HHS and the Department of Defense (DOD) and includes representatives from several federal agencies and includes a subgroup that is focused

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on physical and facility security of biolabs. The WG is expected to issue its final report to the President.[10]

Although CDC has taken some modest steps for studying how to improve perimeter security controls for all BSL-4 labs, CDC has not established a detailed plan to implement our recommendation. Without a detailed plan from CDC on what corrective actions are planned, it is impossible to monitor CDC's progress in implementing our recommendation to improve perimeter security controls for all BSL-4 labs. The ability to monitor progress openly and transparently is especially important because a sixth BSL-4 lab recently became operational, as mentioned above, and CDC expects more BSL-4 labs to be operational in the future.

Two Labs Take Action to Improve Perimeter Security Controls

Although CDC has taken limited action to address our findings from our September 2008 report, the two deficient BSL-4 labs have made progress on their own. In our July 2009 report, we stated that one BSL-4 lab made a significant number of improvements to increase perimeter security, thus reducing the likelihood of intrusion. The second one made three changes and formed a committee to consider and prioritize other changes.

Lab C

We confirmed the following improvements at Lab C:

- Visitors are screened by security guards and issued visitor badges.
- A command and control center was established.
- Camera coverage includes all exterior lab entrances.
- Closed-circuit television (CCTV) is monitored by the command and control center. The cameras currently cover the exterior of the building. Guards can control the cameras by panning, zooming, or tilting.
- One visible guard is present at the main entrance to the lab, but the guard is not armed. A guard mans the entrance 24-hours a day, 7 days a week. Although the guard is unarmed, this improvement does partially

[10]According to an HHS official, the WG completed its draft of the report on July 9, 2009, and is awaiting Secretarial signatures from HHS and DOD before official submission to the President.

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address the requirement for guard presence at lab public entrances. Lab officials described installing armed guards as cost prohibitive.

- While the loading dock is still located inside the footprint of the main building, Lab C improved its loading dock security by building a loading dock vehicle gate. Moreover, a pedestrian gate with a sign forbidding entry was built to prevent pedestrians from entering the building through the loading dock; pedestrians were previously allowed to enter the building through the loading dock as a way of taking a short-cut into the building. These new gates prevent individuals from walking into the building, or vehicles driving up to the building, unchallenged.

Lab officials said additional enhancements would be completed by fall 2009. These include an active intrusion detection system that is integrated with CCTV and the addition of 14 new interior cameras with pan, tilt, and zoom capabilities. The new cameras will enhance the interior perimeter security of the lab. The command and control center also will have access to and control of these new cameras. After these improvements are finished, the lab will have 8 of the 15 controls we tested in place plus 2 others that were partially addressed.

Lab E

We verified three improvements were made at Lab E—heavy concrete planters were added as a vehicle barricade along the roadside adjacent to the building; the window was frosted to block sight lines into the lab from nearby rooftops; and a vehicle barricade is being constructed to block unauthorized access to the parking lot adjacent to the lab, thereby increasing the blast stand-off area. The lab also formed a committee to consider additional perimeter security measures such as widening buffer zones and increasing lighting at the perimeter fence. In all, the lab now has 6 of the 15 controls we assessed in place.

Although lab officials made three improvements and are considering others, the lab's head of research operations at the facility objected to the findings of our September 2008 report and has challenged the 15 controls we deemed critical to strong perimeter security. He said that the officials from the lab were not afforded an opportunity to respond to the report and correct "inaccuracies." Specifically, he made the following comments on our previous findings:

- He questioned the basis for our selection of the specific 15 controls we identified as critical to perimeter security, and noted that CDC also

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expressed similar concerns in its comments on our September 2008 report.

- The lab windows do not provide direct access to the lab. He maintained that a number of features prohibited entry by these windows: the lowermost edge of the windows is more than 7 feet 8 inches above ground level, the windows are certified bulletproof glass and are equipped with inside bars, and breaching the integrity of the outer bulletproof glass triggers alarms for the local guard force. Furthermore, he said that having such a window was deemed programmatically important when the laboratory was designed in order to provide light-dark orientation for laboratory workers. Finally, he represented that a group of nationally recognized security experts has opined that the windows are not a security threat, but did not provide evidence of these experts' assessment.

- Armed guards are present on the campus. He stated that a table in our September 2008 report indicates that armed guards are not present on the campus, although a footnote on a subsequent page acknowledges that an armed security supervisor patrols the facility.

- A vehicle barrier does surround the perimeter of that portion of the laboratory building housing select agents, including the BSL-4 laboratory. He said it was recommended and approved by the Federal Bureau of Investigation during consultations on the safety of the building and installed in 1999 prior to initiation of research in this facility.

We continue to believe that our assessment of perimeter controls at Lab E is accurate. Specifically, we disagree with Lab E's position as follows:

- As stated in the September 2008 report, we developed the 15 security controls based on our expertise in performing security assessments and our research of commonly accepted physical security principles. Although we acknowledge that the 15 security controls we selected are not the only measures that can be in place to provide effective perimeter security, we determined that these controls (discussed in more detail in app. I) represent a baseline for BSL-4 lab perimeter physical security and contribute to a strong perimeter security system. Having a baseline provides fair representation as to what key perimeter security controls do or do not exist at these facilities. The controls represent commonly accepted physical security principles. A lack of such controls represents a potential security vulnerability. For example, as mentioned above, at the time of our original assessment

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Lab E had only limited camera coverage of the outer perimeter of the facility. Camera coverage of a building's exterior provides a means to detect and quickly identify potential intruders.

- As mentioned above, Lab E was the only lab with an exterior window that could provide direct access to the lab. This window allowed for direct "visual" access into the lab area from an adjacent rooftop. Lab E in essence acknowledged this when it informed us in a letter that it "Frosted the BSL-4 laboratory windows to block sight lines from adjacent rooftops." While we credited Lab E for obscuring visual access to the lab by frosting this window, the window continues to pose a security vulnerability because it is not blast proof.

- Armed guards are not present on the campus. As mentioned above, Lab E's head of research operations pointed out that our September 2008 report acknowledged that an armed security supervisor patrols the facility. However, employing one armed security supervisor does not support the plural definition of "guards." The supervisor also is not generally at the entrances to the facility. He normally responds to incidents and would not generally be in a position to confront an intruder at the point of attack. Furthermore, placing armed guards at entrances also functions as a deterrent.

- The vehicle barrier did not surround the full perimeter of the BSL-4 lab building as it adjoined another lab building at the time of our original assessment. The facility has since placed additional barriers as noted in this testimony to give full coverage, thus validating our original assessment. Furthermore, part of the barrier in the area between a small parking lot and the BSL-4 lab building did not provide an adequate blast stand-off area. The lab, as noted in the July 2009 report, has since erected barriers to this parking lot to allow only deliveries into the area.

The following table summarizes the progress the two labs have made on 9 of the 15 controls we initially assessed.

Table 2: Progress on Perimeter Security Controls at Labs C and E as of March 2009

Security controls	Lab C	Lab E
Visitor screening	√	Previously in place
Command and control center	√	Not in place
Camera coverage for all exterior entrances	√	Not in place
CCTV monitored by command and control center	In progress	Not in place

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Security controls	Lab C	Lab E
Active intrusion detection system integrated with CCTV	In progress	Not in place
Visible armed guard presence at all public entrances	Partially addressed	Not in place
Loading docks located outside the footprint of the main building	Partially addressed	Previously in place
Barriers to prevent vehicles from approaching lab	Not in place	√
Blast stand-off area (e.g., buffer zone) between lab and perimeter barriers	Not in place	√

Source: GAO.

Note: √ This symbol signifies control in place after our September 2008 report was issued.

Additional Observations on Federal Oversight of BSL-4 Labs

In our July 2009 report, we made two additional observations that concern perimeter security differences among the nation's five BSL-4 labs that were operational at the time of our assessment:

- All five BSL-4 labs operating in 2008 had a security plan in place when we assessed them. Yet significant perimeter security differences exist among these high-containment labs. A reason for the discrepancies can be found in the additional federal security requirements the three labs with strong perimeter security controls in place had to follow beyond the select agent regulations. For example, Lab B is a military facility subject to far stricter DOD physical security requirements. It had a perimeter security fence and roving patrol guards visible inside and outside this fence. Labs A and D also must meet additional mandates from the federal agencies that oversee them. A lack of minimum perimeter security requirements contributes to sharp differences among BSL-4 labs as well.]

- CDC inspection officials stated their training and experience had been mainly in the area of safety. They also noted that their philosophy is a layered approach to security and safety. According to CDC officials, they are developing a comprehensive strategy for safety and security of biosafety labs and will adjust the training and inspection process accordingly to match this comprehensive strategy.

Agency and Third-Party Comments

We made no new recommendations in our July 2009 report. In responding to our report, CDC stated that multiple groups are assessing the issue of laboratory security and developing related recommendations. CDC stated that it will consider our prior recommendation and the reports from the

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multiple groups together before developing a detailed plan to address security at select agent laboratories. CDC also stated that it is in the process of hiring a Security Officer to provide continued focus on laboratory security. Labs C and E commented on relevant sections of our report, indicating that they have taken or plan to take various actions to improve perimeter security.

Mr. Chairman and Members of the Committee, 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.

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Appendix I: Perimeter Security Controls

To perform our perimeter security assessment of biosafety level 4 (BSL-4) labs, we identified 15 key perimeter security controls. We based their selection on our expertise and research of commonly accepted physical security principles that contribute to a strong perimeter security system. A strong perimeter security system uses layers of security to deter, detect, delay, and deny intruders:

- **Deter.** Physical security controls that deter an intruder are intended to reduce the intruder's perception that an attack will be successful—an armed guard posted in front of a lab, for example.
- **Detect.** Controls that detect an intruder could include video cameras and alarm systems. They could also include roving guard patrols.
- **Delay.** Controls that delay an intruder increase the opportunity for a successful security response. These controls include barriers such as perimeter fences.
- **Deny.** Controls that can deny an intruder include visitor screening that only permits authorized individuals to access the building housing the lab. Furthermore, a lack of windows or other obvious means of accessing a lab is an effective denial mechanism.

Some security controls serve multiple purposes. For example, a perimeter fence is a basic security feature that can deter, delay, and deny intruders. However, a perimeter fence on its own will not stop a determined intruder. This is why, in practice, layers of security must be integrated in order to provide the strongest protection. Thus, a perimeter fence should be combined with an intrusion detection system that would alert security officials if the perimeter has been breached. A strong system would then tie the intrusion detection alarm to the closed-circuit television (CCTV) network, allowing security officers to immediately identify intruders. A central command center is a key element for an integrated, active system. It allows security officers to monitor alarm and camera activity—and plan the security response—from a single location. Table 3 shows 15 physical security controls we focused on during our assessment work.

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Table 3: Perimeter Physical Security Controls

No.	Perimeter physical security control	Rationale
1	Outer/tiered perimeter boundary	There should be a perimeter boundary outside the lab to prevent unauthorized access. Examples include a reinforced perimeter security fence or natural barrier system that uses landscaping techniques to impede access to buildings. Outer/tiered perimeter also includes other structures that screen visibility of the lab.
2	Blast stand-off area (e.g., buffer zone) between lab and perimeter barriers	To minimize effects of explosive damage if a bomb were to be detonated outside the lab, the perimeter line should be located as far as practical from the building exterior.
3	Barriers to prevent vehicles from approaching lab	A physical barrier consisting of natural or man-made controls, such as bollards, designed to keep vehicles from ramming or setting off explosives that could cause damage to the building housing the BSL-4 lab.
4	Loading docks located outside the footprint of the main building	Because they are areas where delivery vehicles can park, loading docks are vulnerable areas and should be kept outside the footprint of the main building.
5	Exterior windows do not provide direct access to the lab	Windows are typically the most vulnerable portion of any building; therefore, there should be no exterior windows that provide direct access to the lab.
6	Command and control center	A command and control center is crucial to the administration and maintenance of an active, integrated physical security system. The control center monitors the employees, general public, and environment of the lab building and other parts of the complex and serves as the single, central contact area in the event of an emergency.
7	CCTV monitored by the command and control center	A video system that gives a signal from a camera to video monitoring stations at a designated location. The cameras give the control center the capability of monitoring activity within and outside the complex.
8	Active intrusion detection system (IDS) integrated with CCTV	An IDS is used to detect an intruder crossing the boundary of a protected area, including through the building's vulnerable perimeter barriers. Integration with CCTV is integral to the IDS's ability to alert security staff to potential incidents that require monitoring.
9	Camera coverage for all exterior lab building entrances	Cameras that cover the exterior building entrances provide a means to detect and quickly identify potential intruders.
10	Perimeter lighting of the complex	Security lighting of the site, similar to boundary lighting, provides both a real and psychological deterrent, and allows security personnel to maintain visual-assessment capability during darkness. It is cost-effective in that it might reduce the need for security forces.
11	Visible armed guard presence at all public entrances to lab	All public entrances require security monitoring. This presence helps to prevent or impede attempts of unauthorized access to the complex.
12	Roving armed guard patrols of perimeter	The presence of roving armed guard patrols helps to prevent or impede attempts of unauthorized access and includes inspecting vital entrance areas and external barriers.
13	X-ray magnetometer machines in operation at building entrances	These machines provide a means of screening persons, items, and materials that may possess or contain weapons, contraband, or hazardous substances prior to authorizing entry or delivery into a facility.
14	Vehicle screening	Screening vehicles that enter the perimeter of the lab includes an identification check and vehicle inspection, in order to deny unauthorized individuals access and potentially detect a threat.
15	Visitor screening	Screening visitors to the lab reduces the possibility that unauthorized individuals will gain access. Visitor screening includes identifying, screening, or recording visitors through methods such as camera coverage or visitor logs so that their entry to the lab is recorded.

Source: GAO.

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Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, the following individuals made contributions to this testimony: Andy O'Connell, Assistant Director; Matt Valenta, Assistant Director; Christopher W. Backley; Randall Cole; John Cooney; Craig Fischer; Vicki McClure; Anthony Paras; and Verginie Tarpinian.

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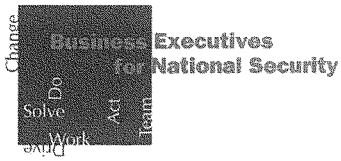

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September 17, 2009

The Honorable Bob Graham, Chair
The Honorable Jim Talent, Vice Chair
Commission on the Prevention of Weapons
of Mass Destruction, Proliferation and Terrorism
80 F. Street, NW Suite 200
Washington Dc 20001

Dear Senators Graham and Talent:

Several months ago, we had the privilege of sharing with you an alternative approach to fostering greater awareness, preparedness, and resilience among individual citizens, American communities, and the nation. The Commission's report, World at Risk, describes the growing threat of WMDs to our homeland, our citizens, and our way of life – and yet with this challenge, there is also great opportunity to build a stronger, more resilient nation. As the Congress begins work on legislation to implement the Commission's recommendations, we recommend consideration of our alternative approach to strengthen public-private collaboration and the principles and framework that can engender a culture of preparedness.

We agree with the Commission's finding that the federal government cannot prevent or protect its citizenry against every potential threat – be it a deliberate act of terrorism, natural disasters, pandemic disease, or other disruptions that pose risk to the security and safety of our nation. We must engage all segments of society in order to build resilience – and that means public-private collaboration is an imperative.

Business Executives for National Security (BENS) has a 27- year history of facilitating public-private collaboration – including seven years of building security and resilience-focused partnerships at the state and local level. BENS' unique niche in facilitating partnerships has been the ability to navigate through the barriers that often divide government and the broader private sector – at all levels of government.

In recent years, we have seen the benefit of community and statewide public-private partnerships established before a disaster strikes, such as the *Safeguard Iowa Partnership* playing a pivotal role during response to the historic 2008 Midwest floods; and partnerships in Northern and Southern California that served a critical function as private sector liaison in state and local emergency operations centers during the 2007 wildfires – sharing situational awareness and securing urgently needed supplies from the private sector.

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Based on the lessons-learned from BENS' partnership-building experience and the collective recommendations of diverse stakeholders with whom it has partnered over the years, we have found strong consensus on the following first principles:

- Resilience must be built ground-up. Community resilience is about horizontal networking, collaboration, and building trusted relationships across many diverse public and private organizations – a process not effectively managed by stove-piped federal systems. The federal government must lead the efforts to improve national preparedness and resilience by trusting people in their communities with more information, providing greater local flexibility, and by respecting locally-determined priorities;

- Community-based public-private partnerships can be consistent with federal or other common doctrine, but if they are to be sustainable, partnerships must be locally "owned" and managed. Resilience-focused collaboration and unity of effort must be developed and mainstreamed in communities – ideally related to broader, community-building goals.

- Neither a federal agency, nor a national organization can prescribe a top-down, one-size-fits-all solution that will work everywhere; every disaster is local, and each community unique.

- The federal government cannot mandate the human endeavor of public-private collaboration; but it can help enable it.

- There are numerous regulatory, legal, cultural, and political barriers to effective public-private collaboration that require mediation/facilitation to resolve.

- The private sector must be at the table as equal partners from the beginning; however, for this to occur, private organizations – and all stakeholders – need assurance that their respective interests will be represented and respected.

There is widespread recognition of the need for a national mechanism or framework to help strengthen community resilience through public-private collaboration. Our collective experience suggests it should not be another government program, but rather a federally recognized, but independent, neutral entity – an honest broker that will:

- ✓ protect the interests of business and other private organizations willing to partner with government;
- ✓ support government in its efforts to engage the private sector in all phases of disaster management;
- ✓ ensure greater cross-sector communication to help inform federal policy;
- ✓ enable a nationwide network of resilience-focused community-based partnerships;
- ✓ serve as an objective, independent broker that can convene professionals from all sectors and disciplines to address the barriers to effective private-public collaboration;
- ✓ work closely with government and private partners, but operate as an independent non-profit corporation;

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- ✓ allow best practices to set a guild standard for community partnerships and public-private collaboration;

Last year, BENS convened a coalition of experienced homeland security professionals and diverse representative stakeholders to explore the feasibility of creating a new entity to serve the roles described above. BENS facilitated the Coalition's work, providing a neutral venue for these subject matter experts and practitioners to build consensus around practical, effective, and scalable solutions.

The product of this effort was the Coalition's proposal for a nationally-recognized, non-profit public benefit organization, dedicated to facilitating and sustaining public-private collaboration toward the goal of American resilience. The proposed organization would serve as a national resource for businesses, all levels of government, private organizations, and communities that wish to establish effective private-public partnerships.

This proposal reflects the collective experience, knowledge and wisdom of those who served with us on the Coalition, but the proposal also benefited from the comments and recommendations of many others – including relevant professional organizations, academics, business leaders and public servants from all levels of government.

The proposed entity would:

- Become an objective, independent source for best practices and lessons learned pertaining to public-private collaboration and disaster resilience – to include the collection, analysis and distribution of findings;
- Serve a coordinating function that connects those seeking assistance to other jurisdictions or private organizations with relevant expertise and experience in resilience-focused public-private collaboration;
- Advocate public policy that will encourage and empower community-based partnerships, reduce legal and regulatory barriers to collaboration at all levels of government, and increase the efficient delivery of services, resources and capabilities to those in need;
- Enlist the private sector to provide expertise and active participation in the planning and execution of national level exercises;
- Serve as an independent, neutral forum for convening diverse government and private sector stakeholders, facilitating discussion, and mediating compromise that respects the interests of all partners and enhances unity of effort;
- Work with research institutions and Federally Funded Research and Development Centers (FFRDC) to ascertain our current state of preparedness/resilience, and to explore incentives and rewards for demonstrable improvement;
- Build a national repository of subject matter expertise, to include a collection of innovative programs, partnership models and business plans, resources for resilience education, and information on related technology solutions.

Today's challenges require our nation's best collective capabilities and resources – including those of the private sector. The proposed public benefit organization would in no way supplant

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the role of government; rather, it would serve as an independent honest broker. It will offer government at all levels the opportunity to realize the full potential of public-private collaboration, to the benefit of our nation.

"Just as our challenge is new, so must we think anew and act." The words of President Abraham Lincoln are timeless.

We encourage the Congress, the Administration, and federal agency partners to embrace the objectives and potential of this proposal to harness our nation's collective capabilities – and to recognize the willingness of individual citizens and communities to rise to the challenge.

On behalf of the entire Coalition, and in coordination with BENS, we thank you for your leadership in this critical area and extend our offer to assist, however you deem most appropriate.

Respectfully,

General (USA-Ret) Dennis J. Reimer
Former Chief of Staff, United States Army
Co-Chair, Public Benefit Coalition

Lynne R. Kidder
Sr. Vice President, Public-Private Partnerships
BENS

CC: General Charles G. Boyd (USAF-Ret)
President and CEO
BENS

Joe DePinto
President and CEO
7-Eleven, Inc.

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GAO

Perimeter Security Controls Verified by GAO during 2008 Assessment And 2009 Follow-up

	Lab A	Lab B	Lab C	Lab D	Lab E
Perimeter boundary	●	●		●	●
Blast stand-off area	●	●		●	●
Vehicle barriers	●	●		●	●
No loading dock	●	●		●	●
No lab access through windows	●	●	●	●	
Command and control center	●	●	●	●	
Monitored CCTV	●	●		●	
Intrusion detection integrated with CCTV		●		●	
Camera coverage for entrances	●	●	●	●	
Perimeter lighting	●	●	●	●	●
Visible armed guard presence	●	●			
Armed guard patrols	●	●	●	●	
X-Ray machines at entrances	●	●		●	
Vehicle screening	●	●			
Visitor screening	●	●	●	●	●

● Originally in place ● In place for follow-up

Source: GAO.

53840.038

Public and Scientific Affairs Board

September 18, 2009

The Honorable Joseph I. Lieberman
Chair, Committee on Homeland Security
and Governmental Affairs
United States Senate
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Lieberman:

The American Society for Microbiology (ASM) submits the following comments for the hearing record on the Weapons of Mass Destruction Prevention and Preparedness Act of 2009, S 1649. The ASM is the largest single life science organization with approximately 40,000 members. The ASM is devoted to the study and advancement of the scientific knowledge of microbiology for the benefit of human welfare. ASM members are involved in basic and applied research, clinical laboratory testing and public health activities that are focused on developing new preventions, therapies and cures for infectious diseases. To meet the challenges of emerging and reemerging infectious diseases, microbiologists work in laboratories in which highly pathogenic agents are stored and studied. The ASM is interested in assuring that such agents are maintained in a manner that is safe for laboratory personnel and the public.

The ASM commends your efforts and that of the Senate Committee on Homeland Security and Governmental Affairs to prevent the proliferation of weapons of mass destruction and to enhance preparedness for biological terrorism. The ASM supports responsible regulation, oversight, practices and guidelines that promote biosecurity and improve biosafety in laboratories. We appreciate the opportunity to meet with your staff and to offer comments on the proposed legislation.

General Comments on Title I – Enhanced Biosecurity

The ASM supports the critical role of the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the US Department of Agriculture Animal Plant Health Inspection Service (APHIS) and the Department of Justice (DOJ)/FBI in administering the select agent and toxin regulations for facilities that possess, use or transfer select agents and toxins. The HHS, CDC and APHIS are experienced and knowledgeable about infectious diseases and are committed to the protection of public health and safety. The DOJ/FBI assists in establishing security requirements for registered entities and a personnel screening protocol for access to select agents and toxins.

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Since 1995, the ASM has submitted recommendations to Congress, the Administration and federal agencies on policies to enhance biosafety and biosecurity. In those comments, the ASM has emphasized the need to balance enhanced security with the critical need to conduct public health activities, clinical diagnostic testing and research on pathogens that will lead to new and improved vaccines, therapeutics, diagnostics, and other measures that will protect public health against infectious diseases, whether naturally occurring or the result of an act of bioterrorism. The ASM supports the central role of HHS/CDC in protecting public health and fostering research on human pathogens in a safe and secure manner. It supports the role of USDA/APHIS in performing similar functions to protect plant and animal health. Further, the ASM and Congress have supported locating the Select Agent Program at the HHS/CDC for human and overlap agents and at the USDA/APHIS for animal and plant pathogens because these agencies have the appropriate public health expertise, experience in the life sciences, and oversight capacity for biosafety and biosecurity.

The Select Agent regulations, first established in 1996 for transfers of select agents and toxins and expanded in 2002 to include registration for possession and use, mandate an FBI security risk assessment for entities and individuals authorized to have access to select agents and toxins and they require safety and security plans to safeguard select agents based on risk assessment. The Select Agent regulations were enacted to ensure reasonable safety and security requirements to prevent misuse of select agents and toxins; to date there is no documentation that they are not fulfilling that mandate.

In 2002, the Department of Homeland Security (DHS) was established and given a role with respect to risk assessment of select agents for purposes of developing countermeasures, but not to inform regulation. An interagency committee reviews the select agent list every two years and it is published for comment in the Federal Register where there is opportunity to make changes to the list of regulated agents.

The ASM position regarding the primacy of HHS and USDA is supported by the 2008 Report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism which calls for the HHS to take the lead on regulatory programs, including registration of laboratories. The report states on page 29, "The Department of Health and Human Services, in coordination with the Department of Homeland Security, should take the lead for an interagency effort to tighten government oversight of high containment laboratories."

The ASM is concerned about a number of the provisions in Title I of S 1649. The bill's focus is on creating a role for the DHS as compared to HHS and establishes multiple lists of regulated agents which will be confusing and cumbersome to administer. Further, passage of legislation at this time would precede the issuance of two important reports from the Executive Order Working Group on Strengthening the Biosecurity of the United States and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. We understand that these reports should be released in the relatively near future.

The ASM recommends that Title I be omitted from the current legislation and that Congress wait for the recommendations of the Executive Order Working Group on Strengthening Biosecurity and the Trans Federal Task Force on Optimizing Biosafety and Biocontainment Oversight before moving forward with legislation mandating new or changed regulations. If changes are needed to improve biosafety and biosecurity, we recommend that any such changes

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be made after careful consideration of the recommendations in these reports and build upon existing programs, including the Select Agent Program, rather than through new statutory programs.

We also are concerned that the legislation would establish a largely redundant oversight program at DHS, an agency which does not have the appropriate experience or expertise in the life sciences. Creating another list of biological agents for biosecurity will be confusing to the user community and will be a strong disincentive to conduct work on any of the agents that end up on the list. Insertion of DHS in the process may impede research and public health activities related to select agents without significant improvement in biosafety and biosecurity. Further, inclusion of the DHS on inspections done by HHS and USDA under the select agent program raises concerns. Substantive oversight of the regulatory program by DHS appears only to create confusion or, even worse, to require that an agency issue rules and conduct inspections notwithstanding the absence of expertise in the area being regulated or the facilities being inspected.

Specific Comments on Title I

Section 101—Designation of Tier 1 Agents

In discussions with the EO Working Group, the ASM has supported the tiering of select agents so that some agents would require more security over others. In effect this already occurs for smallpox which is limited by international agreement and federal law to the CDC laboratory. The ASM view is that a broad discussion among the public health, scientific and security communities could define which agents are the most significant biothreats requiring greater security measures and which agents may have lesser security requirements. Title II, Enhancing Controls on Dangerous Biological Agents and Toxins, of PL 107-188 already gives HHS and USDA the authority to revise the list of select agents and toxins commensurate with risk to public health and safety, including the risk of use in terrorism.

Under the Select Agent regulations, agents or toxins have been listed under Paragraph 1(A) of Section 351A of the Public Health Service Act (42 U.S.C. 262a) based on criteria mandated in Title II of PL 107-188. Title II requires that the HHS Secretary shall consider the following four criteria: 1) the effect on human health of exposure to the agent or toxin; 2) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans; 3) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin and 4) any other criteria, including the needs of children and other vulnerable populations that the Secretary considers appropriate.

Section 101 of S 1649 would require that an agent or toxin must be classified as a Tier 1 agent if either (a) it has been determined to be a Material Threat under Section 319F-2(c)(2) unless inclusion is not warranted, or (b) it meets the criteria identified in subparagraph (B). Material Threat Determinations (MTD) currently have been issued for: *Bacillus anthracis*, Botulinum toxins, *Burkholderia mallei, Burkholderia pseudomallei*, Ebola virus, *Francisella tularensis,* Junin virus, Marburg virus, Multi drug resistant *Bacillus anthracis*, Radiological/Nuclear agents, *Rickettsia prowazeki*, typhus, Variola virus, Volatile nerve agents and *Yersinia pestis*.

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It is not clear that an agent with an MTD must necessarily be classified as a Tier I agent. Further, the criteria in the legislation for designation as a Tier I agent include (a) significant potential to be used effectively in an attack, (b) risk requires biosecurity measures beyond those required for select agents, (c) information available from bioterrorism risk assessments, and (d) "other criteria" determined by DHS. Given the breadth and relative subjectivity of these criteria, it is difficult to identify parameters to predict which, if any, agents other than those for which a MTD has been made would trigger the expanded security and safety measures required in Section 102. As a result, it is difficult to understand the scope and impact of the potential enhanced classification of certain agents as Tier I agents.

Section 102—Enhanced Biosecurity Measures

The proposed legislation requires that the DHS establish through negotiated rulemaking enhanced biosecurity measures for entities registered under section 351A(d) of the Public Health Service Act to use in handling Tier I agents, which shall include (1) standards for personnel reliability programs; (2) standards for training and requirements for responsible officials, lab personnel and support personnel employed by registered entities; (3) standards for performing laboratory risk assessments; (4) risk based laboratory security performance standards; (5) any other standards determined necessary by the Secretary; and (6) procedures, with appropriate restrictions on access, for sharing information, including vulnerability assessments, site security plans, and other security related information, as the Secretary determines appropriate, with State, local, and tribal government officials, including law enforcement officials and emergency response providers.

We do not believe DHS is the appropriate agency in which to place authority for rulemaking regarding enhanced biosecurity measures for agents and toxins. As stated above, the DHS does not have the expertise to promulgate regulations in the areas specified for regulation, including laboratory practices. The required expertise is different from, and more extensive than, the ability to make threat determinations or to undertake other DHS enforcement actions. Any additional rulemaking for select agents and toxins should be managed and promulgated jointly by HHS in coordination with the Department of Agriculture.

The proposed legislation mandates that the Secretary of Homeland Security shall inspect laboratories that handle Tier I agents for compliance with the new regulations required for such agents. Part (B) Inspections by the DHS, HHS and USDA, states that inspections of the same laboratory for compliance with the Select Agent and Tier I regulations shall be conducted simultaneously "to the extent practicable." Is it practicable if each agency has its own set of rules and who will determine "practicality"? What recourse does a laboratory have if it believes that inspections are not being done jointly and under common standards to the maximum extent practicable or if contradictory findings or recommendations are made under the two programs.

Section 103—Laboratory and Facility Registration and Database

Section 103 raises the issue of the desirability of a separate registration for laboratories handling a new category of Registry Agents and the implementation of the vague criteria for Registry Agents in Subsection (f)(2) (C).

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Section (f)(1) requires the HHS to maintain a database and register laboratories and facilities that have a sufficient potential to pose a public health threat. The HHS Secretary shall by regulation establish criteria defining which laboratories and facilities to include in the database and shall by regulation require the registration of laboratories and facilities that meet the criteria. The criteria shall include (i) whether a laboratory or facility handles a biological agent or toxin designated as a Registry Agent; (ii) whether a laboratory or facility has specified characteristics, features or equipment that could facilitate the misuse of the laboratory or facility for the purposes of developing a biological weapon, which may include (I) technology that is particularly suitable to the development of an effective biological weapon, such as technology that would enable synthesis of Tier I agents and (II) features that would protect an individual developing a biological weapon from accidental exposure or discovery and (iii) such other characteristics as the Secretary determines appropriate.

The broad language in the proposed legislation effectively leaves the extent of the database and registration of laboratories and facilities entirely in the discretion of the regulatory authority. Laboratories that do not handle agents that pose a serious threat could be included in the database and registry on the vague criteria specified in Section (f)(2) (C), which is not precise or determinative.

Section 103 (4) Registry Agents, provides that the HHS Secretary establish and maintain by regulation a list of biological agents and toxins that have the potential to pose a serious threat to public, animal or plant health but for which the potential to be used effectively in a biological attack has not been clearly established. Section 103 excludes Select agents and toxins from the list and requires a review of the select agent and toxin list to determine which listed agents and toxins more accurately fit the criteria for Registry Agents as described in subsection (f)(4). The DHHS Secretary "shall promote biosecurity and biosafety best practices to registered entities."

Section 103 lacks details on important aspects of creation of the database and registration of laboratories and facilities. The conferral of broad and discretionary authority to require registration of laboratories without details of the information that constitutes "registration" and extent of penalties for noncompliance is a major concern. The bill does not provide for the development, including the procedure to be used for the development of biosecurity and biosafety practices. Further, there is no indication what the word "promote" means or implies. The criteria for Registry Agents are vague and unclear and could include all microorganisms and require registration of thousands of research and testing laboratories.

In its consultation with the Trans Federal Task Force on Optimizing Biosafety and Biocontainment, the ASM has supported registration of high containment laboratories. This is consistent with the position taken by the WMD Commission. The ASM has recommended carefully defining the scope of high containment laboratories that would be required to register and the additional requirements that would be imposed upon those registered laboratories. In this regard the ASM has recommended a step-wise approach that would begin by assessing the costs and benefits of moving toward an accreditation system for high containment laboratories. The ASM also supports adequate and validated training of laboratory personnel, including technical, support and facilities personnel, rigorous implementation of appropriate laboratory practices and containment, biosafety oversight at multiple levels, ensuring the safety and upkeep of equipment and the maintenance of facilities, formal risk assessment for biosafety and biosecurity and reporting and analysis of laboratory acquired infections.

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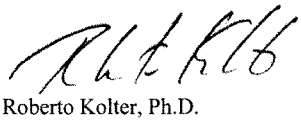
We have submitted comments to the Committee staff on other titles of the legislation and have attached the comments to this letter. Again, we appreciate the opportunity to comment on the proposed legislation and hope that our comments and recommendations will be useful to the Committee.

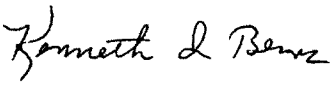
Sincerely,



Roberto Kolter, Ph.D.
President
American Society for Microbiology

Ruth L. Berkelman, M.D.
Chair
Public and Scientific Affairs Board

Ronald M. Atlas, Ph.D.
Co-Chair
Committee on Biodefense
Public and Scientific Affairs Board



Kenneth I. Berns, M.D., Ph.D.
Co-Chair
Committee on Biodefense
Public and Scientific Affairs Board

cc: Senator Susan M. Collins, Ranking Minority Member

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September 18, 2009

The Honorable Joseph I. Lieberman
Chair, Committee on Homeland Security
and Governmental Affairs

The Honorable Susan M. Collins
Ranking Member, Committee on Homeland Security
and Governmental Affairs

United States Senate
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Lieberman and Senator Collins:

On behalf of the Galveston National Laboratory (GNL), located on the University of Texas Medical Branch (UTMB) campus in Galveston, Texas, we welcome the opportunity to comment for the hearing record on S. 1649, the *Weapons of Mass Destruction Prevention and Preparedness Act of 2009*.

UTMB's research activities using Select Agents began before the federal program's inception in 1997, and we have been active participants in adapting to enhancements in regulatory requirements. In addition to well established Select Agent research, our institution also hosts a National Biocontainment Laboratory (the GNL), the Western Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, and the National Biocontainment Training Center. Therefore, we are intimately involved with the continuing impact of the Select Agent Rules on research, safety and security practices. Also, successful management of a Select Agent program with 380 U.S. Department of Justice-approved individuals affords UTMB an understanding of the complexities surrounding the Select Agent rules.

As practitioners in this vital industry, we have grave concerns about many of the new measures being proposed in S. 1649. Specifically, we question the wisdom of empowering the U.S. Department of Homeland Security (DHS) as the lead agency for the existing Select Agent program. The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) have jointly administered the Select Agent program successfully for 10 years, establishing a productive rapport with academic scientific and biosafety programs. This decade-long relationship between government and academic centers not only closely monitors the practice of Select Agent research, but also assures the continued productivity of crucial scientific inquiry.

Moreover, we have heard many of our research colleagues throughout various public consultations of the desire to have a tiered Select Agent list. Working within the framework of the Select Agent regulations, a tiered Select Agent list would provide a concise approach to regulatory oversight.

INSTITUTE FOR HUMAN INFECTIONS AND IMMUNITY
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Accordingly, a large number of the current Select Agents might be removed from the list or subject to a lower level of biosecurity as we question whether all of the currently listed agents are, indeed, high-risk organisms for bioterrorism.

Our institutional experience and participation in microbiology and infectious disease research for many years compels us to suggest that a fine balance is needed between regulation and the ability of qualified scientists to do essential research. Over-regulation that impedes research can have negative consequences, leaving the nation vulnerable to natural infectious disease threats, and thus having effects contrary to national security. An example is the impact of current regulations on the exchange of samples and reagents between foreign scientists and those working in the U.S. This has degraded the ability of U.S. scientists to monitor the natural evolution and emergence of infectious diseases in overseas regions in a timely manner, and threatens to reduce U.S. awareness of the current situation with respect to natural infectious threats which are at least as great and, in all probability, greater than the threat of purposeful deployment of an infectious agent.

Finally, stringent restrictions are already in place for working with Select Agents, and our institution shares the concern of fellow scientists noting that further restrictions, such as those that may follow a Tier 1 designation, will almost certainly discourage further study on these agents, making the research even more costly and potentially depriving the U.S. of much needed advancement on cures and diagnostics for the diseases affecting human and animal health.

In an effort to add constructive commentary on this legislation, the following comments have been specifically categorized by respective bill section.

SEC.101.(a)(2)(B)
It is our strong belief that the Tier I designation process established in this section could circumvent and adversely affect the current Select Agent designation process. As written, DHS, independent of HHS, may issue a Material Threat Determination (MTD) on an agent granting it automatic designation as Tier I. Subsection(a)(2)(A)(ii) also requires that Tier I agents be included on the Select Agent list no later than 60 days after DHS issues a Tier I designation. Accordingly, any agent designated as Tier I will automatically be included on the Select Agent list. Allowing such action would provide DHS with unprecedented authority to add additional agents to the Select Agent list, avoiding the checks and balances that current law affords prior to such action. The MTD process is somewhat obscure, with much of it contained in documents that are classified and not available for scrutiny by the scientific community. This approach is not transparent and is contrary to the intent of the *Public Health Service Act* (PHSA) and the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Response Act of 2002), which requires consultation with the scientific community.

The PHSA SEC. 351A.(a)(1)(B) provides criteria for determining whether to include an agent or toxin on the Select Agent list. As a component of this determination, the PHSA requires that an entity *"consult with appropriate federal departments and agencies and with scientific experts representing appropriate professional groups including groups with pediatric expertise."* Additionally, notice is posted in the *Federal Register* seeking public comments, as well as input from the Intragovernmental Select Agent and Toxins Technical Advisory Committee (ISATTAC), which provides scientific expertise to the HHS Secretary in making such determinations. It is shortsighted to afford DHS the authority to create a security-minded Tier I list without acknowledging the impact of such a designation on the current Select Agent list. The HHS Secretary should be granted sole veto authority

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on such automatic designations of Tier I agents, preventing an unbalanced designation process. Implementing a collaborative process that fosters informed interagency discussions between DHS and HHS would protect the checks and balances already established under current law and utilize the security and scientific expertise of both agencies. In addition, the PHSA requires consultation, thus similar provisions could benefit the Tier I designation process by offering additional scientific perspective on the agents being considered for Tier I designation.

SEC.318.Enhanced Biosecurity Measures
With the possible exception of the personnel reliability and security standards, this section effectively brings DHS into the realm and practice of biology, a scientific area that has not been part of the agency's portfolio and is more appropriately regulated by the expertise of the agencies currently responsible for the Select Agent program – HHS and USDA.

SEC.318.(B)(5) states "*any other standards determined necessary by the Secretary.*" Counter to the cooperative spirit of this bill, this statement appears to offer the DHS Secretary authority to add further standards without participation by partner agencies or the community affected by the legislation. This open-ended and exclusive rule-making authority, which has not been previously used in the PHSA or the Response Act of 2002, should be replaced with concise requirements and language that clearly frames standards, authority and responsibilities that promote balance.

SEC.318.(f)(8) Joint Inspections
Ensuring compliance under federal regulations regarding agency inspections is vitally important. This bill could address that concern through clear inspection criteria and a requirement that inspections of entities be conducted jointly, thus reducing the often cumbersome task of redundant preparation for multiple agency inspections. Utilization of combined agency expertise would mitigate the confusion that often occurs when multiple agency inspectors differ on rule interpretation. We also support the sentiment expressed by a number of our colleagues, urging the need for experienced, better-trained inspectors than those currently charged with reviewing the Select Agent program, and for greater coordination between the two agencies.

SEC318.(f)(3) Personnel Reliability Programs
Consistent with the recommendations of the National Science Advisory Board for Biosecurity (NSABB)[1], we support Personnel Reliability Programs that are managed on a local basis by the entities themselves and would urge that the subsequent Personnel Reliability Program rules promulgated as a result of this legislation reflect a similar philosophy.

SEC318.(f)(6) Harmonization
Harmonization of the applicable Select Agent rules is critical to successful implementation of proposed changes. Bill authors are aware of this critical component, as evidenced by the inclusion of this section in the bill. We strongly encourage significant emphasis on ensuring that rules written and developed for registry, Select and Tier I agents are fully integrated. The security plan and risk assessment requirements must be clear in both content and applicability, such that they may be consistently evaluated by inspecting agencies.

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1 NSABB. Enhancing Personnel Reliability among Individuals with Access to Select Agents. May 2009. *See* http://oba.od.nih.gov/biosecurity/meetings/20090511/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf

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The tiered system, as outlined in this legislation, has the potential to become quickly complicated as it would consist of three lists which build upon one another. Thus, each list would have a set of rules that applies to itself and the higher level category above it. This situation would be further complicated by the potential Tier I agent list that could include agents from biosafety levels 2, 3 and 4.

SEC.103.(f)(4) Registry Agents

We have serious concerns regarding the concept of the creating a new category of "registry agents," as stated in SEC.103.(f)(4), especially given the potentially broad interpretation of this category. Additionally, our institution strongly opposes the proposed establishment of three distinct groups of pathogens: Tier 1 agents; Select Agents; and Registry Agents. Current biosafety considerations have proven adequate for ensuring the safety of researchers and the environment when studying pathogens that might be considered "Registry Agents." Moreover, even when defined as "Registry Agents," security risks posed by this classification are not established. The costs in terms of both financial demands upon, and lost research opportunities by scientists unable to conduct important research due to the regulatory burden of such measures is disproportionate when compared to the theoretical risk that these naturally occurring pathogens might somehow be weaponized.

The promotion of biosecurity and biosafety practices may be more effectively encouraged by accrediting individual biosafety training programs, creating scholarships for individuals to become trained at accredited training programs, or via groups such as the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment. Following the hand-in-hand approach of this bill, involving this task force could allow non-Select Agent entities to improve their practices, while decreasing the regulatory burden on institutions that may otherwise be required to manage three differently regulated categories across multiple biosafety levels and users.

In addition, we encourage consideration of the need for exemptions to the Tier I list, *i.e.* in the case of diagnostic laboratories and public health emergencies. We note that each Tier I agent is a Select Agent, however, the Select Agent exemptions would only exempt those rules under 42 CFR 73, and not those promulgated as a result of this bill.

SEC.318.(f)(7)(B)(III) Penalties

The description of the proposed penalties is similar to those applicable under current Select Agent rules with the exception of: "*payment for the costs of onsite monitoring.*" This section does not adequately define the type of violation that would result in onsite monitoring. We discourage the determination of violations and the creation of penalties that would have a detrimental impact on Personnel Reliability Programs. Personnel reliability is most appropriately managed on a local basis, given that communication and trust among participants and program administrators is paramount. Punitive onsite monitoring via external agencies would degrade personnel morale and trust, thereby limiting open communication necessary for successful Personnel Reliability Programs.

Tier I agents are also required to be Select Agents and currently have penalties associated with them. Considering the anticipated harmonization of this bill with existing Select Agent rules, additional penalties should not be necessary, particularly since the Select Agent rules allow for fines as well as imprisonment for up to five years. Harmonization would sufficiently apply penalties to inadequate security plans and risk assessments.

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SEC. 103(f)(1) Laboratory and Facility Registration and Database
UTMB has worked diligently to develop consistent and open communication with our local community. Maintaining a safe workplace, developing vaccines, improving drug efficacy and serving as resource to the nation during a public health emergency are areas in which we continually strive to excel. We are proud to be the only U.S. public academic institution to routinely post our potential laboratory exposures on our website.

The language in this section regarding *"a data base of laboratories and facilities that have sufficient potential to pose a threat to public health and safety,"* is objectionable to an institution such as ours that has helped forge the path forward in preventing and responding to public health emergencies.

A list of registered Select Agent facilities already exists, and, alongside that list, are detailed reports from inspecting agencies, including DHS and HHS, documenting security measures and biosafety practices as well as deficiencies and recommendations. The proposed database contents are excessively broad, epitomized by SEC.103.(f)(2)(C)(II)(iii) *"such other characteristics as the Secretary determines appropriate."* We urge decision makers to utilize the extensive in-depth inspection reports provided by DHS and HHS to review the information they deem pertinent, rather than develop a new database that, once released to state and local authorities could be used for nefarious purposes.

Subtitle B SEC.321.(c)(3)(A)-(B) Response to a weapon of mass destruction attack
We fully support a bioforensics strategy and appreciate the need for access to comprehensive information regarding possible threat agents for attribution of bio-crimes. We are concerned with the language in this section, particularly the statements, *"...shall provide all relevant biological agents and toxins..."* and *"...shall encourage the contribution of public and private biological agent and toxin collections to the national bioforensics repository collection..."* suggesting collections and repositories of pathogens be provided to the national bioforensics repository collection.

Clearly it is essential for academic and governmental scientists and researchers to retain access to and control of specialized reference collections. Therefore, clarification of this essential point in the bill is greatly needed. Specifics as to which essential information may be required by the national bioforensics laboratory, such as complete pathogen sequence information, would allow the bioforensics repository to meet their responsibilities, while preserving access to critical reference collections by the greater scientific community. This could be accomplished through a special grant or contract mechanism that would allow curators of specialized collections to generate key characteristics of pathogens or toxins held in their collections in partnership with the bioforensics repository leadership. The maintenance of large collections of pathogens presents a challenge that would be best met by experts in the field who possess the needed specialized knowledge, rather than by those in a centralized government facility who could be challenged by the enormity of the task of maintaining such a large number of biological entities.

Should all U.S. private collections be subject to immediate deposition in the national forensics collection, such policy shift could produce international suspicion of motives, particularly if the agents may be utilized in research beyond forensic deposition and characterization, and even more so, if there are any classified aspects to the various uses for the collection. In addition, restrictions on international distribution of current collections could have a negative impact on the flow of research materials into the existing collections, as this section clearly states that access to the repository will be

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limited to the discretion of the Secretary. This would serve only to limit scientific exchange and access to biological materials necessary for research.

Title III—International measures to prevent biological terrorism
We support the various activities proposed to further international engagement promoting threat assessment of pathogens and the facilities where they are held, efforts to strengthen international biosecurity, science and technology exchange, and fostering secure biotechnology advancement. Activities to promote global pathogen surveillance are also commended, as are enhanced training opportunities and assistance to developing countries. We highlight the robust capabilities that exist within the academic sector which could propel the implementation of these activities, provided such participation is not restricted to governmental agencies. Specifically, the National Institutes of Health (NIH) has invested heavily in the creation of Regional Centers of Excellence, national and regional biocontainment laboratories and a large international grants and contracts awards program to serve as resources for furthering our understanding of human health.

SEC.302.(b)(1)(B)Reducing And Securing Dangerous Pathogen Collections
The spirit of this section is apt, but we also suggest including the phrase, "*as appropriate,*" to SEC.302.(b)(1)(B) as it is important to remember that the technologies in use for disease diagnosis in this country may not be sustainable in some parts of the world where technologies, such as isolation by plating or inoculation of lab animals yielding viable agents, may be the most appropriate. SEC.302.(b)(1)(C) merits careful consideration by decision makers because collections of organisms considered to be dangerous by the U.S. may be endemic and everyday facts of life and medicine in other parts of the world. These political and practical ramifications are not fully acknowledged by the purview of this section.

Again, thank you for the opportunity to add our comments on S. 1649 to the official hearing record.

At UTMB and the GNL, we value our work and its importance to local, national and global health, and we keenly understand the need to balance security with the conduct of public health activities, clinical diagnostic testing and research on pathogens. We share your goal of responsible, transparent regulation, oversight, practices and guidelines that improve biosecurity and biosafety and we hope that our comments will be useful to the Committee as you continue to refine this legislation.

Sincerely,

Stanley M. Lemon, M.D.
Director, GNL

Thomas G. Ksiazek, DVM, Ph.D.
Director, NBTC

James W. LeDuc, Ph.D.
Deputy Director, GNL

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Post-Hearing Questions for the Record
Submitted to Gregory D. Kutz
From Senator Michael F. Bennet

"World at Risk:
Weapons of Mass Destruction Prevention and Preparedness Act of 2009"
September 22, 2009

1. **Can you elaborate on why these laboratories were not meeting some of the basic security measures that GAO identified? I know your report mentioned that part of the difference in security stems from who owns and operates the facility. Are there any additional barriers that you identified? If so, what are your recommendations for addressing security shortfalls? Do any security measures go beyond the 15 basic measures that the GAO identified, that we should incorporate throughout all biological laboratories, not just BSL-4 laboratories?**

Answer

We found that there were several factors that contributed to a difference in the level of perimeter security at the biosafety level 4 (BSL-4) labs we reviewed as part of the two reports on which our testimony was based (GAO-08-1092 and GAO-09-851). Primary among these factors, as noted in our testimony, is that the Select Agent Regulations do not mandate specific perimeter security controls that must be in place at all BSL-4 labs. The regulations require each lab to implement a security plan that is sufficient to safeguard select agents against unauthorized access, theft, loss, or release. The regulations also require that all BSL-4 labs registered with the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins must base their security plans on site-specific risk assessments. However, the regulations do not specify who must perform the site-specific risk assessment at each lab, meaning that officials of the labs themselves could perform the assessments. In addition, the thoroughness of a lab's site-specific risk assessment could be a contributing factor to the overall strength of the lab's perimeter security system.

As you mentioned, the issue of what parties own and operate each lab is a contributing factor to overall perimeter security. As we discussed in our testimony, among the five BSL-4 labs that we reviewed, the three labs with strong perimeter security controls in place had to follow additional federal security requirements beyond the Select Agent Regulations. For example, one lab that we reviewed is a military facility subject to far stricter Department of Defense physical security requirements.

We are not making any additional recommendations as part of this letter. However, we encourage the CDC to work to implement our recommendation from our original report (GAO-08-1092). In that report, we recommended that CDC take action to implement specific perimeter security controls for all BSL-4 labs to provide assurance that each lab has a strong perimeter security system in place, and encouraged CDC to work with the U.S. Department of Agriculture to coordinate its efforts. In our reports and testimony, we focused primarily on 15 physical security controls that contribute to a strong perimeter physical security system based on our expertise and research of commonly accepted physical security principles. We believe that the 15 controls we identified represent a baseline for lab perimeter physical security. Although the presence of the 15 controls we assessed does not automatically ensure a secure

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perimeter, having most of these controls in place and operating effectively reduces the likelihood of intrusion. We did not assess biosafety laboratories other than those designated as level 4 and cannot make recommendations about the lower-level facilities at this time. Individual labs may have security measures that go beyond the 15 perimeter security controls that we tested and might improve their perimeter physical security. However, we did not assess perimeter security controls beyond the 15 controls discussed in our reports and testimony.

2. **You note in your report that the security assessment does not address internal security, cybersecurity or threats posed by those inside the laboratories. Are there any efforts underway at the GAO to review these other kinds of security challenges? If not, I think the Committee should work to promote a broader review of security so that the nation does not get caught flat-footed in any emerging threat area. On the issue of cybersecurity, how would threats to smart programs impact the perimeter of these laboratories? If an integrated system is in place, should we be worried that cyber attacks could jeopardize our ability to conduct coordination and response?**

Answer

Our testimony did not address internal security, cybersecurity or threats posed by those inside the laboratories. These objectives were beyond the scope of our investigation.

We have one effort underway related to the security matters you raise. GAO's Applied Research and Methods team is reviewing three executive branch reports (one issued, two pending) that cover these issues. This effort follows the team's recent evaluation of national strategy for oversight of high-containment labs across the United States (GAO-09-574 and GAO-09-1045T). This evaluation included a review of several cases illustrating different types of threats to high-containment labs. Four highly publicized incidents in high-containment laboratories, as well as evidence in scientific literature, demonstrate that (1) while laboratory accidents are rare, they do occur, primarily due to human error or systems (management and technical operations) failure, including the failure of safety equipment and procedures, (2) insiders can pose a risk, and (3) it is difficult to control inventories of biological agents with currently available technologies. Taken as a whole, we found that these incidents demonstrate failures of systems and procedures meant to maintain biosafety and biosecurity in high-containment laboratories. For example, they revealed the failure to comply with regulatory requirements, safety measures that were not commensurate with the level of risk to public health posed by laboratory workers and pathogens in the laboratories, and the failure to fund ongoing facility maintenance and monitor the operational effectiveness of laboratory physical infrastructure.

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