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STRENGTHENING SECURITY AND OVERSIGHT AT BIOLOGICAL RESEARCH LABORATORIES

HEARING

BEFORE THE

SUBCOMMITTEE ON TERRORISM AND HOMELAND SECURITY

OF THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

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STRENGTHENING SECURITY AND OVERSIGHT AT BIOLOGICAL RESEARCH LABORATORIES

TUESDAY, SEPTEMBER 22, 2009

U.S. SENATE,
SUBCOMMITTEE ON TERRORISM AND HOMELAND SECURITY,
COMMITTEE ON THE JUDICIARY,
Washington, DC

The Subcommittee met, pursuant to notice, at 2:42 p.m., Room 226, Dirksen Senate Office Building, Hon. Benjamin Cardin, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S. SENATOR FROM THE STATE OF MARYLAND, CHAIRMAN, SUBCOMMITTEE ON TERRORISM AND HOMELAND SECURITY

Senator CARDIN. Well, the Subcommittee will come to order. Let me apologize for being a few minutes late. The Senate was taking its traditional every, I think, 2-year photograph, so that's one of the busy moments on the floor of the U.S. Senate. So, I apologize for the late start.

I also want to express Senator Kyl's regrets. He's going to try to come by. He is involved in the Senate Finance Committee right now on health care reform, and obviously is very busy on that issue. So he's going to try to come by, but he wanted me to express his strong support for this hearing, the oversight role that the Judiciary Committee needs to play on the labs that we have, the biological research laboratories in this country, and he is very much interested in the recommendations that are coming out from the various workgroups and commissions that are looking into this matter.

After the 9/11 terrorist attacks, Americans suffered another type of terrorist attack in October of 2001: the biological attacks. Letters were mailed to Members of Congress using the U.S. Postal Service, ultimately resulting in the death and sickening of dozens of individuals. The Federal Government responded by increasing funds for bio-defense. Congress also implemented the 9/11 Commission recommendations, which called for the creation of the Department of Homeland Security and urged the government to take stronger measures to deny weapons of mass destruction to terrorists.

High-containment laboratories played a critical role in the bio-defense effort and evolved collaborative efforts between the public and private sectors, military and civilian communities, as well as our international partners. At the same time, increasing the number of personnel in laboratories with access to these deadly agents

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may increase the chances of accidental or deliberate misuse of hazardous materials, posing a significant public health threat.

Today's hearing will examine the current security measures at our laboratories, including both physical security and personnel reliability, and look at the best practices in both the government and private sector, including our Nation's preeminent research laboratories.

We will also examine the various government agencies that have oversight responsibilities for these programs, as well as recommendations from organizations as to how to strengthen and improve our security at these laboratories, while not unduly chilling innovation, research, and collaborative efforts with our international allies.

The FBI recently concluded that the October 2001 anthrax attacks were carried out by a government scientist working in a biological research lab at Ft. Detrick, in my own State of Maryland. I have visited this military base on numerous occasions. Just last month, the Army broke ground on a new $680 million headquarters building for the U.S. Army Medical Research Institute for Infectious Diseases at Ft. Detrick, Maryland, which will house the most cutting-edge research on dangerous biological organisms in the highest possible bio-safety space known as a Bio-Safety Level IV, BSL–IV. This precaution is being used in order to protect the workers at Ft. Detrick and the surrounding communities in Frederick, Maryland.

The laboratories will conduct research on the most deadly pathogens known to mankind, including anthrax, the plague, and the Ebola virus. I know that our Ft. Detrick employees have also been working to help the government to combat swine flu and the West Nile virus, among others.

Panel one this afternoon will examine the executive branch's current efforts to strengthen and improve bio-security and bio-safety at laboratories, including personnel reliability, physical and perimeter security, and inventory control. I look forward to hearing from the witnesses from the Departments of Justice, Defense, and Homeland Security.

In panel two, we will receive testimony from outside experts, including the recent report on the Commission on the Prevention of Weapons of Mass Destruction, chaired by the distinguished former Senator from Florida, Senator Graham, who has also served as Chairman of the Senate Intelligence Committee. We will also receive testimony from the Government Accountability Office and the Center for Health and Homeland Security at the University of Maryland at Baltimore.

With that, we will go directly to our first panel, who will consist of Daniel Roberts, who is the Assistant Director of the FBI's largest division, the Criminal Justice Information Services Division, established in 1992 to serve as the focal point and central repository for Criminal Justice Information Services in the FBI.

Jean Reed is the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization in the Office of the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Programs.

Brandt Pasco was appointed to be the Deputy Secretary to be the DHS Compliance Assurance Program Manager. He is an attorney in the Department of Homeland Security, Office of General Counsel, who supports the Science and Technology Directorate, managing an office with 14 staff.

With that, if I could ask the three of you to please stand in order to take the traditional oath of our Committee, and then we'll get started with your testimony.

[Whereupon, the witnesses were duly sworn.]

Senator CARDIN. Thank you all very much. Please have a seat. Mr. Roberts, we are glad to hear from you.

STATEMENT OF DANIEL D. ROBERTS, CRIMINAL JUSTICE INFORMATION SERVICES, FEDERAL BUREAU OF INVESTIGATION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. ROBERTS. Good afternoon, Chairman Cardin, Ranking Member Kyl, and the distinguished members of the Subcommittee on Terrorism and Homeland Security. I am Daniel D. Roberts, Assistant Director of the FBI's Criminal Justice Information Services Division, or CJIS, located in Clarksburg, West Virginia. I have served in the FBI for over 22 years, but have only held my current position since June of 2009. I thank you for the opportunity to appear before this Subcommittee.

The CJIS Division maintains oversight of two major background assessment programs: the more commonly known, National Instant Criminal Background Check System, assesses a person's eligibility to possess a firearm or explosive; the lesser known program, the Bio-Terrorism Risk Assessment Group, or BRAG, is similar in mission. BRAG's role is to enhance national security and public safety by providing the timely and accurate determination of an individual's eligibility to use, possess, or transfer select agents and toxins.

Candidates are evaluated for access to select agents and toxins against criteria delineated within the Public Health, Security, and Bio-Terrorism Preparedness and Response Act of 2002, and against prohibitive categories defining a restricted person within the USA Patriot Act. Pursuant to the Bio-Terrorism Act, the Attorney General of the United States is charged with using criminal, immigration, national security, and other electronic data bases to determine whether an entity or an individual is a restricted person.

The Attorney General delegated this authority to the Director of the Federal Bureau of Investigation in January of 2003. The BRAG began conducting Security Risk Assessments, or SRAs, in collaboration with officials from the Department of Health and Human Services and the Department of Agriculture in April of 2003.

SRAs are conducted on entities, except Federal, State, and local government agencies, including public accredited academic institutions, any individual who owns or controls the entity, responsible officials, and alternate responsible officials managing entity operations every 3 years.

SRAs are conducted not less frequently than once every 5 years on individuals requiring access to select agents and toxins. A typical SRA takes about 1 month to complete. The SRA is different than a full background investigation, such as those conducted for

security clearances, and complies with the requirements of the Bio-Terrorism Act.

The SRA commences when BRAG receives a candidate's Form FD–961 and two legible fingerprint cards. The fingerprint cards are processed by the FBI's integrated automated fingerprint identification system and flagged to identify the record as belonging to an individual who underwent an SRA. The FD–961 data, supplied by the candidate in response to questions directly concerning each prohibitor, is then entered into BRAG's stand-alone bio-terrorism data base maintained by CJIS.

The candidate's case is subsequently assigned to a BRAG personnel security specialist for research. Upon completion of all data base searches, the candidate's status is determined and the results are submitted to the sponsoring agency. The sponsor provides, in writing, the decision indicating denial or approval of access to the candidate.

If the access is denied, the candidate is advised of the specific prohibiting factor applied to them. Candidates may appeal the decision via their sponsor within 30 days of notification of denial. The sponsor will forward a statement of factual basis for the appeal and supporting documentation provided by the candidate to the FBI for reconsideration.

The FBI will review the candidate's documentation and research the appropriate data bases. The FBI will either overturn the results of the original SRA or sustain the original determination of status. The sponsor is again advised of the results and, in turn, notifies the candidate in writing of the decision.

Since the inception of the program, the BRAG has completed 32,742 SRAs; 208 individuals have been restricted. The CJIS Division, in close coordination with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service, is continually scrutinizing and evaluating the SRA process. Efforts are ongoing to automate the workflow and improve information sharing capabilities.

Mr. Chairman, I would like to conclude by thanking you, Ranking Member Kyl, and this Subcommittee for your service and support. I look forward to working with you in the years to come as we continue to counter bio-security threats of the future. I would also like to personally thank the Department of Health and Human Services, Centers for Disease Control and Prevention, and the Department of Agriculture's Animal and Plant Health Inspection Service for years of unwavering support.

Thank you for the opportunity to appear before your Subcommittee, and I look forward to answering any questions you may have.

[The prepared statement of Mr. Roberts appears as a submission for the record.]

Senator CARDIN. Thank you very much for your testimony.

Mr. Reed.

STATEMENT OF JEAN REED, DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE, CHEMICAL AND BIOLOGICAL DEFENSE/CHEMICAL DEMILITARIZATION, U.S. DEPARTMENT OF DEFENSE, ARLINGTON, VA

Mr. REED. Chairman Cardin, I would request that my printed statement be entered in the record.

Senator CARDIN. Without objection, the full statements of all of the witnesses will be included in the record today.

[The prepared statement of Mr. Reed appears as a submission for the record.]

Mr. REED. Mr. Chairman, it's a pleasure to testify before the Committee today. I'm accompanied by Major General James Gilman, Commanding General, U.S. Army Medical Research and Materiel Command in Ft. Detrick; and Colonel John Skvorak, Commander of the U.S. Army Medical Research Institute for Infectious Diseases, whom I believe you know; and also by Captain Kenneth Cole, who's the Medical Director for the Chemical/Biological Defense program, and they're here to bail me out if I get in trouble, so I would beg leave to perhaps have them provide some of the detailed answers to the questions.

Senator CARDIN. You've got a good support team.

Mr. REED. Great. They are good people.

It's a pleasure, again, to be able to have the opportunity to discuss with you the safety and security of our Nation's biological research laboratories. They are a keystone to our Nation's life science research and are essential to developing public health infrastructure and medical countermeasures crucial to protecting U.S. citizens from biological threats, whether as a result of natural or intentional actions.

Today I will briefly discuss Department of Defense regulations, practices, and procedures put in place since the 2001 anthrax incidents that can be applied to improve laboratory bio-security. It is imperative that the implementation of best practices on a national scale optimize the security of biological agents, while providing minimal impact on that life science research necessary to develop public health and medical countermeasures against these agents. I will provide an overview of how DOD regulations came into existence, how they have been implemented, their proposed integration into current national efforts, and a possible way forward to develop best practices and procedures for Bio-Safety Level, BSL–IV, laboratory safety and security.

Our BSL–III and BSL–IV laboratories operate as a critical element of our bio-defense efforts to understand pathogens of concern and to develop medical countermeasures to defeat these pathogens, whether they are biological warfare agents, or are infectious diseases to which our armed forces may be exposed.

Following the 2001 anthrax incidents, Congress passed a series of legislative initiatives to control human, plant, and animal pathogens of concern. This legislation led to the expansion of Select Agent Regulations, which require each Federal agency to conduct safety and risk assessments, but did not preclude agencies from implementing efforts above and beyond those required by the regulations for safeguarding biological select agents and toxins.

The term "select agent" refers to a specific group of chemical or biological agents that historically have been evaluated and developed for use in weapons. Although the United States does not have a biological weapons program, the use of this term and its historical connotation as being associated with weapons programs heavily influenced the direction the Department would take to safeguard biological agents in its laboratories.

Accordingly, the Department drew, from its current chemical and nuclear programs, safeguarding measures in developing the regulations for so-called biological select agents and toxins, which the Department uses only for basic and applied research in the development of vaccines, therapeutics, and protective countermeasures.

The current DOD risk management framework for safeguarding select agents and toxins consists of a fourfold approach: bio-safety, bio-security, personal reliability, and agent accountability.

Bio-safety consists of the application of knowledge, techniques, and equipment to prevent personal, laboratory, and environmental exposure to potentially infectious agents or bio-hazards. Bio-security refers to the protection, control, and accountability of high consequence biological agents and toxins, critical relevant biological materials and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release. The biological personal reliability program consists of security background investigations, as well as medical, mental health, and drug screening.

Agent accountability consists of the registration of agents, personnel, entities, and locations, agent inventory control, and limiting access to registered personnel.

All of the above measures implemented by the Department of Defense exceed the prescribed requirements of the Select Agent Rules. This does not mean that the additional measures constitute a series of best practices and procedures, but only represents the extrapolation of the DOD current weapon materiel safeguarding policies as applied against biological agents. In fact, they highlight the challenges that arise from the direct application of DOD current policies for safeguarding weapons materiel to the unique situation of defense research on biological organisms.

Biological agents differ from nuclear and chemical threats by their nature and by virtue of their context. Nuclear and chemical agents are entirely man-made; biological agents are found throughout nature and exist in the context of infectious disease and public health threats, notwithstanding that they can be potentially used for hostile purposes.

This is not to say that there are elements of these regulations that could not be incorporated into best practices. However, a series of studies, both within the DOD and externally, suggest that some elements of this program may be too extreme and could not be implemented by other agencies or the civilian sector without severe impact.

For example, the use of Single-Scope Background Investigations precludes foreign nationals or personnel having limiting factors, such as financial difficulties or prior non-criminal legal actions, from working with select agents. Such background investigations are time-intensive and expensive.

Additionally, they would preclude a large segment of exceptionally qualified and talented researchers, particularly foreign national researchers who currently make daily contributions to the advancement of medical or other life science research, from participating in this activity that is so important to the Nation.

Several recent studies highlight the lack of data to demonstrate that such detailed background investigations provide substantial value over the current Department of Justice Security Risk Assessment. There have been a number of internal DOD studies and external studies over the past 2 years that have explored the efficacy and efficiency of current and proposed regulations and policies to strengthen laboratory bio-security.

Reports from the National Science Advisory Board for Bio-Security and the Defense Science Board were submitted to the executive branch with a series of recommendations and policy options that can be applied to establishing best practices and procedures for the Nation. Reports of Executive Order 13486 Working Group on Strengthening the Laboratory Bio-Security of the United States and the National Academy of Sciences are in their final stage of staffing and will be submitted to the executive branch in the very near future. Additionally, the Trans-Federal Task Force on Optimizing Bio-Safety and Bio-Containment Oversight is soon submitting its report to the executive branch.

A potential way forward would be to allow the National Security Council to use its interagency policy committee process in conjunction with input from industry and academia, to review the recommendations and policy options from the collective reports, and develop an approach for the Nation that optimizes the balance between science and security. Once such an approach is identified, legislative action could be well-targeted to ensure the full range of helpful measures needed to enable its implementation.

In summary, the current DOD safety and security measures for safeguarding biologicals, select agents, and toxins are derived from its protocols that were originally developed to safeguard nuclear and chemical weapons materiels, and not the biological organisms that are critical to developing defenses against our adversaries' biological weapons and naturally-occurring infectious diseases.

Although these practices derive from a robust history of security, they might not constitute the basis for best practices and procedures for the Nation, as they could discourage participation by critical organizations and could be limiting to medical and other life sciences research programs.

A more prudent approach would be to exploit the information gathered by the various studies conducted over the past 2 years, develop a series of appropriately tailored policies and practices that balance between safety and security and the pursuit of a robust biological research and development program necessary to ensure the ability to respond to naturally-occurring pathogens, defense of the U.S. homeland, and protection of our service members.

Senator, thank you for this opportunity to address you on this matter of national importance, as well as your continued support to the Department of Defense. I would be happy to answer any questions the Subcommittee may have.

Senator CARDIN. Thank you very much, Mr. Reed.

Mr. Pasco.

STATEMENT OF BRANDT PASCO, COMPLIANCE ASSURANCE PROGRAM MANAGER, U.S. DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Mr. PASCO. Chairman Cardin, Ranking Member Kyl, and distinguished Senators, thank you for the opportunity to talk about the good work being done today at DHS related to bio-security. It's a pleasure to be back in the U.S. Senate, where I started my professional life. I have submitted testimony for the record, so I will be brief to ensure there's time for questions.

By way of introduction, allow me to explain, briefly, my role at DHS. I was appointed by the Deputy Secretary to be the Department's Compliance Assurance Program Manager. I'm an attorney in the Office of the General Counsel, who supports the Science and Technology Directorate. I manage an office with 14 staff and an fiscal year '09 budget of approximately $2.8 million, and I oversee compliance efforts at the Science and Technology Directorate, including for biological safety and security.

DHS's compliance program provides an objective and independent review of all ongoing DHS life science programs. It is a complete programmatic life cycle review. Treaty compliance is ensured both at the program's inception and when significant changes are proposed. Regulatory compliance is checked throughout the life of project execution, and information generated by the program is continually reviewed for national security concerns.

The cornerstone of the process is the Department's Compliance Review Group, which oversees arms control treaty compliance. The Compliance Review Group is comprised of DHS senior leadership and chaired by the Deputy Secretary. All biological research conducted by the Department must be determined by the Compliance Review Group to be compliant with U.S. law and our international obligations.

In generating compliance assessments for the Compliance Review Group, projects fall within one of three categories. Category 1 projects, as presented, do not raise compliance concerns. Three hundred and sixty-eight Category 1 projects have been approved by the Compliance Review Group to date.

Category 2 projects, as presented, might reasonably raise the perception of a compliance issue but do not involve the National Science Advisory Board for Bio-Security Research concern. Eighteen Category 2 projects have been approved by the Compliance Review Group to date.

Category 3 projects, as presented, might reasonably raise a perception of compliance and likely do involve research of concern. Twenty-two Category 3 projects have been approved by the Compliance Review Group to date.

DHS has established a regulatory compliance program for biosafety, select agent and toxin security, and the care and use of animals in research. DHS's select agent and toxin research is subject to the regulatory control of the Centers for Disease Control and Prevention and Animal and Plant Health Inspection Service. At DHS, we conduct significant additional oversight because of unique

sensitivities related to bio-defense research, as distinct from conventional public health research.

The regulatory compliance program is significantly driven by our treaty compliance efforts. Laboratories conducting Category 2 or 3 projects are subject to onsite inspections. Other laboratories are visited because we have some indication that there may be problems with non-compliance.

To assist the Under Secretary in exercising original classification authority, the Science and Technology Directorate established the Classification Review Panel, which I co-chair with the Director of Security. DHS has a significant priority in maintaining openness in life science research, but the nature of bio-defense threat characterization studies requires that some elements remain classified to protect the public from harm. The Classification Review Panel co-chairs are responsible for ensuring that all Science and Technology Directorate programs have, and are appropriately applying, classification guidance.

In conclusion, DHS has an exceptionally effective record at strengthening biological safety and security in DHS-funded laboratories. I thank you for your attention and I would be pleased to take any questions you may have.

[The prepared statement of Mr. Pasco appears as a submission for the record.]

Senator CARDIN. Well, once again, let me thank all three of you for being here and the work that each of your agencies do. I have been to Detrick, as I said in my opening comments. I've seen the work that's being done there, the dedicated men and women who are serving our country in a very dangerous situation, and we very much appreciate their professionalism and their dedication to trying to deal with these extremely difficult subjects.

I know that we have a working group that is prepared to make recommendations, or at least make a report to the administration, and we're looking forward to receiving that report. Quite frankly, we thought it would be available by now, but we do have at least some of the information that's coming out of their work, which I think is useful for us today.

Let me just raise the first fundamental issue. There are about 15 Federal agencies that deal with labs and no one agency has primary or full responsibility here. So I listened to your testimony. I see Department of Justice indicating that they've done Security Risk Assessments on about 32,000 individuals.

I listened to what Department of Homeland Security said, that they're dealing with 42 labs and have done 23 onsite inspections. My staff tells me that when we take a look at the information on select agents regulations, that there are 390 entities that have gotten registered, with 15,000 employees. So these numbers seem to be not totally consistent.

I guess my concern is, I don't know who to ask the question for in the Federal Government as to, where are the labs? Are we satisfied they're properly secure, that are dealing with agents that we have concerns about? Does anyone have a handle on the inventories we have on these agents, select agents that we're concerned about? Is anyone primarily responsible to make sure that we have

adequate securities in place dealing with these labs? Shouldn't we have more direct responsibility?

I know that, again, I expect that the working group is going to deal with this. We have some recommendations from other groups that have looked at it. Mr. Pasco, most will turn to Department of Homeland Security and say that's the logical place to have the responsibility. I had a chance to talk to Director Mueller at the FBI. He said his role is pretty limited. He does the reviews, gets the information out, but he's certainly not responsible for the labs.

Mr. PASCO. Thank you, Senator. It's an important question and I understand why you would be concerned. The Department of Homeland Security is, at this point, a funding agency. That is to say, we conducted research. My job as the Compliance Assurance Program Manager is to ensure that that research is compliant with existing regulatory standards. So we have 42 laboratories that are currently or have recently been involved in DHS-funded research.

As I indicated, we prioritized those for inspections based on the nature of the work that's being done there, and then also if we have reason to think that there may be compliance issues. But our inspections are essentially under authorities granted by the FAR, that we would have to inspect work that's being performed under contract. So we don't have distinct regulatory authority for this type of thing.

Senator CARDIN. I understand that the authority is not there. The question is, should you have the authority? Should you be able to track what is happening in our Nation on those who handle select agents so that we have some understanding of the training, some understanding of the best practices.

Let me just give you one example. You might visit a lab and see a procedure that's used for a select agent that is worthy of being utilized in more labs around this Nation for the purposes of protecting the workforce and protecting the public. Is there a mechanism where that information gets out, where we can share that type of security information? A university may not be dealing with you. They may not be one of the 42 that you're talking about, and that's certainly one that you haven't inspected, but they may be dealing with the same pathogens. How do we coordinate and make sure that we are dealing with these pathogens in the safest possible way? Mr. Reed?

Mr. REED. Sir, the Centers for Disease Control, Department of Health and Human Services, and the Animal and Plant Health Inspection Service, Department of Agriculture have the responsibility for inspecting all facilities for compliance with the select agent programs and maintain——

Senator CARDIN. How did I know that you would mention one of the agencies we didn't have at the table today as the responsible——

[Laughter.]

Mr. REED. Well, you know, it gives the staff something to work on.

Senator CARDIN. We could have had 15 of you up there. My point is, there's 15 agencies that do have some responsibility.

Mr. REED. Right. And I want to come to that point in just a moment. Those two activities maintain a listing of each Biological Se-

lect Agent being operated on at each laboratory, the personnel who are cleared for handling of BSAT and inventories, and approve transfers of BSAT between laboratories. What we have been doing as a body within the interagency for about a year now is to review these issues. (And you just alluded to the report that has been provided in draft to the administration in response to the President's Executive Order is going through its final coordination with the interagency.) There needs to be, clearly, someone in overall charge of directing that oversight.

All of the reports that are coming forward note the need for activity that can bring that all together. But what we're looking for, quite frankly, is the development of, if you will, a set of minimal requirements in terms of personnel reliability, accounting, security, training, best laboratory practices that take into account the views of all the stakeholders, and then bringing that together and saying, okay, here's what we have done that does represent that balance between the critical elements of security for the select agents, which quite frankly are of varying degrees of virulence. So, you might come out with the idea of a stratified system that one might use.

Senator CARDIN. The Commission to prevent the proliferation of weapons of mass destruction has suggested a tier approach.

Mr. REED. Yes.

Senator CARDIN. I think there are 80 agents today that are of concern that are under the regulation. They are suggesting tier one would be about eight.

Mr. REED. Yes, sir.

Senator CARDIN. Does that make sense? Does that make it easier for you to be able to really track those agents that are of the most concern, those pathogens that require much closer scrutiny on inventory and access?

Mr. REED. With my colleagues who have been participating in those studies, there would be agreement—yes, there would be. It then becomes a question of, what goes in what bin: the guidelines for what in terms of the BSL Levels I through IV agent categories.

Senator CARDIN. Mr. Roberts, you talked about the background checks that you do in regards to the regulations. If I understand that correctly—and you were very clear, it's not at all the same as what we do for people who need clearance. That's a different type of a background check—it seemed like what you were describing is mostly getting information from the applicant and checking your data bank.

But do you actually go out in the field? Do you do interviews? Is there anything more done as far as checking the person's psychological capacities, weaknesses, or checking their sources to make sure that it's accurate, the information they've given you, which is what we do on clearance where there is more direct contact?

Mr. ROBERTS. You're right, Mr. Chairman. There is quite a bit of difference between what we do for an SRA and what we would do for a Top Secret security clearance, for example. No. To answer your question, we don't do any interviews, neighborhood interviews or interviews of friends or associates of the individuals. We do more than just data base checks of FBI data bases. We, for example, will check the terror screening center data bases, which has access to

the entire intelligence community. Much of it also filters through ICE and their law enforcement center in Vermont as well, so it's not just the FBI data base.

However, I will tell you that the FBI has a very robust fingerprint data base, maybe the most robust in the world when it comes to criminals being stored—fingerprints being stored. We have 60 million-plus fingerprints of subjects on record with us at CJIS in West Virginia. So it is a wealth of information that we do tap into when we receive the individual's SRA package. That's the first place we will start, but it isn't the last. But you are correct, sir, that it is just a data base check. We do not do further checks in terms of information of the individual more than data bases.

Senator CARDIN. And after the person has been cleared by the review that you do, what would trigger you looking at that person again, if anything?

Mr. ROBERTS. There is something. Actually, what we do is we put a stop on the individual's fingerprint records. So if, for example, any of the 18,000-plus law enforcement agencies that are in the United States were to arrest an individual who had been through an SRA, we would be notified of that. We place what would be a stop in our systems so that we are notified anytime they are arrested, and then we would then notify the sponsoring agency of that arrest.

Senator CARDIN. So you're actually putting their fingerprints into the data bank then, I take it?

Mr. ROBERTS. We're actually putting stops into the data bank, yes. We're not putting their fingerprints into the whole criminal data base, no. We're just putting stops against them, their names.

Senator CARDIN. So it's a name? I'm a little confused as to how that would come——

Mr. ROBERTS. Yes. I'm sorry.

Senator CARDIN. How would they know that's the person?

Mr. ROBERTS. Yes. It would be a biographic. It would be a biographic, not a biometric. It would be a name search.

Senator CARDIN. And then you would confirm that's the right person before, I take it, you would take action?

Mr. ROBERTS. Absolutely.

Senator CARDIN. But as a matter of routine, if the person was hospitalized for a mental condition, that would not come to your attention, would it?

Mr. ROBERTS. That is correct, sir. That is a gap in the system. If you ask my personal opinion, we have no national data base of mental health records that we can lean on. As you know, we also manage the firearms check program for the FBI as well, and that is also a prohibiting factor for purchasing firearms.

We have some records that have been submitted to us in the firearms programs from hospitals, such as the VA hospitals, for example, but we are not allowed to share, by law, that firearms individual with the BRAG group that does the SRAs.

So you're correct in that there's a gap there, that we rely a great deal on the person's self-admission to a mental problem. There are some criminal histories which do identify the fact that the individual arrested may have a mental deficiency if you query that person and they have a criminal record, but beyond that, there isn't

much information there available, other than what the person self-reports.

Senator CARDIN. So let me come back to Mr. Reed for a moment. If we were to use a tiered approach as far as regulatory responsibilities, is it conceivable that the background check could be—you could differentiate between those that are handling the pathogens that are in tier one to require a more sophisticated background check for those that have access to those types of agents?

Mr. REED. I think, Senator, that would quite possibly be something one might choose to employ. You would also have different levels of security in terms of how the agents are handled and stored. In all cases, there would have to be the matter of training of the individual investigator in terms of the safety and security that had to be employed within the laboratory, and there could be very well gradations of that.

One example that has been used in transferring from the so-called "two-man" rule of nuclear practice—nuclear weapons practice or of chemical weapons practice, where you had to have two fully qualified individuals, one to check the other and to report on the other.

There are cases, particularly in terms of working with the Level I biological agents, if you will, in particular, where (in order to reduce the potential for exposure and reduce the potential for a mistake, one worker getting in the way of the other while working in a quite tight situation) you would have a single individual, but under observation remotely. So there are a whole series of gradations that could be applied, but the issue of training, of oversight by the supervisors and peer review, and then self-reporting if an individual felt that they were getting stressed out and incapable of operating properly.

Senator CARDIN. I think that's very—that's the types of observations I think we need to take a look at. The burden to have you do security clearances on every person that would be—you couldn't handle that, I understand that. But I think we have to have a more sophisticated way in which we look at those that are handling the most dangerous of the pathogens.

I think there are some common-sense ways that we can differentiate here and could have that done. I know at Ft. Detrick there was an issue concerning the inventory of the pathogens. I don't know who I want to ask this question to. It's not really specific to Ft. Detrick. It's more general as to inventory.

Are you confident that we know where these pathogens are in this country and that we have inventory controls, and that if something is missing there are adequate procedures in place to find out where those pathogens are at all times? It's really, I think, a Homeland Security issue more so than a specific agency, but I'd be more than happy to let Defense also have a crack at it.

Mr. PASCO. Thank you, Senator. For DHS-funded programs, we spend quite a lot of attention on inventory issues. It's one of the reasons——

Senator CARDIN. That's not the real question. The real question is, Homeland Security is responsible for homeland security. We don't really care whether you're giving money to a different group or not. If they have control over a pathogen that can be used for

biological mischief to America, we want to make sure that you know where that pathogen is at all times, at least our government knows where those pathogens are at all times.

Mr. PASCO. Thank you, sir. You're right, that is the question that is underlying it. The Department of Homeland Security only has visibility into the programs that we fund as far as pathogen inventories. Of course, all of the select agent inventories are subject to Centers for Disease Control and APHIS regulatory process, but the Department of Homeland Security only reviews inventory processes of our own laboratories and programs that we are funding.

Senator CARDIN. Well, that's clearly inadequate. I assume, DOD, you take responsibility for your own labs? Is that what you're——

Mr. REED. Yes, sir. But also in the context, we are subject to the CDC and APHIS oversight. But it really becomes a question of discipline and a culture of safety and security at the individual installations. Of course, they're subject to inspection on an annual basis by the other two activities, and DOD labs in particular, and John Skvorak can probably testify to it, and the subject to inspections within the Department as well.

The key issue from my perspective—and I hearken back to my experience as an artillery battalion commander—is standards—a common set of standards that one can work towards—and a common set of inspections and inspection criteria. In order to facilitate the research, a common view is that there be a minimum standard possible in order to give you the flexibility you need, but it needs to be a standard that we apply and that we arrive at, I think, administratively and through rulemaking, as opposed to through legislation.

Senator CARDIN. Yes. Certainly?

Mr. REED. John, do you want to comment on that at all?

Colonel SKVORAK. I think, Senator Cardin——

Senator CARDIN. Could you just state your name for the record?

Colonel SKVORAK. I'm John Skvorak, Colonel John Skvorak.

Senator CARDIN. Yes.

Colonel SKVORAK. Mr. Reed, in his opening statement, explained a little bit of the challenge that biological agents represent as far as inventory relative to chemical and nuclear, being naturally occurring and replicating. You know, the inspections are a very important part of our ability to maintain an accurate inventory. We have the CDC inspections and the Army IG inspections. We do 100 percent inventories annually. We do disinterested party audits of our inventories within the Institute.

We have different categories of agents as far as long-term and working stocks that present unique problems, and we have to find unique solutions to inventory those. We have developed an in-house data base for us to help maintain and to track inventory.

Obviously the folks at USAMRID understand how important inventory is, with the inventory stand-down that we did back in February through about 4 months for us to complete that process. It is a difficult challenge, but it is, as also was said, a cultural change that has to be instituted within the laboratory. It's a leadership issue and it's something we can just continue to enforce, continue to monitor, and continue to use the peer review and outside reviews to make sure that we can maintain accurate inventories.

Senator CARDIN. Well, thank you for that. We will wait for the recommendations of the in-house working group, but there really needs to be better lines of responsibility here. I think we all would appreciate having those lines understood. I think we also need to differentiate between the different types of pathogens as far as the degree of interest.

Mr. Pasco, I come back to your point. You're giving money to a particular entity, let's say, a research lab on a particular campus. I've been told that there's a lot of collaboration among different institutions on a lot of the pathogens, and therefore I assume it's possible, though the funds go to one lab, there may be more than one lab involved in the work that's being done.

In fact, it may be done outside the United States. I know there's a lot of—so I'm not sure I understand your responsibility, even under the limited requirements, limited authority that you have. Are you just reviewing the work at the lab that is the recipient of your grants? You certainly are not—are you looking at who they're working with? Do you have any responsibility outside of the United States, if they're collaborating with an entity outside of our country?

Mr. PASCO. Thank you, sir. Yes. In fact, we follow the money where it goes through the chain of providers. So it is, indeed, possible that you would have—for example, NBAC, the national biodefense laboratory that we're building at Ft. Detrick, would have as a subcontractor other companies or laboratories around the country, and that they in turn might subcontract with laboratories either elsewhere in the country or outside of the United States.

That certainly does happen. So it becomes my responsibility to make sure that we are examining the work where it's being done. We have not—typically, to address specifically your point on international work, we do make sure that, to the greatest extent possible, things are being done in a safe way, wherever it happens to be done. Is that responsive to your question, sir?

Senator CARDIN. Well, you mentioned 42 labs.

Mr. PASCO. Yes, sir.

Senator CARDIN. And that you do physical inspections on 23, because I assume you have reason—you said you had reason to go onsite. Are those 42 labs all located in the United States?

Mr. PASCO. Yes, sir.

Senator CARDIN. So then, in fact, if the collaboration is outside of the United States, you really don't have much ability to follow that money.

Mr. PASCO. Well, what we would likely be doing is probably a paper-based review. That is to say, we would ask the laboratory—whether it's in the United States or not, we would ask them to provide certain basic documents to us. We'd like to see what their security protocols are, what their safety protocols are, what is the type of training that they require for their staffs?

Information could be requested about the basic facility. And you can learn a lot about the health of a program by that type of documentation review, and we would use that, whether the lab was in the United States or not, to understand the management practices of that facility and whether we would have a reason to want to send inspectors to physically visit.

Senator CARDIN. Let me ask one last question on perimeter security for our government labs. Is there a uniform protocol for perimeter security if you're dealing with the Level IV labs? Is that established? Is there a need for a review of that, considering the higher risk factors today in regards to those interested in weapons of mass destruction?

Mr. REED. Let me attempt to respond to that in a general sense in terms of what needs to be there, if I may. We have a bio-defense campus that you're very familiar with that is being established at Ft. Detrick, where we're having laboratories from Department of Homeland Security, from the Department of Health and Human Services, and from the Department of Defense co-located and contiguous.

If we do not have a common approach to the establishment of security for that laboratory, that laboratory complex, we will have three independent laboratories that are not able to coordinate their activities in the way that I think was originally intended when that was established in concept.

And so from that standpoint, I think that's one of the key things that we really need to get to, and then to extend those sorts of standards, those sorts of requirements really throughout so we know the way the various materials are being protected and we have an ability to inspect against that.

I'm going to ask Captain Cole to respond, if I may, just for a moment from the standpoint of the international issue.

Ken.

Captain COLE. I am Captain Kenneth Cole. I'm the Medical Director of the Chemical/Biological Defense Program within DOD. With respect to your question of overseas labs, of course, the DOD does operate several overseas labs. These laboratories—our primary mission is bio-surveillance, for the protection of not only our service members overseas, but for also providing data for the World Health Organization, as well as our own public health infrastructure in the United States on emerging diseases, as well as endemic diseases like the seasonal flu, among other things.

Part of the agreements we have with the countries which we participate in is to have full and open collaboration with those countries in terms of the monitoring and the exchange of information, as well as exchange and collaboration of samples with those laboratories. So in those aspects, we do inspect those laboratories on our own for compliance with select agent rules and the DOD regulations.

However, we do have to put into certain places waivers to certain exemptions of the requirements in order to allow, under treaties and other agreements we have with these countries, the exchange of information, as well as exchange of samples that are required to have a rapid response to an emerging or endemic disease outbreak.

Senator CARDIN. Well, let me thank you again for your testimony and answering our questions. This is an ongoing interest to our Committee. I know there are other committees in the Senate that are also interested. We're going to try to coordinate our response. We clearly are interested in the recommendations that come out of the working group and we'll look forward to not only their report, but the administration's response to those reports.

We will follow up with Health and Human Services to get their feedback. I know we're all interested in protecting the security of our country. These labs, they do extremely important work and we want to make sure there's a working ability to get the job done, but with maximum protection to the public and the security of our country. So, thank you all very much. Appreciate it.

Our second panel will consist of Hon. Bob Graham, our former colleague and Chairman of the Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. He has spent a total of 38 years in public service; a two-term Governor of the State of Florida, before serving for 18 years in the U.S. Senate. He's also spent 12 years in the Florida State legislature. Senator Graham is recognized for his leadership on issues ranging from health care and environmental preservation to his 10 years of service on the Senate Select Committee on Intelligence, including 18 months as its chair from 2001 to 2002.

We also welcome Dr. Nancy Kingsbury, who's the Managing Director for Applied Research and Methods at the U.S. Government Accountability Office, where she is responsible for managing GAO's advanced analytical staff, including economists, computer engineers, statisticians, social scientists, analysts, program evaluation experts, and scientific specialists.

And last, let me welcome back Michael Greenberger, who's the Director of the Center for Health and Homeland Security at the University of Maryland, and a professor at the School of Law. The center works on a broad range of homeland security and emergency response issues for the Federal, State, and local governmental agencies, as well as medical researchers. It's a pleasure to have all three of you.

As is the tradition of the Judiciary Committee, if I could ask you to stand for the oath, and then we can get on with your testimony. Thank you.

[Whereupon, the witnesses were duly sworn.]

Senator CARDIN. Thank you all very much. Please have a seat.

Senator Graham, it's a pleasure to have you back here in the U.S. Senate. I miss your good advice that I remember with fondness, working with you when I was in that other body that, quite frankly, I don't understand why we need today now that I'm over in the Senate.

[Laughter.]

Senator CARDIN. But it's a pleasure to have you before our Committee.

STATEMENT OF HON. ROBERT GRAHAM, FORMER U.S. SENATOR FROM FLORIDA, CHAIR, COMMISSION FOR THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM, WASHINGTON, DC

Senator GRAHAM. Thank you very much, Mr. Chairman. And no comment on your last comment.

[Laughter.]

Senator GRAHAM. Mr. Chairman, I appreciate the opportunity to testify before your Subcommittee today.

First, a little background. The Commission that I chair was founded by the Congress at the suggestion of the 9/11 Commission,

which had found that the ultimate catastrophe for this country would be when the worst weapons fell into the worst hands. The response of the Congress was to establish a commission to review our current policies to avoid proliferation and make recommendations for the future.

We did so in a report entitled, "World At Risk", which was published in December of '08. Then the Congress asked us if we would stay for another year and work with it, as well as the administration, in implementing our recommendations, which we were honored to do, and I appreciate the opportunity that you are affording me today on behalf of the Commission to do so.

I would like to use my time to give somewhat of an overview of where I see the issue of biological weapons fitting into the larger picture of preventing the proliferation of weapons of mass destruction.

Mr. Chairman, our Commission made three basic findings. One, that since 9/11, we have become less safe, not because we have not been diligent in executing policies designed to increase our security, but because our adversaries have been moving at a more rapid pace and the environment in which this competition is occurring gives an advantage to the kind of people that our adversaries are.

The second finding was that, without urgent action, that it is more likely than not that a weapon of mass destruction will be used someplace on earth between December 2008 and the end of 2013. That was an assessment reached after consultation with a wide range of scientific, intelligence and law enforcement experts in this country and abroad. We were given some underpinning in that recommendation when, two weeks after our report was issued, the then-Director of National Intelligence, Mike McConnell, made almost precisely the same prediction.

The third, is that a weapon of mass destruction is more likely to be a biological weapon than a nuclear weapon, for reasons that I will comment on in my further statement.

I believe that there are three clocks running. The first clock is a 2013 clock. As I stated, the Commission concluded that it was more likely than not that a weapon of mass destruction would be used by 2013. The second clock is a 2010 clock. Under the principal international treaty for nuclear proliferation avoidance, the nonproliferation agreement, there is, every 5 years, a meeting of the signatories to review what's happened in the last 5 years and make recommendations for the future. 2010 will be such a year. We believe it is critically important that 2010 be used aggressively to deal with some of the current gaps and weaknesses in our international treaty on nuclear proliferation.

That issue is primarily in the executive branch. The Congress has legislated extensively in the area of nuclear proliferation. Most of the heavy lifting to be done must be accomplished by the executive branch. I'd like to commend President Obama for his initiative, the statements that he has made, such as that that he made in Prague, and calling for a summit in March of 2010 to precede the conference of the signatories to the nonproliferation treaty that should energize the work of that conference.

The third clock is a 2011 clock. As the nonproliferation treaty is the basic document for nuclear nonproliferation, the Biological

Weapons Convention of 1972 has the same role for biologicals. It also has provision for periodic review. The next review will take place in 2011.

We believe it is imperative that the United States use its influence in order to achieve some significant reform in the structure of our dealings with biological proliferation. In many ways, the biological treaty is in greater need of amending than the nuclear treaty. We also believe that, for the United States to play that role of leader, we must lead by example.

This issue is primarily a Congressional issue. We believe that the legislation that Congress, hopefully, will enact in the next few months will set the gold standard of what a country should do to avoid the proliferation of biological weapons, and that that will put us on the moral high ground as we go into the 2011 convention to get other countries to see our standard as one to which they should also aspire.

Mr. Chairman, we have felt that there were two principal strategies for biological defense against proliferation. One, is very similar to the basic strategy for nuclear, which is to avoid the terrorists getting access to the materials necessary to make, and then distribute and disseminate, biological materials.

This is a much more difficult issue in biological than it is in nuclear because the biological materials are so ubiquitous, and they do not require the same skill level or the technology. They can be transported more readily; a mere vial of the right pathogen can do enormous damage.

The second strategy which is peculiar to biologicals is a deter-by-being-prepared strategy. In our discussions, including some recent discussions within the intelligence community, the feeling is that if an adversary, particularly a non-state actor, were to get access to the materials for a weapon, they would use it fairly quickly.

Unlike North Korea, which has a strategy of stockpiling the nuclear bombs that it's developing because they want to have a second-strike capability, a typical non-state terrorist would want to use the material quickly, in part because of safety concerns, and second, because it fulfills their rationale for wanting to use a weapon of mass destruction.

The adversary would be looking at a number of potential targets to use their biological materials. We think that they would be inclined to want to use it against the target where they felt they would have the greatest consequence, the greatest number of casualties. So the degree to which a community has prepared itself not only for a terrorist attack, but also for an epidemic, such as what we might be dealing with this year with swine flu, that preparation is one of the best deterrents that a community can have. The issue that you're discussing today, lab security, touches on both of those strategies.

Lab security is a fundamental part of preventing weapons of mass destruction from falling into the wrong hands. Also, lab security procedures play an important role in our continuing ability to be creative and innovative in developing the vaccines and other pharmaceuticals that will be a key part of our ability to reduce the consequences of the use of a biological weapon of mass destruction.

Mr. Chairman, that is sort of the broad framework. I would just conclude by mentioning three areas of action. One, the need to have an overall strategy of how we're going to deal with the biological issue. I testified earlier today where a representative of the Government Accountability Office presented a report which had the headline of, "We Do Not Have Anyone in Charge of Our Biological Response." It's now been 8 years since the attack that occurred, in part, in this very building, was launched. It is inexcusable that we don't have an overall strategy, and I think it's incumbent upon the Congress to take those steps to demand that the executive branch establish such a strategy.

Second is the international dimension. The title of our report was consciously selected. It is: "World at Risk," underscoring the fact that this is not a problem that the United States can solve in isolation. We've got to see this as a global threat. The 2011 conference, and our preparation for it, will be key.

Finally, returning to the three clocks, we don't have an indefinite amount of time. This is my assessment, not the Commission's. The Commission assessed that, as of December 2008, there was better than a 50/50 chance that there would be a weapon of mass destruction used between that date and the end of 2013.

It would be my assessment today, on the 22nd of September of 2009, that the chances of there being a successful use of a weapon of mass destruction are greater than they were even last December. That is a testimony to the alacrity and the commitment of our opponents, our adversaries, to achieve and use this technology.

So, Mr. Chairman, I thank you for the opportunity to share these thoughts on behalf of the Commission. I would be pleased to answer any questions.

[The prepared statement of Senator Graham appears as a submission for the record.]

Senator CARDIN. Well, again, thank you very much for your testimony. It's very, very helpful.

Dr. Kingsbury.

STATEMENT OF DR. NANCY KINGSBURY, MANAGING DIRECTOR, APPLIED RESEARCH AND METHODS, UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Dr. KINGSBURY. OK. I'll try to be brief, if I can get my microphone on.

We're very pleased to be here to discuss the report that we issued yesterday on the need for a national strategy for high-containment laboratories in the United States. High-containment laboratories have proliferated in recent years. In 2007, we reported on several issues associated with the proliferation of these labs in the United States, and some of the risk posed by bio-safety incidents that occurred in the past.

The FBI's allegation in August of 2008 that a DOD scientist was the sole perpetrator of the 2001 anthrax attacks raised additional concerns about the possibility of insider misuse of high-containment laboratory facilities, material, and technology.

Highly publicized laboratory errors and controversies about where high-containment labs should be located have raised ques-

tions about whether the governing framework, oversight, and standards for bio-safety and bio-security are adequate.

We have three findings to report. First, since 2001, the number of BSL–III and BSL–IV labs in the United States has increased, and this expansion has taken place across Federal, State, academic, and private sectors. By increase, we have some data in our report that would suggest it's more than doubled in terms of the numbers.

Information about the number, location, activities, and ownership is available for high-containment labs that are registered with CDC's or USDA's select agent programs, but not for those outside those outside those programs. The expansion that began after the anthrax attacks in 2001 lacked a clear, coordinated national strategy.

Decisions to fund the construction of high-containment labs were made by multiple Federal agencies in multiple budget cycles. Federal and State agencies, academia, and the private sector considered their own individual requirements, but an assessment of national needs was lacking. Even now after more than 7 years, we were unable to find any projections based on a government-initiated strategic evaluation of current and future capacity requirements linked to national public health goals, or for that matter, weapons of mass destruction goals. Such information is needed to ensure that the U.S. will have facilities in the right place with the right research capabilities.

Second, no executive or legislative mandate directs any Federal agency to track the expansion of all high-containment laboratories. Accordingly, no Federal agency knows how many such labs exist in the United States, and no single agency is responsible for determining, or able to determine, the aggregate risks associated with the expansion of these labs. Consequently, no Federal agency can determine whether high-containment lab capacity is now less than, meets, or exceeds the national need.

Finally, four highly publicized bio-safety incidents in high-containment laboratories, as well as evidence from scientific literature, demonstrate that, while laboratory accidents are rare, they do occur, primarily due to human error or system failure. One of the incidents we reviewed involved the allegations that Dr. Bruce Ivins of DOD was the source of the 2001 anthrax attack.

These allegations highlighted two lessons: first, an ill-intentioned insider could pose a risk by removing dangerous material from a high-containment laboratory; and second, it is impossible to have 100 percent effective inventory control of biological material with currently available technologies.

At Ft. Detrick, ineffective procedures for the control of inventories and the unrestricted use of lab facilities allegedly allowed Dr. Ivins the opportunity to pursue his own ends. As the number of high-containment labs increases, there will inevitably be an increase in the pool of scientists with expertise and, thus, the corresponding risk from insiders is likely to increase.

Taken as a whole, the incidents we reviewed demonstrated failures of systems and procedures meant to maintain bio-safety in high-containment labs. They revealed the failure to comply with regulatory requirements, safety measures that were not commensu-

rate with the level of risk to public health posed by lab workers and the pathogens in those labs, and the failure to fund ongoing facility maintenance and monitoring the operational effectiveness of lab physical infrastructure.

In conclusion, I want to stress that oversight plays a critical role in improving bio-safety and ensuring that high-containment labs comply with regulations. However, some aspects of the current oversight programs provided by CDC and USDA are dependent upon entities monitoring themselves and reporting incidents to Federal regulators.

Furthermore, personal reliability programs have been established since 2001 to counter insider risks, but their cost-effectiveness and programmatic impact has not been evaluated. We would note that the incident at Ft. Detrick is the only known incident of insider behavior.

If an agency were tasked or a mechanism were established with the purpose of overseeing the expansion of high-containment labs, it could develop a strategic plan to ensure that the number and capabilities of potentially dangerous high-containment labs are no greater or less than necessary, it could balance the risks and benefits of expanding such labs, and it could determine the type of oversight needed.

To address these issues, we recommended that the National Security Advisor, in consultation with the Secretaries of Health and Human Services, Agriculture, Defense, and Homeland Security, along with the National Intelligence Council and other executive departments as appropriate, identify a single entity charged with periodic strategic evaluation of high-containment labs that will determine the number, location, and mission of the laboratories needed to effectively meet national goals to counter bio-threats, the existing laboratory capacity within the United States, the aggregate risks associated with the laboratories' expansion, and the type of oversight needed.

It would also develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically and importantly including provisions for long-term maintenance.

We also recommend that the Secretaries of HHS and Agriculture develop a clear definition of exposure to select agents. The voluntary reports that come back from labs obviously demonstrate that there is some confusion about that issue. They can also develop a mechanism for sharing lessons learned from reported laboratory accidents so that best practices for other operators of high-containment laboratories can be identified.

Recognizing that biological agent inventories cannot be completely controlled at present, we also recommended that the Secretaries of HHS and Agriculture review existing inventory control systems and invest in, and develop, appropriate technologies to minimize the potential for the insider misuse of biologic agents.

Finally, should the Secretaries consider implementing a more stringent personnel reliability program for high-containment laboratory employees to deal with insider risk, we recommend that they evaluate and document the cost-effectiveness and programmatic impact of such a program. In an earlier hearing today,

a representative of the American Society for Microbiologists emphasized quite a bit the need to balance the security factors and the ability for researchers to do their work.

Mr. Chairman, that's my prepared statement and I'll be happy to answer your questions.

[The prepared statement of Dr. Kingsbury appears as a submission for the record.]

Senator CARDIN. That's very helpful. Thank you very much.

Mr. Greenberger.

STATEMENT OF MICHAEL GREENBERGER, DIRECTOR, CENTER FOR HEALTH AND HOMELAND SECURITY, UNIVERSITY OF MARYLAND, BALTIMORE BALTIMORE, MD

Mr. GREENBERGER. Thank you, Chairman Cardin. And I want to congratulate you and the Subcommittee for holding this hearing today. If we've learned any lesson from our National security perspective, and maybe even from our financial perspective, is that when you don't pay attention to issues we tend to get banged in the side of the head. You can go all the way back to the Great Depression and Pearl Harbor or you can look at the 9/11 attacks or the anthrax attacks.

I know the Senate's docket is very, very busy, and I know that, for example, Ranking Member Kyl is understandably preoccupied with health reform, and you've got global warming, reform of the Financial Regulatory System, and a host of international relations issues, Afghanistan probably being at the top. But I think your Subcommittee's wisdom in looking at an issue that can come back to bite us big-time is to be congratulated.

I have had the fortune, as the Director of the Center for Health and Homeland Security at the University of Maryland, of working with medical researchers at the School of Medicine and their collaborative, the Mid-Atlantic Regional Center of Excellence, which deals with bio-defense and emerging infectious diseases issues.

Let me say in the first instance, the money that is being spent by the Federal Government for this research is money that is well spent. We only have to look at the fact that we are going to have an H1N1 vaccine in October. When things go well we don't tend to congratulate people. The fact that that vaccine is available, given scientific and commercial problems in the vaccine industry, is nothing more than a minor miracle and shows what scientific research can do to be of assistance to the United States.

However, the anthrax episode at Ft. Detrick demonstrates that, imbedded within all of that good work can be very dangerous activity. It is a high irony that the anthrax episode of 2001 was the principal motivator for all of this research, and then we found out a year ago that the researchers may have been the problem of the anthrax incident itself.

Now, let me say, I have studied the Ft. Detrick situation. I'm not at all convinced that Dr. Ivins is necessarily the perpetrator, and I think it was unfortunate that, after his suicide, blame was heaped upon him. But I am convinced, based on the DNA evidence that was done, that the source of the anthrax emanated from a flask at Ft. Detrick. Somebody got access to that information.

And while Senator Graham makes the excellent point that we have to worry about outsiders doing damage to us, this provokes the classic Pogo commentary that "We have found the enemy and he is us". It was an insider, one of our researchers, that perpetrated maybe the third serious terrorist attack on the United States that got access to that flask.

I think we have, in our testimony to you today, made six recommendations. I think there is a consensus here: you must have somebody in charge of this situation. I would take some—I would quibble somewhat with the DOD's testimony today. I think having an interagency task force do this is a big mistake. I think putting it in the National Security Council is a big mistake.

If there were a spill, or the stealth of, say, Ebola bacteria from a laboratory, somebody in Congress would right away want to know, what has happened? I think what we've learned today is, we wouldn't know which of the 15 different agencies in the Federal Government to call up here, and we all know the difficulty of getting the National Security Advisor up here. No blame to the National Security Advisor, but he has a lot of things on his plate. There must be somebody in the Federal Government that assumes overall responsibility.

The BSL labs, unlike any professional institution, are not required to be accredited. Right now, my own law school is worried about an accreditation process that is going to happen over a year from now. That is forcing our school, medical schools, all kinds of institutions who have to be accredited to do the most thorough self-evaluation to meet that accreditation.

The single regulator must set up an accrediting process. We've heard that there's 1-year inspections, some inspections, what have you. But the four big episodes that are identified as the cause of our concern, starting with anthrax and some of the other universities, were people reporting to a regulator a problem, not the fact that the inspectors found the problem. You have to have a system that goes through an accreditation process.

Also, what has been said today, we agree with: mishaps at the laboratories are not promptly and fully reported to the Federal Government, and even worse, the experience from those mishaps is not sent out to the other laboratories as a "lessons learned" modality. It's a very incomplete process and it's a very slow process, and again, a single overseer could fix that problem.

The final thing that's been talked about today that I think is very important, you have military laboratories on one extreme and university laboratories on another extreme. It is impossible—and I was pleased to see the Department of Defense advocate—to apply military precision and security to a university laboratory, not just because you don't have the resources, but most medical researchers at universities would say that there is an element of the openness of those labs that would be defeated by a super-security process.

I think many people have testified, some of the committees that have issued reports today have testified, that you can reach the security goals here without developing a full military security apparatus, and not using some of the techniques like psychological testing of researchers and other things that would only hinder being able to bring the best researchers to the table.

I've cited the University of Maryland, Baltimore. They supervise 1,500 laboratories, some of them are BSL laboratories. They use guidelines that have been developed by CDC and NIH. They are very serious about the work they do. Those guidelines can be applied institution to institution to assure safety and security. There has never been a leak or stolen materials from the BSL. That's the next-highest secure laboratory at the University of Maryland. Through a single regulator, accreditation, the use of the best practices within university industries, we can have the best of both worlds: good science and good security.

Thank you.

[The prepared statement of Mr. Greenberger appears as a submission for the record.]

Senator CARDIN. Well, thank you very much. In fact, thank all three of you. It's a pretty direct presentation of the risk factors that we confront. Senator Graham, I think it's very sobering, your predictions that your Commission came up with, the vulnerability of the United States to weapons of mass destruction, and most likely the biological being the more likely vulnerability. It puts additional attention on the subject that we have here today, which is the security of our containment labs.

You all are raising the same point. You're saying we need to have a coordinated strategy. That is one of the points that, Senator Graham, you pointed out that is missing, an overall strategy. It's difficult for us to look at who is responsible on biological containment labs' security when there's 15 agencies involved and they each have different responsibilities.

Quite frankly, some of these labs are dealing with a lot of agents that are not a particular interest, or they're important to keep control over them, don't get me wrong, but they're not going to fall into the category that you are concerned about, Senator, about being used as a weapon of mass destruction.

That's why I thought one of the recommendations I believe that your Commission has made that I found very helpful is to have tiers of interest in regards to the agents, the pathogens that are of the most concern, tier one, would be categorized in that way so it would get the special attention. Then you could do what Mr. Greenberger is suggesting as far as being able to trace those types of agents.

At the same time, I am concerned with the point that Dr. Kingsbury raised about, how do you do this in a climate that allows the type of collaboration among our universities and private entities and international partners that are going to be important for the type of academic work necessary to prepare us, as you pointed out, so that we are prepared to deal with the risks that are out there.

So let me start off with that recommendation on the tiering of the pathogens. The previous panel seemed also to support that type of concept. You indicate you might be able to limit to eight—at least that's what I thought I saw in the Commission's report. Is that a reasonable number that you think would end up in tier one? And what is your criteria for tier one?

Senator GRAHAM. Mr. Chairman, the criteria for inclusion in tier one are those pathogens that are the most deadly and the most

readily weaponized. The scientific community that we consulted with felt that that might be as few as eight pathogens. There are now, I think, over 80 that are on the special agent list, so it would be a very focused group of pathogens which could have the highest level of security.

We also propose that there be two other tiers, a tier two which would be those pathogens that have great potential, but are not at this point as amenable to weaponization as those that would be in tier one. They would get the second level of review. Then tier three would be everything else, including some items that are of lesser potential threat, but maybe more ubiquitously distributed around the world.

Senator CARDIN. And I want to point out, I think we need protection on all of the pathogens because it could be extremely dangerous for those who are handling it. It may well not be suitable as a weapon of mass destruction, but it is an agent that requires special attention. We should know where they are, how they're being used, and there should be certain standardized protections.

Senator GRAHAM. Yes. I think there is a difference between the regulatory pattern for safety, which might be more common across those three tiers. As an example, there was a story yesterday or today about a scientist at the University of Chicago who has died, and there is the possibility that he died because he was handling an agent which is generally thought of to be relatively mild in terms of its potential. We'll learn more about the full circumstances of this gentleman's death.

But safety is one concern for which there's probably not the need or desirability for such high levels of stratification, but the security level, we want to be able to put our maximum attention on those pathogens that have the greatest potential to be converted into weapons.

Senator CARDIN. Dr. Kingsbury, you raised the issue of the freedom, academic freedom and the ability to work with your colleagues around the world. How do you balance that?

Dr. KINGSBURY. Well, I think it's just a factor that needs to be taken into account. With respect to the tiering question, while I have a fair amount of sympathy for the importance of the security of those highly vulnerable pathogens, I'm not sure we know enough about the mix of pathogens in different laboratories to have a view yet of whether that kind of strategy would actually work. If you're working with anthrax or whatever else is on that list of eight, but you're also working on something else that's more benign or not likely to—or there are treatments for it, and so they're inventing new treatments, it's not sure how that relationship would work and I'd just be interested in knowing more about it.

Senator CARDIN. I also think we need to know, of all the people who registered, how many would have had to have registered for tier one if we had a different registration system.

Dr. KINGSBURY. Yes.

Senator CARDIN. I don't know if we know that or not, because we——

Dr. KINGSBURY. We don't, I don't think. Do we? No. OK. We don't.

Senator CARDIN. One of the issues here is budget and workload as to——

Dr. KINGSBURY. Oh, sure. Sure. Absolutely. Several months ago—a couple of months ago—we issued a report looking at the question of the building of the national agro and bio-defense facility that the Department of Homeland Security is proposing, and there we limited our whole analysis to the issue of foot-and-mouth disease and whether the Department of Homeland Security had adequately demonstrated that foot-and-mouth disease, which does not affect humans—OK, so I don't think it would be a very good weapon, except economically—whether or not the ability to control escape of that pathogen from a lab that is built in the middle of the most prolific cow country in the country, and we reported, frankly, that we didn't think DHS had demonstrated that. It doesn't mean it can't be done, perhaps. I have my own concerns about that. But they haven't demonstrated it yet, and it's clear they're going to go ahead with the decision.

But we thought focusing on that, because it is economically so significant and because the virus is so infectious—it's the single most infectious virus on the planet. If it starts getting into cattle herds, the cost associated with both the trade impact of that event and the cost of cleaning it up is really important to think about. There may be special circumstances around some of these other select agents that might need the same kind of analysis.

Senator CARDIN. Mr. Greenberger, you don't believe the best solution is the interagency approach. Do you have a specific recommendation as to how the line of responsibility should work in this area?

Mr. GREENBERGER. Well, I think the two principal agencies that have had regulatory responsibility—in other words, DHS came before you today and said, effectively, they're supervising researchers. They're overseeing their researchers in the 42 labs. But the people who have had over-arching responsibility are CDC and the Department of Agriculture for plants and animals. I think in all candor, you'd have to say the record here is that CDC is the superior record. There have been problems with the Department of Agriculture. It's own Inspector General has identified it.

This reminds me very much of the Hurricane Katrina problem when, after the clean-up of Hurricane Katrina, there was this big debate whether the Department of Homeland Security was in charge as the then-national response plan indicated, or whether HHS, because of the public health factors in the clean-up, should be in charge.

In December 2006, Congress passed the Pandemic and All Hazards Preparedness Act, took the responsibility away from DHS and gave it to HHS, and created a separate Assistant Secretary within HHS to oversee catastrophic public health experiences. Now, one thing I would say about that: oversight is very important. It took 13 months to get a Director of that agency. But I think that that kind of episode—I think this is a public health situation. I think you should look to HHS as the overriding regulator here. They should be in charge.

Whether CDC, who's now overloaded with H1N1 problems, has enough resources to do this, I don't know, but I would start with

them. They should be established—they should be the single agency setting up standards, both safety standards, security standards for all these laboratories, having the entire inventory, being responsible for having evidence of mishaps, and setting up an accreditation process. And by the way, the accreditation process doesn't necessarily have to be completely public. You can get the best universities who have proven laboratory experience here to be the accrediting committees, and change them from time to time.

As I said, your worry about the tension between security and openness, I think, is being met in the vast majority of universities who have laboratory issues today. They are following NIH/CDC guidelines, they are deadly serious about a deadly issue, they have training programs, and they hold their researchers accountable. As the National Science Advisory Board on Biologics report says, we have to get that culture in the good institutions imbedded throughout. The single regulator should be the one who does that. It can be done without converting universities into military operations.

Senator CARDIN. I think we all agree with that.

I think, Senator Graham, your report sort of points to Department of Homeland Security as the key agency.

Senator GRAHAM. Our recommendation in this area, Mr. Chairman, is on page 29 of our report. It says, "The Department of Health and Human Services, in coordination with the Department of Homeland Security, should lead an interagency effort to tighten government oversight of high-containment laboratories. So our recommendation was that it be interagency in nature with the Department of Health and Human Services in the lead.

In addition to the factors that Professor Greenberger has just outlined, I would add another: that is, urgency. It would be our hope that the Congress would act in sufficient time that the administration could show some actual results of your actions in terms of standards for high-containment laboratories before that 2011 conference.

We think the United States needs to be in the strongest position of leadership before that conference in order to be able to have the influence that we think is critical in order to strengthen the global network against the proliferation of biological material. We must lead by example.

Senator CARDIN. So there is some agreement here between the two, HHS. How about the GAO?

Dr. KINGSBURY. Well, if I could add two things. One is, as a part of our work on the report that we issued yesterday, we did talk to all of the agencies who have an interest in this oversight question. All of them told us they didn't feel they had the authority to take a leadership role. That's why we think there is some action that needs to be taken here. It's the lack of authority to direct another agency how to spend its appropriations that is the sort of weakness in——

Senator CARDIN. That's our responsibility.

Dr. KINGSBURY. That's your responsibility.

Senator CARDIN. I understand that. That's our responsibility to clarify. I'm trying to get the best advice, if there is consensus in Congress to give a lead agency, who that lead agency should be. It seems like Senator——

Dr. KINGSBURY. Well, for exactly the reasons that Dr. Greenberger said, HHS is at least a leading candidate here. I would put it at the HHS level, not the CDC level, because of NIH and the other places in HHS where these laboratories go.

Senator CARDIN. So let me just get back to Senator Graham, then, on what your thought is, using the interagency. But you still want the responsibility to be with HHS, if I understand correctly?

Senator GRAHAM. Yes.

Dr. KINGSBURY. If I could offer up one other example. We are aware that the United Kingdom has completely centralized oversight of these laboratories in an organization called the Health and Safety Executive. There were two different—like we have with CDC and APHIS, there were two different organizations with somewhat different approaches and standards and so forth dealing with the animal and plant side, and with the human side, and they made a decision, after the outbreak of foot-and-mouth disease in Pirbright, to centralize all of it in the Health and Safety Executive and operate by the same standards.

Senator CARDIN. Senator, as I understood, you're suggesting that this type of action would be very helpful for the United States to complete prior to going to the review conference?

Senator GRAHAM. Yes. And I think that the Department of HHS, because of the reasons that have been stated, is the one most likely to be able to show some quick results of being assigned this leadership role.

Senator CARDIN. Let me ask one last question generally of whoever wants to respond to it. That is whether it is useful for us to pursue a more sophisticated way of doing background checks on those who have access to the most dangerous pathogens. Mr. Greenberger, you raise a very valid point, that the attack on our country, the third most serious, was from within and that the person who—at least, one of the—the person who has been labeled responsible had certain issues that could have been discovered through a background or a review of his current situation.

Is it feasible and the right use of resources to try to develop a more sophisticated way to license those who have access to the most dangerous pathogens, or are we in an area that to do more than is currently being done is probably not realistic to expect?

Mr. GREENBERGER. If I can take a crack at that. I think that the National Science Advisory Board on Biology, which has one of the big reports on this, if you read their message between the lines, is that the present system for non-military facilities, mostly university facilities, has to be fine-tuned. Some of it is too stringent. Even as the Department of Defense testified today, there are too many foreign nationals that are excluded only because they're foreign nationals and not because they're a threat to the country, and that's hurting our scientific effort.

Some of the—for example, the Dr. Ivins thing might suggest that some of the things the military uses as a screening device, which are psychological profiling, might be appropriate. I agree with the National Science Advisory Committee that that is a mistake. I think, anecdotally, many of us have had the experience of people being disqualified from national security clearances for unknown

reasons for failure of the psychological profiling, and I don't think there's a lot of confidence in it.

The National Science Advisory Board, for example, expressly says that should not be used for the university system. On the other hand, if you have a single regulator establishing standards, it certainly would be appropriate to have them report on somebody who's been experiencing in the real world some kind of psychological difficulty. Now, that's a very sensitive issue. It raises all sorts of privacy points.

But here you have to balance the Nation's security in a Dr. Ivins-like situation against privacy concerns. It's a delicate balance. But a single regulator, with the advice of an interagency consultation and the best private minds, I think, can draw up regulations that assure privacy but do the reporting so that those kinds of issues do dwell up to the top.

Right now, in fact, all the building blocks are there. They're spread among 15 different agencies. Nobody—even the tiering issue, I think, is—I agree that that is a good response and it could easily be done, but nobody has been assigned the responsibility of doing it. I think all these things can be accomplished. You've got to find somebody to take charge, given them general guidelines.

Senator CARDIN. Your point is, you would, as part of this overall structural change, give HHS the authority to revise or change the current structure that's in place where the Department of Justice is doing these background checks for those that are dealing with agents.

Mr. GREENBERGER. Yes. And I think that you can set the goals. The general goal is assuring security without undercutting private research. You've got the best—the National Science Advisory Board has already laid out parameters where this fine-tuning can take place.

Senator CARDIN. Do better in some cases, but in some cases we're over-restricted.

Mr. GREENBERGER. I agree.

Senator CARDIN. Senator Graham.

Senator GRAHAM. I would agree with Professor Greenberger's assessment. I would also say that, of the various ways in which the materials for a biological weapon of mass destruction might fall into evil hands, such as being produced outside the country and brought into the country, or someone driving a truck through a fence at a secured facility, or a person on the inside turning and becoming a rogue scientist, I think that third option is the most likely option. It happens to be the only option which has actually been utilized in recent history.

So I think it's a very important question. I would associate myself with the sophisticated recommendation that the Professor has made as to how to go about balancing all of those interests.

Senator CARDIN. Doctor.

Dr. KINGSBURY. I think we would agree that if you're going to do a personnel security program with uniform requirements across the whole community, some kind of collaborative way of doing it is certainly absolutely needed. But it's not going to come cheap. As you well know, the government is facing considerable budgetary pres-

sure these days. I would not want to think about that personnel security program in complete isolation.

I think there is not a lot of evidence about its being successful in what it sets out to do. The case at Ft. Detrick is the only known case of an insider doing the sorts of things that he did. Yet, there are, what, 1,600 of these laboratories around the country. So whether you want to get into the business of doing that without, as we recommend in our report, looking at what the costs are going to be, looking at what the benefits are going to be and evaluating it—we are aware, for example, of a case at the University of Texas at Austin where they are trying to hire a couple of very high-end scientists from Brazil, and they're having to wait 18 months. They haven't been cleared to come into the country even, let alone to work at the laboratory. So all those issues need to be worked through with the scientific community.

Senator CARDIN. I don't think we're going to be able to resolve the problems of people getting visas to come to America at this hearing.

Dr. KINGSBURY. Probably not.

Senator CARDIN. But I think you raise a very valid point on cost. My point is this. I think what Professor Greenberger is saying is that we might be able to get savings by doing this more efficiently than we we're doing it today and that, if we have a tier approach, there may well be a less costly way to deal with the majority of people that are dealing with pathogens at our labs or the type of lab they're dealing with, the type of work that they're dealing with, that there should be more sophistication in the way that we go about doing it.

I expect, if HHS had the authority, they could then have more impact on DOJ, if that's the agency that's actually going to be doing the reviews for the process, and they may be able to avoid some of the time delays that we have. At least, I would hope that would be part of the game plan that would be developed.

But I must tell you, someone who is dealing with anthrax and the potential danger that that can cause, the potential risk factor of a weapon of mass destruction, it seems to me that we have a responsibility to the public that someone who could have access to remove anthrax from a lab, that that person is scrutinized at a much higher level, including their psychological make-up, so that we do protect the public from that type of attack that we had here in the U.S. Senate and in our country.

With that, let me thank all three of you for adding to this discussion. As I said at the beginning, there are other committees that are interested in this subject, and we do expect that the Congress is going to want to continue this effort. I thank all three of you for your contribution.

Senator Graham, the work of your Commission, which was, as you pointed out, set up by Congress, is a valued part of our process. There's been a lot of discussion about it among your former colleagues, so we appreciate your continued contribution to this very important debate, and we look forward to this continued dialog with all three of you as we try to get this right for the sake of our National security and the safety of Americans.

With that, the Subcommittee will keep the record open for 1 week for questions that members of the Committee might wish to pose. With that, the Subcommittee will stand adjourned.

[Whereupon, at 4:32 p.m. the Committee was adjourned.]

[Submissions for the record follow.]

SUBMISSIONS FOR THE RECORD

Statement of

The Honorable Benjamin L. Cardin

United States Senator
Maryland
September 22, 2009

OPENING STATEMENT OF

SENATOR BENJAMIN L. CARDIN

CHAIRMAN, TERRORISM AND HOMELAND SECURITY SUBCOMMITTEE

OF THE SENATE JUDICIARY COMMITTEE

HEARING: "STRENTHENING SECURITY AND OVERSIGHT

AT BIOLOGICAL RESEARCH LABORATORIES"

TUESDAY, SEPTEMBER 22, 2009

The subcommittee will come to order.

After the 9/11 terrorist attacks, Americans suffered another type of terrorist attack in October 2001: biological attack. Letters were mailed to members of Congress using the US Postal Service, ultimately resulting in the deaths and sickening dozens of individuals. The federal government responded by increased funding for biodefense. Congress also implemented the 9/11 Commission recommendations, which called for the creation of a Department of Homeland Security, and urged the government to take stronger measures to deny WMD to terrorists.

High-containment laboratories play a critical role in the biodefense effort, and involve a collaborative effort between the public and private sectors, military and civilian communities, as well as our international partners. At the same type, increasing the number of personnel and laboratories with access to these deadly agents may increase the chances of accidental or deliberate misuse of hazardous materials, posing a significant public health threat.

Today's hearing will examine the current security measures at our laboratories, including both physical security and personnel reliability, and look at best practices in both the government and private sector, including our nation's preeminent research laboratories. We will also examine the various government agencies that have oversight responsibility for these programs, as well as

recommendations from organizations as to how to strengthen and improve our security at these laboratories while not unduly chilling innovation, research, and collaboration with our international allies.

The FBI recently concluded that the October 2001 anthrax attacks were carried out by a government scientist working at a biological research laboratory at Ft. Detrick, in my own state of Maryland. I have visited this military base on numerous occasions. The laboratory is the U.S. Army Medical Research Institute of Infectious Diseases, commonly known as USAMRIID.

Just last month, the Army broke ground on a new $680 million headquarters building for USAMRIDD, which will house the most cutting-edge research on dangerous biological organizations in the highest possible biosafety space, known as Bio-Safety Level 4, or BSL 4. This precaution is being used in order to protect the workers at Ft. Detrick and the surrounding community of Frederick, Maryland.

The laboratory will conduct research on the most deadly pathogens known to humankind, including anthrax, the plague, and the Ebola virus. I know that our Ft. Detrick employees have also been working to help the government to combat swine flu and the West Nile virus, among others.

Panel I of the hearing will examine the executive branch's current efforts to strengthen and improve biosecurity and biosafety at laboratories, including personnel reliability, physical and perimeter security, and inventory control. I look forward to hearing testimony from the Departments of Justice, Defense, and Homeland Security.

Panel II of the hearing will receive testimony from outside experts, including the recent report of the Commission on the Prevention of Weapons of Mass Destruction, chaired by the distinguished former Senator from Florida, Bob Graham, who also served as the Chairman of the Senate Intelligence Committee. We will also receive testimony from the Government Accountability Office and the Center for Health and Homeland Security at the University of Maryland at Baltimore.

I will now recognize Senator Kyl, the Ranking Member of our Subcommittee, for any remarks that he would care to make at this time.

INFORMATION FOR THE RECORD

Strengthening Security and Oversight at Biological Research Laboratories
Senate Committee on the Judiciary
Subcommittee on Terrorism and Homeland Security
October 16, 2009

Select Agent Program
Centers for Disease Control and Prevention (CDC)

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) (the Act) authorized the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant products (select agents).

HHS and USDA delegated the authority to establish regulations to implement the Act to the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), respectively. CDC and APHIS have implemented robust oversight of entities that possess, use, or transfer these agents. Entities[1] that possess, use, or transfer select agents must comply with the Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121).

A key consideration of the Select Agent Program is the need to balance the regulation of select agents with the promotion of laboratory research. The Act requires HHS and USDA to provide for appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

Roles and Responsibilities

The regulation of entities that possess, use and transfer select agents is a shared federal responsibility involving HHS, USDA, and the Department of Justice (DOJ).

- HHS/CDC regulates entities that possess, use and transfer select agents that have the potential to pose a severe threat to human health and safety. USDA/APHIS regulates entities that possess, use and transfer select agents that have the potential to pose a severe threat to animal or plant health, or animal or plant products. CDC and APHIS coordinate the regulatory authority for those entities that possess, use and transfer select agents that have the potential to pose a severe threat to both human and animal health. As of September 29, 2009, CDC and APHIS oversee 389 registered entities, from sectors including federal, state, and local government; university; commercial; and non-profit.

[1] Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

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- DOJ has the authority and responsibility to conduct electronic database checks (i.e., the security risk assessments) on entities that apply to possess, use, or transfer select agents, as well as personnel that require access to select agents and toxins. The Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS), has been delegated authority for conducting these security risk assessments.

Oversight

CDC in collaboration with USDA/APHIS promotes laboratory safety and security by inspecting entities that possess, use or transfer select agents; developing, implementing, and enforcing the Select Agent Regulations; and providing guidance to regulated entities.

- CDC has built a team of experienced inspectors with expertise in laboratory science and safety. Entities must apply to become registered with the Select Agent Program. Entities receive a comprehensive inspection to assess their biosecurity and biosafety practices at the time of application, and on at least a three-year cycle thereafter. CDC also inspects entities for registration renewals and registration updates when entities add a select agent, a new laboratory, or a new practice.

- In 2008, CDC expanded its inspection program to include unannounced and short notice inspections of registered entities. Entities are targeted for inspection for a variety of reasons, including investigation of a theft, loss, or release incident and verification that deficiencies noted during a routine inspection have been corrected.

- CDC has developed a Performance Improvement Plan (PIP) program to more rigorously engage with entities needing assistance in complying with the Select Agent Regulations. This program combines non-routine site visits with the development of a compliance plan by the entity. The compliance plan includes specific goals, milestones, and deadlines to be met in order to retain the entity's registration with the Select Agent Program. Since the initiation of this program in 2008, a compliance plan of action has been developed for 10 entities.

- When CDC identifies violations of the Select Agent Regulations, several types of enforcement actions can occur: administrative actions, referrals to the HHS Office of Inspector General (OIG), and referrals to the FBI. As of September 29, 2009, CDC has referred 51 entities to the HHS-OIG for apparent violation of the Select Agent Regulations. HHS-OIG has levied $1,997,000 in civil monetary penalties against 13 of these entities. CDC has suspended the registrations of two entities for violations of the Select Agent Regulations. One of these entities has worked with CDC to bring its safety and security programs into compliance with the Select Agent Regulations and its Certificate of Registration has been reinstated. We are currently working with the other entity to bring its programs into compliance. CDC has revoked one entity's registration.

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- While CDC's primary responsibility is enforcing the Select Agent Regulations, the Select Agent Program also promotes laboratory safety and security by providing technical assistance and guidance to registered entities.

- CDC has agreements to promote information-sharing with federal and state partners:
  - The Select Agent Program has a Memorandum of Understanding (MOU) with the Department of Homeland Security (DHS) to share information about registered entities and the agents they possess. DHS uses this information to identify potential risks and threats to laboratories working with select agents and to also take appropriate mitigating actions, which could include vulnerability assessments, site surveys, and the provision of DHS grant funds for enhanced security at these locations.
  - CDC shares select agent information with the FBI Weapons of Mass Destruction (WMD) Directorate to assist the FBI with investigations regarding potential misuse or illegal acquisition of select agents.
  - To help facilitate preparedness coordination efforts, CDC also has a process in place to share information with state officials about the registered entities in their jurisdictions.

Key Federal Partners

- United States Department of Agriculture, Animal and Plant Health Inspection Service
- Department of Justice, Criminal Justice Information Service
- Department of Homeland Security

Key Stakeholders (organizations/members that may be affiliated with the regulated entities)

- American Biological Safety Association
- American Society for Microbiology
- Association of Public Health Laboratories
- National Laboratory Response Network

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U.S. Senate Judiciary Committee
Subcommittee on Terrorism and Homeland Security
Hearing September 22, 2009

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

Mr. Chairman, Senator Kyl, and distinguished Members of the Subcommittee:

Thank you for the opportunity 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. 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.

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

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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.

But today, we are not talking about al Qaeda labs on the far side of the globe. We are talking about the security of our own labs here at home.

Enhanced Biosecurity Measures in U.S. Laboratories

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

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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 recently introduced by Senators Lieberman and Collins 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 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 their bill. Our primary objective, again, is to distinguish those pathogens that pose great danger from those that do not.

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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.

I 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 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

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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 last December, we "have too many agencies, too many turf fights, and unclear oversight entities." That must end.

We recognize that the recently introduced Lieberman-Collins bill 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.

To sum up, we recommend that the tiered-system proposed in the Lieberman-Collins bill be expanded to three tiers, not just one. 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.

I look forward to your questions.

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Testimony of

Michael Greenberger

Founder and Director
University of Maryland Center for Health and Homeland Security

and

Law School Professor
University of Maryland School of Law
500 West Baltimore Street
Baltimore, MD 21201

before the

Senate Committee on the Judiciary
Subcommittee on Terrorism and Homeland Security

on

"Strengthening Security and Oversight at Biological Research Laboratories"

Tuesday, September 22, 2009
Senate Dirksen Office Building Room 226
2:30 p.m.

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Tuesday, September 22, 2009
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2:30 p.m.

Introduction

I want to thank the Subcommittee for inviting me to testify on the important issue that is before it today.

I am the founder and director of the University of Maryland Center for Health and Homeland Security ("CHHS"), as well as a professor at the University of Maryland School of Law. CHHS is a university academic center with a staff of over 50 professionals that work side-by-side with the nation's top federal, state, and local public health and emergency responder institutions, assisting them in the development of plans, strategies and policies to ensure the safety of our citizens in the event of man-made or natural catastrophic events. A critical part of CHHS work consists of advising medical researchers developing countermeasures to biopathogens and highly infectious diseases on emergency operations planning, including those researchers at the Center for Vaccine Development at the University of Maryland of Medicine

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and at the Middle-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research ("MARCE"). MARCE is a fourteen-university consortium focusing on research to enable rapid defenses against bioterror and emerging infectious diseases, including Anthrax, West Nile Virus, Smallpox, and Cryptosporidiosis.

Summary

With the advent of the Anthrax attacks in the fall of 2001, this Nation has been confronted with a serious policy conundrum. On the one hand, we have strengthened programs that encourage the use of our best scientific resources to develop countermeasures to the weaponization of highly dangerous biopathogens. On the other hand, research on those countermeasures requires the use of the very biopathogens we seek to defeat. There have been many mishaps in the handling of those pathogens, which raises the frightening prospect that the research may be as (or more) dangerous than the potential bioterrorist acts themselves. Indeed, the very Anthrax attack that motivated increased research now seems likely to have been the caused by research being conducted in the United States on Anthrax. Leaving aside which researcher evaded security measures of the United States Army at its Ft. Detrick laboratory facility, the forensic evidence appears very strong that an "insider" accessed Anthrax at that facility to perpetrate the 2001 attacks.

It is the thesis of this testimony, that the Nation can upgrade security measures at those biosafety level ("BSL") laboratories that handle the most dangerous pathogens ("BSL-3" and "BSL-4" labs), so that federal government can develop countermeasures to potential terror attacks without having that research in and of itself pose a threat to national security. At the end of this testimony, we make recommendations in aid of such a policy. To put the recommendations in context, the testimony establishes the following foundational evidence: (1) a summary of statutory and regulatory mandates addressed to BSL-3 and BSL-4 labs; (2) a summary of leading reports that have been issued recommending improved biosecurity measures at those labs; (3) a brief description of biosafety mishaps at BSL-3 and BSL-4 labs that have provoked the controversy at hand; and (4) an examination of biosafety practices employed at the University of Maryland, Baltimore BSL-3 laboratories that deploy "best practices" for biosecurity. UMB's measures have successfully ensured safety within those laboratories, and may serve as a model for the operation of non-military biosafety laboratories in the United States.

We therefore recommend that this Subcommittee draft legislation that will: (1) replace the present fragmented federal agency oversight system for biosafety laboratories by creating consolidated oversight responsibilities within a single agency; (2) through this agency, establish an accreditation system for BSL laboratories to ensure that they are operated safely and securely; (3) establish a reporting system, which ensures that all laboratory mishaps are promptly reported

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to, and promptly reviewed by, the oversight agency so that the facts pertaining to these mishaps can be made available in a meaningful way to other laboratories in a "lessons learned" modality; (4) improve the process of personnel reliability assessments; and (5) recognize that a 'one-size fits all' model of compliance is too great a burden on most non-military BSL laboratories, and thus foster a private sector model of strong, but appropriate and practical, biosecurity procedures for those BSL labs.[1]

I. Background information

The October 2001 Anthrax attacks resulted in 11 cases of cutaneous anthrax, 11 cases of inhalational anthrax, 5 deaths and an overwhelming nationwide fear about public safety and the threat of biological attacks.[2] That episode sparked an increased scientific effort to develop medical countermeasures that could prevent or ameliorate the dispersion of biological agents that would likely be used as part of a terrorist attack.[3]

Prior to the 2001 Anthrax incident, the scientific and regulatory community concerns about improper handling of biological select agents used for research focused on possession, use and transport of those agents. However, as awareness of the highly dangerous threats posed by these agents emerged, the regulatory focus shifted to: (1) regulating access to the most deadly agents; (2) reporting security issues at laboratories where research on deadly agents was conducted; and (3) developing codes of conduct for these laboratories.[4] "Select Agents" were chosen by the Secretary of the United States Department of Health and Human Services ("HHS") and the Secretary of the United

[1] This testimony was prepared with the research and drafting help of Marita Mike, M.D., J.D. and CHHS Heath Director; Talley H.S. Kovacs, J.D., M.B.A. and CHHS Law & Policy Analyst; and Elizabeth Murray, Candidate for J.D. degree 2010 and CHHS Research Assistant. James Jaeger, PhD, Director of Environmental Health & Safety for the University of Maryland Baltimore (UMB) and Melissa A. Moreland, M.S., R.B.P., C.B.S.P., S.M., Assistant Director and Biosafety Director for UMB, provided extensive and valuable background and guidance on biosafety laboratory management in general and at UMB, the latter of which guidelines and practices are referenced below as a potential model for private biosecurity laboratory safety.

[2] Ronald Atlas, *Biosecurity concerns: Changing the face of academic research*, 12 JOURNAL OF CHEMICAL HEALTH AND SAFETY, at 15, 17 (2005), *available at* www.sciencedirect.com (last accessed Sept. 21, 2009).

[3] Yudhijit Bhattacharjee, *The Danger Within*, SCIENCE, Mar. 6, 2009 at 1283, *available at* http://www.sciencemag.org/cgi/content/full/323/5919/1282 (last accessed Sept. 21, 2009).

[4] Caitriona McLeish & Paul Nightingale, *Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy*, 36 RESEARCH POLICY 1635, 1641 (2007), *available at* www.sciencedirect.com (last accessed Sept. 21, 2009).

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States Department of Agriculture ("USDA") using criteria set out by statute.[5] The Select Agents identified pose high threats to human, plant and animal life because of their methods of transmission, potential for misuse, and toxicity.[6]

Since 2001, funding for biodefense research has substantially increased. In 2001 the National Institutes of Health Biodefense Research Funding totaled $25 million, but by 2005 had increased to $1.7 billion.[7] Funding for biodefense work increased to $50 billion and was either spent by, or allocated to, other federal agencies including the Department of Homeland Security ("DHS"), the Department of Defense ("DOD"), and the USDA.[8] The increased funding directly correlates to an increased number of researchers and laboratories working with deadly biological agents.[9]

The National Science Advisory Board on Biosecurity ("NSABB"), the Commission on the Prevention of WMD Proliferation and Terrorism ("the Commission") and the Government Accountability Office ("GAO") were independently charged with investigating different aspects of biosecurity at biosafety laboratories.[10]

Exposures and incidents at laboratories such as those at Texas A&M University have also drawn widespread attention to the safety and security in those laboratories.[11]

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[5] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. § 262a (2006) [hereinafter "PHBPA"]; *See also* 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* . 7 C.F.R. § 331 (2009) (relating to plants).

[6] *Id.*

[7] Atlas, *supra* note 2, at 16.

[8] *Id.*

[9] *Id.* at 15.

[10] Dennis Kasper, *Report to the NSABB: NSABB Working Group on Personnel Reliability: Preliminary Findings and Recommendations*, NATIONAL SCIENCE ADVISORY BOARD, December 2008, at slide 6, [hereinafter "Kasper"] *available at http://oba.od.nih.gov/biosecurity/nsabb_past_meetings.html#dec2008* (follow "*Personnel Reliability Working Group: Preliminary Findings and Recommendations*" hyperlink); U.S. Gov't Accountability Office, Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories, (2008), [hereinafter "BSL-4"], *available at* http://www.gao.gov/new.items/d081092.pdf (last accessed Sept. 21, 2009).

[11] Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response to Richard Ewing, Responsible Official, Texas A&M University (Aug. 31, 2007), [hereinafter Texas A&M] *available at* http://www.sunshine-project.org/TAMU/CDCTAMUReport.pdf (last accessed Sept. 21, 2009).

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II. Identified Problems

Based on review of the legislation and regulations regarding BSL-3 and BSL-4 laboratories, Select Agents;[12] the NSABB and GAO reports;[13] and reports of incidents and accidental exposures[14] the following problems in the biosecurity and biosafety protocols have been identified:

1. The regulatory structure for BSL-3 and BSL-4 laboratories is fragmented across several federal agencies.
2. Incident reporting of biosafety and biosecurity incidents at BSL- 3 and BSL-4 laboratories is not centralized.
3. Incident review does not produce protocol modification in a timely manner across all laboratories, thereby inhibiting collaboration on best practices.
4. Physical BSL laboratory facilities do not require accreditation.
5. Protocols that are in place to gauge personnel reliability could be improved. There is great interest in increasing personnel reliability within research laboratories, but to date, some compliance measures may be compromising the efficient production of social benefits gained from investigation of the Select Agents because of overly broad screening measures for personnel and a deterrent effect on potential hires.
6. The 'one-size fits all' model of compliance is too great a burden on most non-military level laboratories. Military laboratories have heightened security models, but military level security is not practical for university campuses. A private sector model of appropriate and practical biosecurity procedures for those BSL labs is needed.

III. Supporting Material

A. Pertinent Statutory Review: Oversight of BSL laboratories is fragmented across multiple agencies. Only statues most closely related to direct BSL research activities are reviewed below.

[12] PHBPA, *supra* note 5.

[13] Kasper, *supra* note 10; BSL-4, *supra* note 10.

[14] Texas A&M, *supra* note 11.

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1. Antiterrorism and Effective Death Penalty Act of 1996

The Antiterrorism and Effective Death Penalty Act of 1996 ("AEDPA") requires HHS to promulgate regulations to identify biological agents that pose a potential threat to public health and safety and to identify protocols governing the transfer of those agents.[15] Under the resultant regulations, the Centers for Disease Control and Prevention ("CDC") Laboratory Registration/Select Agent Transfer Program was established.[16]

The AEDPA addresses the possibility of weaponization of biological agents.[17] The regulations mandate that facilities safeguard these agents from individuals who might use them in acts of domestic or international terrorism by identifying hazardous biological agents and requiring registration of laboratories that transported hazardous biological agents.[18]

2. The PATRIOT Act.

The PATRIOT Act,[19] which was passed in October 2001, defines "Restricted Persons" who are statutorily ineligible for clearance from the Department of Justice

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[15] Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, § 511, 110 Stat. 1214 [hereinafter Antiterrorism Act]. (After the Oklahoma City bombing of the Alfred E. Murrah Building in April 1995, Congress passed the Antiterrorism and Effective Death Penalty Act of 1996 in October 1996. HHS delegated authority for operating the Laboratory Registration and Select Agents Tracking Program, a provision of the act, to CDC. Regulations under the act were promulgated under 42 CFR 72.6).

[16] *See* 42 C.F.R. §§ (2009) 73.1-73.21 as amended.

[17] Antiterrorism Act, *supra* note 15.

[18] *Id.*

[19] Genevieve J. Knezo, *Possible Impacts of Major Counter Terrorism Security Actions on Research, Development, and Higher Education*, Congressional Research Service Report, Apr. 8, 2002, at 19, *available at* http://74.125.113.132/search?q=cache:jVdHCeEo1gsJ:www.au.af.mil/au/awc/awcgate/crs/rl31354.pdf+critique+of+Sec.+511+of+the+Antiterrorism+and+Effective+Death+Penalty+Act+of+1996&cd=8&hl=en&ct=clnk&gl=us&client=firefox-a (stating "Section 817 of P.L. 107-56, the PATRIOT/USA antiterrorism act expanded the government's ability to prosecute persons suspected of possessing biological agents to be used for terrorist acts, and addressed some of the limitations perceived in the 1996 law. The PATRIOT Act amended the biological weapons statute to fine or imprison (for up to 10 years) a person who "knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.")

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("DOJ") to work with Select Agents.[20] A Restricted Person is an individual who is: under indictment, or has been convicted of a felony; a fugitive; an unlawful user of a controlled substance; an unlawful or illegal alien; a national of a country determined to sponsor or support terrorism; or a person who has been dishonorably discharged from the military or has been committed to a mental institution.[21] The PATRIOT Act does not provide exemptions from these criteria and no appeal process is in place for 'restricted person' determinations. Many medical research institutions have complained that the inability to exempt "foreign" researchers on a case-by-case basis has dramatically impeded the development of medical countermeasures necessary to combat terror attacks.[22]

Section 817 of the PATRIOT Act expands the government's ability to prosecute persons suspected of possessing biological agents to be used for terrorist acts, to fine or imprison (for up to 10 years) of a person who "knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose."[23]

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[20] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Pub. L. No. 107-56, § 817, 115 Stat. 272 (codified as amended 18 USC § 175b (2009) [herinafter PATRIOT Act] (The statute defines a 'restricted person' as one who''(A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;''(B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year''(C) is a fugitive from justice;''(D) is an unlawful user of any controlled substance(as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));''(E) is an alien illegally or unlawfully in the United States;''(F) has been adjudicated as a mental defective or has been committed to any mental institution;''(G) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section6(j) of the Export Administration Act of 1979 (50 U.S.C.App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section40(d) of chapter 3 of the Arms Export Control Act (22U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or ''(H) has been discharged from the Armed Services of the United States under dishonorable conditions.")

[21] *Id.*

[22] McLeish & Nightingale, *supra* note 4 at 1641. (*stating* "In 2005, 40 leading scientific societies and higher education associations released a joint statement calling for modifications to restrictions on foreign researchers because the US 'risk[s] irreparable damage to our competitive advantage in attracting international students, scholars, scientists, and engineers, and ultimately to our nations' global leadership.")

[23] PATRIOT Act, *supra* note 20.

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3. Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("PHBPA") requires HHS to establish and regulate a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety, it also expands the Select Agent regulations and imposes a registration obligation on all entities that possess, use, or transport Select Agents. The Select Agent regulations promulgated by both HHS and USDA (as required by PHBPA) are described in more detail below.

4. Agricultural Bioterrorism Protection Act of 2002.

The Agricultural Bioterrorism Protection Act of 2002 ("ABPA") requires the USDA to establish and regulate 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.[24] Both the PHBPA and the ABPA require the review and republication of the lists of Select Agents and toxins on at least a biennial basis.[25]

B. Regulations and Advisory Guidelines

1. Select Agent regulations

As directed by the PHBPA, HHS and USDA have expanded the Select Agent regulations to encompass possession and use of Select Agents; have requirements for their registration; require designation of an institutional Responsible Official; mandate implementation of security and safety measures to deter theft, loss, or release of Select Agents; require training of staff and record keeping, as well as the assessment of the security risk of all those who request access to the agents. [26] When adding a biological

[24] PHBPA, *supra* note 5.

[25] *Id*; Agricultural Bioterrorism Protection Act of 2002, Pub. L. No. 107-188, 116 Stat. 647 [hereinafter ABPA]; (The first publication of the Select Agents Regulations 42 C.F.R. § 73, 7 C.F.R. § 331, 9 C.F.R. § 121 in the Federal Register occurred on March 18, 2005. The Final Rules were published in the Federal Register on March 18, 2005 and became effective on April 18, 2005. The Animal and Plant Health Inspection Service (APHIS) and the Centers for Disease Control and Prevention (CDC) published final rules in the Federal Register on October 16, 2008 that complete the biennial review and republication of the lists of Select Agents and toxins. The Final Rules published on October 16 became effective on November 17, 2008).

[26] *See also* 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* 7 C.F.R. § 331 (2009) (relating to plants). The Select Agent Rules require that all entities that possess, use, or transport Select Agents must register with either the Centers for Disease Control and Prevention or the U.S.

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agent to the Select Agent list, HHS and USDA must consider: the effect of exposure on human health; the degree of contagiousness; availability of treatments or immunizations; and any other criteria particularly addressing the potential exposure of vulnerable populations.[27] If denominated as Select Agents, the biological agents must be registered with the National Select Agent Registry.[28] As of the last biennial review there were 36 Selected Agents listed by HHS, 24 by USDA and 10 overlapping agents where oversight authority and responsibility is shared between the two agencies.[29]

Department of Agriculture, that personnel who have access to these materials must undergo a Security Risk Assessment. There are civil and criminal penalties for non-compliance with the Select Agent Rules.

[27] PHBRA, *supra* note 5. (Criteria for placing an agent or toxin on the Select Agent Registry)

[28] National Select Agent Registry, http://www.selectagents.gov/index.html (last accessed Sept. 21, 2009).

[29] *See* http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html (last accessed Sept. 21, 2009) (HHS Select Agents and toxins: Abrin, Botulinum neurotoxins, Botulinum neurotoxin producing species of Clostridium, Cercopithecine herpesvirus 1 (Herpes B virus), Clostridium perfringens epsilon toxin, Coccidioides posadasii/Coccidioides immitis, Conotoxins, Coxiella burnetii, Crimean-Congo haemorrhagic fever virus, Diacetoxyscirpenol, Eastern Equine Encephalitis virus, Ebola virus, Francisella tularensis, Lassa fever virus, Marburg virus, Monkeypox virus, Reconstructed replication competent forms of the 1918, pandemic influenza virus containing any portion of the, coding regions of all eight gene segments (Reconstructed1918 Influenza virus), Ricin, Rickettsia prowazekii, Rickettsia rickettsii, Saxitoxin, Shiga-like ribosome inactivating proteins, Shigatoxin, South American Haemorrhagic Fever viruses, Flexal, Guanarito, Junin, Machupo, Sabia, Staphylococcal enterotoxins, T-2 toxin, Tetrodotoxin, Tick-borne encephalitis complex (flavi) viruses, Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever, Russian Spring and Summer encephalitis, Variola major virus (Smallpox virus), Variola minor virus (Alastrim), Yersinia pestis; Overlap Select Agents And Toxins: Bacillus anthracis, Brucella abortus, Brucella melitensis, Brucella suis, Burkholderia mallei (formerly Pseudomonas mallei), Burkholderia pseudomallei (formerly Pseudomonas pseudomallei), Hendra virus, Nipah virus, Rift Valley fever virus, Venezuelan Equine Encephalitis virus, USDA Select Agents And Toxins, African horse sickness virus, African swine fever virus, Akabane virus, Avian influenza virus (highly pathogenic), Bluetongue virus (exotic), Bovine spongiform encephalopathy agent, Camel pox virus, Classical swine fever virus, Ehrlichia ruminantium (Heartwater), Foot-and-mouth disease virus, Goat pox virus, Japanese encephalitis virus, Lumpy skin disease virus, Malignant catarrhal fever virus(Alcelaphine herpesvirus type 1), Menangle virus, Mycoplasma capricolum subspecies capripneumoniae (contagious caprine pleuropneumonia),Mycoplasma mycoides subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), Peste des petits ruminants virus, Rinderpest virus, Sheep pox virus, Swine vesicular disease virus, Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, Virulent Newcastle disease virus 1; USDA Plant Protection And Quarantine (Ppq) Select Agents And Toxins: Peronosclerospora philippinensis (Peronosclerospora sacchari), Phoma glycinicola (formerly Pyrenochaeta glycines), Ralstonia solanacearum race 3, biovar 2, Rathayibacter toxicus, Sclerophthora rayssiae var zeae, Synchytrium endobioticum, Xanthomonas oryzae, Xylella fastidiosa (citrus variegated chlorosis strain).

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There are three sets of relevant regulations: one promulgated by the CDC for the protection of public health[30]; and two promulgated by the Animal and Plant Health Inspection Service ("APHIS") relating to animals[31] and plants.[32] Both sets of regulations establish essentially the same requirements with regard to Select Agents, including: (1) agents must registered and an eligible official must be assigned responsibility for them; (2) access to them must be restricted; (3) a security plan must be put in place; (4) a biocontainment and biosafety plan must be put in place; (5) experiments with them must be restricted; (6) an incident response plan must be put in place; (7) biocontainment and security training must be provided; (8) transfers of the agents must be limited; (9) proper records must be maintained; (10) facility inspections by APHIS and/or CDC must be allowed; and (11) reports must be filed if agents are lost or stolen.[33]

2. Security Risk Assessments

Security Risk Assessments ("SRA") are mandated by the PHBPA, for every individual who seeks to work with Select Agents.[34] Using the criteria from the PATRIOT Act, the SRA is intended to preempt "Restricted Persons" from gaining access to these potentially harmful bioagents.[35] APHIS and CDC work with the Federal Bureau of Investigation's ("FBI"), Criminal Justice Information System ("CJIS") to identify individuals who should be precluded from gaining access to select agents and toxins.[36] The SRA most notably involves comparing an applicant's fingerprints against criminal and terrorist databases and must be renewed every five years.[37]

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[30] *See* 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* 7 C.F.R. § 331 (2009) (relating to plants).

[31] *See* 9 C.F.R. § 121 (2009) (relating to animals).

[32] *See* 7 C.F.R. § 331 (2009) (relating to plants).

[33] *See* 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* 7 C.F.R. § 331 (2009) (relating to plants).

[34] PHBPA, *supra* note 5.

[35] PATRIOT Act, *supra* note 20.

[36] For a list of the steps of the process of applying for a Security Risk Assessment see http://www.selectagents.gov/sra.html

[37] For a list of the steps of the process of applying for a Security Risk Assessment see http://www.selectagents.gov/sra.html

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The CDC notified the NSABB that recently the FBI has begun to bi-annually crosscheck approved individuals against specified databases to verify that the individuals have not slid into a restricted category.[38] This interim measure is crucial in maintaining a current accounting of all individuals involved in work with Select Agents and toxins given that applications for renewal are only due every five years. However, the FBI's interim crosscheck is not presently required by law or regulation.

Personnel screening processes differ between military and private sector research facilities. Some military research laboratories have instituted formal Personnel Reliability Programs ("PRP") –a more extensive screening process than that called for by SRA -- which may include a number of the following: extensive background checks, character references, security clearances, medical evaluations, psychological testing, drug and alcohol testing, polygraph examinations, credit checks and review of service or employment records.[39]

One reason for the marked difference between the military and non-military laboratories is that the PRP programs in military facilities are remnants of surety programs developed by the Department of Energy ("DOE") and DOD for research on chemical and nuclear weapons.[40] A culture of strict security has always been the norm in these facilities and so the PRP are not seen as a hindrance to the recruitment and retention of talented scientists. Conversely, most research on biological Select Agents is conducted in universities, which have a long history of openness and international collaboration. To these institutions, the more onerous PRP program elements might fundamentally change this cultural norm and inhibit the way university-level research is conducted without evidence of improved reliability above that emanating from strict enforcement of, for example, the SRA process.[41]

3. Centers for Disease Control and Prevention and National Institutes of Health ("NIH") Advisory Guidelines: *Biosafety in Microbiological and Biomedical Laboratories*, (5th ed.):

The advisory guidelines published by CDC and the NIH, *Biosafety in Microbiological and Biomedical Laboratories*, ("BMBL guidelines") delineate biosafety

[38] Disclosed during a Public Consultation on the Draft Report held on April 3, 2009 in Bethesda, MD. More information can be found at http://oba.od.nih.gov/biosecurity/biosecurity.html (last accessed Sept. 21, 2009).

[39] Kasper, *supra* note 10, at 4.

[40] Kasper, *supra* note 10, at 5.

[41] *Id.*

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and biosecurity protocols for laboratories depending on the threat posed to laboratory staff and scientists as well as surrounding communities.[42]

a. Biosafety Level Designations:

The BMBL guidelines delineate four biosafety levels ("BSL") in order of ascending levels of containment.[43] At each level, an appropriate containment procedure is prescribed with reference to specific facility safeguards, safety equipment and microbiological practices. BSL-3 and BSL-4 protocols require heightened oversight of security procedure because of the dangerous nature of the agents and toxins examined in those facilities.[44]

1. **Biosafety Level 1** is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and that present minimal potential hazard to laboratory personnel and the environment.[45]

2. **Biosafety Level 2** builds upon BSL-1 protocols. BSL-2 designation is suitable for labs whose work involves agents that pose moderate hazards to personnel and the environment.[46]

3. **Biosafety Level 3** is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause *serious or potentially lethal disease* through inhalation route exposure.[47] Examples of agents handled and stored in BSL-

[42]U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, The National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, at 3 (5th ed., U. S. Government Printing Office, 2007) (1984), *available at* http://www.cdc.gov/od/ohs/. [hereinafter "BMBL guidelines"] (According to the CDC and NIH, biosafety considerations include: "infectivity, severity of disease, transmissibility, and the nature of the work being conducted" as well as the agent's origin. These are the "primary risk criteria used to define the four ascending levels of containment, referred to as biosafety levels 1 through 4.")

[43] *Id.* at 17

[44] The United States Army Medical Research Institute for Infectious Diseases located at Fort Detrick, MD has a facility housing laboratories of both biosafety levels. Joe Pappalardo, "Virus Hunters: Inside Maryland's New Biosafety Level 4 Lab" Popular Mechanics, May 209 *available at*: http://www.popularmechanics.com/science/health_medicine/4315093.html?page=1 (stating: "The outer area is the medical research equivalent of a maximum-security prison- Biosafety Level 3. The inner sanctum is supermax or BSL-4.") (last accessed Sept. 21, 2009).

[45] BMBL guidelines, *supra* note 34, at 41.

[46] *Id.* at 44.

[47] *Id.* at 49.

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3 laboratories include: Tuberculosis and St. Louis Encephalitis virus.[48] In addition to the standard microbiological practices employed in BSL-1 and 2 laboratories, BSL-3 laboratories are encouraged to control access to the facility, to decontaminate all waste and laboratory clothing, to conduct all work with agents in a Class I or II Biological Safety Cabinets (BSC) and to regulate air flow in and out of laboratory.[49]

4. **Biosafety Level 4** is required for work with dangerous and exotic agents that pose *a high individual risk of life-threatening* disease, that are contagious by aerosol transmission, or any related agents with unknown risks of transmission.[50] Examples of these types of biological agents include: foot and mouth disease; the Ebola virus; and smallpox. All work with these agents must either be conducted in a "Suit Laboratory" or a "Cabinet Laboratory" to protect the employees and the surrounding community from exposure.[51]

b. Biosecurity Requirements

Biosecurity has been defined as protection of microbial agents from loss, theft, diversion, or intentional misuse.[52]

Apart from the Select Agent regulations, there is no current federal requirement for the development of a biosecurity program, as distinct from a biosafety program at any of the BSL-1 through BSL-4 laboratories.[53] The Select Agent regulations require that a biosecurity plan exist, but they do not establish the specific components of the plan. All biosafety and biosecurity measures not directly related to required registration or

[48] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, The National Institutes of Health, HHS Publication No. (CDC) 93-8395, *Biosafety in Microbiological and Biomedical Laboratories* at 42 (3rd ed., U.S. Government Printing Office, 1993) (1984), *available at* http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl3toc.htm (last accessed Sept. 21, 2009).

[49] BMBL guidelines, *supra* note 34, at 50-56 (Biological safety cabinets provide personnel, environmental and product protection through air flow management and decontamination techniques).

[50] *Id.* at 56.

[51] *Id.* at 57. ("A Cabinet Laboratory where all handling of agents must be performed in a Class III BSC. A Suit Laboratory where personnel must wear a positive pressure protective suit.")

[52] *Id.* at 118.

[53] The Select Agent Regulations are 42 C.F.R. § 73 (2009) (relating to public health), 9 C.F.R. § 121 (2009) (relating to animals), 7 C.F.R. § 331 (2009) (relating to plants).

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reporting in biomedical and microbiological laboratories are principally governed by the BMBL *advisory guidelines*.[54]

The BMBL guidelines recommend that facilities engage in a two-part approach to biosecurity considerations.[55] First, the facility should conduct a risk assessment to determine if it has any agents that require biosecurity measures to prevent loss, theft, diversion, or intentional misuse.[56] Secondly, the facility should conduct a cost-benefit analysis to determine if the costs of additional precautions would be proportional to the risk of exposure to the agents used and stored in the laboratories.[57] The guidelines ultimately establish ten elements that might be incorporated into a biosecurity program, should a facility determine that it is necessary.[58] *The BMBL guidelines are explicit in noting that the biosecurity program elements are not to be viewed as legally binding minimum standards or requirements.*

C. Ancillary Statutes and Regulations

Multiple departments and statues are involved in oversight of Select Agents, due in part to fragmentation of the regulatory scheme regarding BSL laboratories, and in part to the scope of operations which could be involved in BSL research. While a comprehensive listing and review of each applicable statute, regulation, and guideline of be impractical for the scope of this testimony, a few are listed below to illustrate the broad nature of potentially applicable law and practice.

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[54] BMBL guidelines, *supra* note 34.

[55] *See, id.*, at 188-27.

[56] *Id.* at 121 ("[T]he entire risk assessment and risk management process may be divided into five main steps, each of which can be further subdivided: 1) identify and prioritize biologicals and/or toxins; 2) identify and prioritize the adversary/threat to biological and/or toxins; 3) analyze the risk of specific security scenarios; 4) design and develop an overall risk management program; 5) regularly evaluate the institution's risk posture and protection objectives.").

[57] *Id.* at 120 ("Resources are not infinite. Biosecurity policies and procedures should not seek to protect against every conceivable risk. The risks need to be identified, prioritized and resources allocated based on that prioritization. Not all institutions will rank the same agent at the same risk level. Risk management methodology takes into consideration available institutional resources and the risk tolerance of the institution.)

[58] *Id.* at 123-27 (The elements suggested for inclusion into a biosecurity program include: program management, physical security, personnel management, inventory and accountability, information security, transportation, accident response plans, reporting and communication procedures, training and practice drills, and security updates.).

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1. NIH Guidelines For Research Involving Recombinant DNA Molecules – April 2002[59]
2. Hazardous Materials Regulations[60]
3. International transport regulations including those of International Maritime Organization, and the International Maritime Dangerous Goods (IMDG) Code[61]
4. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction[62]

D. Recent Reported Incidents of Non-Compliance At BSL Laboratories:

Select events are discussed below for illustrative purposes.

1. ANTHRAX: Fort Detrick

Bacillus anthracis ("Anthrax"), designated alternately as a BSL-2 or 3 agent depending on application, was the biopathogen responsible for 5 deaths and increased fear regarding public safety when it was dispersed though the United States Postal Service ("USPS") in 2001.[63] After nearly seven years of investigation, there is substantial evidence that the origin of the Anthrax mailings – and possibly the perpetrator – emanate from the BSL laboratory at U.S. Army Medical Research Institute for

[59] Department of Health and Human Services, National Institutes of Health, Guidelines for Research Involving Recombinant DNA Molecules, (April 2002) [hereinafter NIH Guidelines] available at: http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf (last accessed Sept. 21, 2009).

[60] Hazardous Material Regulations, 49 C.F.R. §§171-180 (2009) (relating to the safe and secure transportation of hazardous materials in commerce).

[61] International Maritime Dangerous Goods Code, January 1, 2004, *available at*: http://www.imo.org/Safety/mainframe.asp?topic_id=158#1 (last accessed Sept. 21, 2009) (The implementation of the Code is mandatory in conjunction with the obligations of the members of United Nation Government under the International Convention for the Safety of Life at Sea and the International Convention for the Prevention of Pollution from Ships (MARPOL 73/78)).

[62] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, March 25, 1975, 26 U.S.T. 583, 1015 U.N.T.S. 163, (Under the treaty, the Department of Commerce imposes export controls over certain microorganisms, toxins, biological equipment, and related technology to further U.S. foreign policy interests in opposing the proliferation and use of biological weapons.)

[63] Atlas, *supra* note 2, at 17.

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Infectious Diseases, Fort Detrick, Maryland ("USAMRIID").[64] Dr. Bruce Ivins, an Army researcher at USAMRIID, suspected in the attacks, committed suicide before officially being officially charged. Because of Ivins' death, the government will not be able to present its case in court. According to Assistant Director in Charge Joseph Persichini at the FBI's Washington Field Office, "Bruce Ivins was responsible for the death, sickness, and fear brought to our country by the 2001 anthrax mailings."[65]

Of note, Dr. Bruce E. Ivins, was cleared for his work with Anthrax at Fort Detrick through though their security process.[66] There has been substantial debate whether Dr. Ivins was the perpetrator. Irrespective of the guilt or innocence of Dr. Ivins, strong scientific evidence has been developed that the Anthrax strain used in the attacks came from the laboratory. Another lesson learned from the Anthrax attacks in October 2001 is that protocols to ensure the reliability of personnel can never wholly eliminate the risk of misuse, loss or theft of dangerous biological agents due to inherent human imperfection and inability to pre-screen an individual's intent.[67] Biosecurity must therefore now be deemed as important as biosafety in keeping employees and the public secure in terms of malignant use of these agents.

2. BRUCELLA: Texas A&M University

In April of 2007, the CDC reviewed Texas A & M University's ("Texas A & M") facilities and safety protocols and found that Texas A & M was guilty of a dozen violations.[68] The review was conducted in response to a notification from a source outside Texas A & M facilities, regarding a February 2006 occupational exposure to Brucella, a BSL-3 pathogen.[69] In particular, the exposed lab worker was experienced in handling *M.*

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[64] Press Release, Federal Bureau of Investigation, Anthrax Invesitgation: Closing a Chaper (Aug. 6, 2008), *available at* http://www.fbi.gov/page2/august08/amerithrax080608a.html (last accessed Sept. 21, 2009); Press Release, Federal Bureau of Investigation, Science Briefing on the Anthrax Investigation (Aug. 18, 2008), *available at* http://www.fbi.gov/page2/august08/anthraxscience_081808.html (last accessed Sept. 21, 2009).

[65] *Id.*

[66] Bhattacharjee, *supra* note 3, at 1283.

[67] Kasper, *supra* note 10.

[68] Texas A & M violated multiple provisions of 42 C.F.R. § 73 (2007), including §§ 73.7, 73.9, 73.10, 73.11, 73.12, 73.15, 73.17, and 79.19. Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response to Richard Ewing, Responsible Official, Texas A&M University (Aug. 31, 2007); Letter from John W. O'Brien, Senior Counsel, Office of Inspector General to Eddie J. Davis, Interim President, Texas A&M University; Letter from Eddie J. Davis, Interim President, Texas A&M University to John W. O'Brien, Senior Counsel, Office of Inspector General (Aug. 17, 2007).

[69] The CDC conducted a site visit of Texas A & M on April 16 through 18, 2007 to review the events surrounding the exposure to Select Agent, *Brucella*, on February 9, 2006. The exposure occurred because a laboratory worker,

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tuberculosis ("TB") and had been trained to work safely with that agent. Exposure occurred while working with Brucella in a manner which would have proven safe with TB however she was not trained to work with Brucella and the safety procedures she applied were insufficient for this agent.[70] Texas A & M violations included broad access to Select Agents by employees who were not unauthorized to work with the agents, multiple biosafety infarctions, and inadequate record keeping.[71] In order to protect public health and safety, the Director of the CDC ordered Texas A & M to stop all work with Select Agents until they complied with the Select Agent regulations.[72] In 2008, a settlement agreement between Texas A & M and HHS culminated in payment of $1 million by Texas A & M. Texas A & M accepted responsibility for the lapses noted in the CDC investigation.[73]

3. SHIGELLA: University of Texas at Austin

Between 2002 and 2007, as a result of inquiry from NIH, University of Texas at Austin ("UT-Austin") began a systemic review of all laboratory incidents and adverse

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who was working with *Brucella*, was not trained to handle the agent. Letter from John W. O'Brien, Senior Counsel, Office of Inspector General to Eddie J. Davis, Interim President, Texas A & M University (July 18, 2007).

[70] U.S. Gov't Accountability Office, High-Containment Biosafety Laboratories: Preliminary Observations on the Proliferation of BSL-3 and BSL-4 Laboratories in the United States: Statement of Keith Rhodes (2007), at 19.

[71] Jennifer Couzin, Texas University Responds to Biosafety Complaints, ScienceNOW Daily News, Sept. 6, 2007, *available at* http://sciencenow.sciencemag.org/cgi/content/full /2007/906/1 (last accessed Sept. 21, 2009); U.S. Gov't Accountability Office, HIGH-CONTAINMENT BIOSAFETY LABORATORIES: Preliminary Observations on the Oversight of the Proliferation of the BSL-3 and BSL-4 Laboratories in the United States, GAO-08-108T, 15-20 (Washington, D.C. Oct. 4 2007); Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response to Richard Ewing, Responsible Official, Texas A&M University (Aug. 31, 2007).

[72] Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response to Richard Ewing, Responsible Official, Texas A&M University (Aug. 31, 2007) (following a site visit by CDC representatives on June 30, 2007, the Director of the CDC extended the April 20, 2007 cease and desist order to include all work with Select Agents and toxins at Texas A & M University until the problems were corrected and compliance with the Select Agent regulations was achieved); Press Release, Texas A&M University, Vaccine Research Update (Feb. 20, 2008) *available at* http://vaccineresearch.tamu.edu/news-release.html (last accessed Sept. 21, 2009) (Texas A&M agreed to a $1 million settlement with the Office of the Inspector General at the U.S. Department of Health and Human Services).

[73] Press Release, Federal Bureau of Investigation, Anthrax Invesitgation: Closing a Chaper (Aug. 6, 2008), *available at* http://www.fbi.gov/page2/august08/amerithrax080608a.html (last accessed Sept. 21, 2009); Press Release, Federal Bureau of Investigation, Science Briefing on the Anthrax Investigation (Aug. 18, 2008), *available at* http://www.fbi.gov/page2/august08/anthraxscience_081808.html (last accessed Sept. 21, 2009).

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events occurring between 2000 and 2007.[74] Thirteen laboratory incidents occurred at UT-Austin, including five incidents of exposure to *Shigella,* a BSL-2 agent.[75] All workers recovered without incident.[76] As a result, UT-Austin "undertook a thorough revision of laboratory policies and procedures with an emphasis on surveillance, inspection, training, incident reporting and incident response," and developed and implemented additional safety and laboratory procedures.[77]

4. VACCINA virus in SMALLPOX Research: Philadelphia

In Philadelphia, at an unnamed research institution, an immunology graduate student was exposed to Vaccina, a BSL-2 agent[78] and developed an eye infection resulting in her hospitalization.[79] The review of the laboratory practices revealed lax practices affording manifold opportunities for virus exposure, including: infrequent use of eye protection when working with smallpox; failure to disinfect waste pipettes prior to their removal from the biosafety cabinet; and removal of samples from the biosafety cabinet for experiments and use in other parts of the facility.[80]

5. Foot and Mouth Disease – Pirbright, UK

While not a US incident, this incident is an excellent example for the necessity of facility maintenance, so it will be covered here.

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[74] Press Release, University of Texas at Austin, Statement Concerning Laboratory Incident Review at The University of Texas at Austin (Sept. 18, 2007) *available at* http://www.utexas.edu/news/2007/09/18/lab/ (last accessed Sept. 21, 2009).

[75] *Id.*

[76] *Id.*

[77] *Id.* (The procedures developed by the U. Texas at Austin included training, implementing a rapid response team to report incidents immediately, the University's Institutional Biosafety Committee was given more resources to ensure research is done safely, and surveillance measures were upgraded).

[78] The vaccinia virus is the "live virus" used in the smallpox vaccine. Department of Health and Human Services: Centers for Disease Control and Prevention, Smallpox Fact Sheet: The Live Virus Smallpox Vaccine (2002), http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/live-virus.pdf (last accessed Sept. 21, 2009).

[79] Felicia Lewis, et al., *Dispatch: Ocular Vaccinia Infection in Laboratory Worker*, 12 EMERGING INFECTIOUS DISEASES 134 (Jan. 2006), *available at* http://www.cdc.gov/ncidod/EID/vol12no01/pdfs/05-1126.pdf (last accessed Sept. 21, 2009).

[80] *Id.*

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In 2007, livestock infected with Foot and Mouth Disease, a highly infectious BSL -4 agent, was discovered at several local farms near Pirbright in the UK.[81] Investigation into high containment labs at Pirbright found evidence of long term damage and leakage to the drainage system servicing the site. The resulting exposure was suspected to have been secondary to contaminated waste water leaching into soil then carried off-site by vehicles via contaminated mud. The event cost taxpayers over £3 billion.[82]

E. Government Sponsored Reports:

As a result of a one or more of the episodes described above, several investigative studies were undertaken to evaluate biosecurity risks. We summarize some of the major studies below. The reports highlighted have been selected to reflect key points that are raised in this testimony and are not intended to be exhaustive of the literature on the issues.

1. National Science Advisory Board for Biosecurity: Enhancing Personnel Reliability among Individuals with Access to Select Agents[83]

In the October of 2008, the White House asked the NSABB[84] to consider whether a national PRP should be mandated for the nation's academic, government and private research facilities that handle Select Agents.[85] In April 2009, NSABB produced a draft report recommending security improvements at non-military research facilities whose

[81] U.S. Gov't Accountability Office, High-Containment Biosafety Laboratories: Preliminary Observations on the Proliferation of BSL-3 and BSL-4 Laboratories in the United States: Statement of Keith Rhodes (2007), at 22-23.

[82] *Id.*

[83] National Science Advisory Board for Biosecurity, Report: Enhancing Personal Reliability Among Individuals with Access to Select Agents, (May 20, 2009) [hereinafter NSABB Draft Report] *available at:* http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf (last Sept. 21, 2009).

[84] The National Science Advisory Board for Biosecurity is chartered by the Department of Health and Human Services to "provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security." NSABB advises the Secretary of the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the heads of all federal departments and agencies that conduct or support life science research. 42 U.S.C.§ 217a; The NSABB is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees. Information about NSABB *available at* http://oba.od.nih.gov/biosecurity/about_nsabb.html (last accessed Sept. 21, 2009).

[85] Bhattacharjee, *supra* note 3, at 1283.

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employees have access to Select Agents, but it explicitly rejected the need for promulgation of a formal, national PRP.[86] The challenge before regulators, as identified by NSABB, is to address the risk of an "insider threat" to BSL-4 facilities without unduly hindering the pace of research on biological agents that could be misused against the American public in a bioterrorist attack.[87] NSABB concluded that a national PRP would have "unintended and detrimental consequences for the scientific enterprise that in the future could result in more harm to public health and safety and to national security than an insider threat poses."[88]

NSABB found that local institutions,[89] meaning non-miltary institutions, have significantly increased security protocols under the existing select agent program; that there is little evidence that supports the predictive value of additional assessments of individuals; and that institutional leadership is often the most effective way to mitigate the risk of an "insider threat".[90] NSABB specifically considered the merit of requiring facilities to use three commonly used personnel reliability assessments: psychological testing, national security clearances, and medical examinations.[91] Due to concerns over cost, efficacy, and deterrent effect, NSABB did not recommend adopting any of these as mandates for facilities doing research on Select Agents.[92] NSABB ultimately recommended strengthening the SRA procedure; institutional enhancement of a culture of responsibility and accountability; and a reduction or stratification of the list of Select Agents.[93]

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[86] NSABB Draft Report, *supra* at 83.

[87] *Id.* at 1.

[88] NSABB Report, *supra* note 83, at v.

[89] NIH: Office of Biotechnology Activities, Presentation: Institutional Biosafety Committees: The Linchpin of Local Oversight, at 2, *available at*: oba.od.nih.gov/oba/IBC/ASGT_2007_Training/IBCs.pdf (last accessed Sept. 21, 2009).

[90] NSABB Draft Report, *supra* note 83, at 8.

[91] NSABB Draft Report, *supra* note 83, at 9-10.

[92] *Id.*

[93] NSABB Draft Report, *supra* note 83, at 13-15.

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2. Commission on the Prevention of WMD Proliferation and Terrorism[94]: World at Risk[95]

Congress tasked The Commission on the Prevention of WMD Proliferation and Terrorism ("the Commission") to assess the Nation's activities, initiatives and programs to prevent weapons of mass destruction proliferation and terrorism.[96] The Commission focused their study on what has been perceived as the greatest threats to national security: biological and nuclear attacks. With regard to biological threats, the Commission advanced many recommendations including conducting "a comprehensive review of the domestic program to secure dangerous pathogens" and tightening "government oversight of high–containment laboratories".[97] The Commission noted the absence of a comprehensive regulatory framework and found that "no single entity in the executive branch is responsible for overseeing and managing the risks associated with all the high-containment (BSL-3) laboratories operated by the U.S. government, industry, or academia."[98]

3. Government Accountability Office: BIOSAFETY LABORATORIES: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories[99]

This GAO report specifically addressed perimeter security of the five operational BSL-4 laboratories in its report issued in September 2008. Perimeter security was assessed pursuant to 15 security controls that GAO identified.[100] GAO concluded that two of the five BSL-4

[94] Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110-53,§1851, 121 Stat. 266, 502. Through House Resolution 1, Congress established the bipartisan Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism to address the threat that the proliferation of weapons of mass destruction poses to the United States. The Commission was directed to conduct an assessment of current activities and programs related to the threat of proliferation and to make recommendations to strengthen preventive efforts.

[95] Bob Graham, et. al, World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism (Vintage Books: A Division of Random House, Inc. 2008).

[96] *Id.* at xi.

[97] *Id.* at 27.

[98] *Id.* at 25.

[99] U.S. Gov't Accountability Office, Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories, (2008), *available a t* http://www.gao.gov/new.items/d081092.pdf (last accessed Sept. 21, 2009).

[100] *Id.* at 14 (stating "(1) Outer/tiered perimeter boundary; (2) blast Stand-off area 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 lab; (6) command and control center; (7) CCTV

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laboratories had significant shortfalls in security controls that could be expected to preclude unauthorized access, loss or theft of select agents.[101] HHS commented on this report noting that the CDC will, in coordination APHIS, seek input from relevant stakeholders about the need and advisability of Federal regulation regarding specific perimeter controls.[102]

4. Government Accountability Office: HIGH CONTAINMENT BIOSAFETY LABORATORIES: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States 2007[103]

This GAO report addresses preliminary observations on the oversight of high containment laboratories. The report identifies lessons learned from past exposure events and specifically raises the issue that no single federal agency has the mission and therefore, is accountable for all BSL labs.[104] The GAO concludes that reporting barriers must be overcome in order to enhance biosafety though shared learning from past mistakes and to assure the public that accidents are examined and contained.[105] This report also emphasizes the critical importance of facility maintenance in preventing environmental exposure and contamination as clearly demonstrated in the Pirbright exposure.[106]

F. University of Maryland, Baltimore: A Laboratory Biosecurity Model

While there are many examples of biosecurity failures with regard to BSL laboratories, many private institutions have established model procedures to assure that mishaps are prevented. I have had the good fortune to work closely with laboratory researchers on our own campus, the University of Maryland Baltimore ("UMB"), where successful protocols have been put in place that meet and exceed federal requirements.

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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; (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; and (15) visitor screening.

[101] *Id.*

[102] *Id.* at 19.

[103] U.S. Gov't Accountability Office, High-Containment Biosafety Laboratories: Preliminary Observations on the Proliferation of BSL-3 and BSL-4 Laboratories in the United States: Statement of Keith Rhodes (2007), at 19.

[104] *Id.* at 7.

[105] *Id.* at 7-8.

[106] *Id.* at 8.

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UMB is one of thirteen schools in the University of Maryland System. The campus is comprised of professional and graduate schools including: Medicine, Pharmacy, Dentistry, Nursing, Law, and Social Work. There are approximately 6000 students and 5000 staff and faculty. In the fiscal year 2008, UMB was awarded over $450 million in grants for research conducted in its 1500 laboratories. Among these laboratories are a BSL-3 suite with numerous laboratories and multiple animal BSL-3 laboratories. UMB has used the 5th edition of the *Biosafety in Microbiological and Biomedical Laboratories* ("BMBL") manual (described above) to draft its own BSL-3 Safety Manual. This manual is designed to protect researchers from contamination by the biological agents used in the laboratory, as well as protect the campus at large from accidental exposures to those agents.

1. UMB Biosecurity Measures:

The UMB, Department of Environmental Health and Safety recognized the need to develop a comprehensive, interactive course to cover issues of laboratory safety operations training for BSL-3 laboratories.[107] The UMB laboratories employ strict measures to protect the employees, staff, and surrounding community from exposure to the select agents and toxins used in its research laboratories. In fifteen years, the UMB has not experienced an instance or attempt of theft of select agents or hazardous materials or a loss or release from a UMB facility.[108]

The CDC and APHIS Select Agent regulations require that the facilities maintain a security plan that establishes policy and procedures to ensure the security of areas containing select agents and toxins.[109] Every facility working on Select Agents within UMB conducts an annual security risk assessment, event-based assessments, employs key card and/or security guard challenges at every entrance, and maintains secure file storage for all research documentation.[110] As recommended by the BMBL guidelines, UMB has a comprehensive approach to security planning including: annual personnel training accompanied by tests to demonstrate understanding; annual tests of the security, biosafety, and incident response plans; physical security including at least three distinct

[107] University of Maryland, Baltimore, Environmental Health and Safety, BSL-3 Training Course, http://www.ehs.umaryland.edu/Biosafety/bsl3course.cfm (last accesed Sept. 21, 2009).

[108] Interview with Melissa A. Morland, Biosafety Officer, University of Maryland, Baltimore, in Baltimore, Md. (Sept. 17, 2009).

[109] 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* 7 C.F.R. § 331 (2009) (relating to plants).

[110] Interview with Melissa A. Morland, Biosafety Officer, University of Maryland, Baltimore, in Baltimore, Md. (Sept. 17, 2009)

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levels of physical barriers; accountability of leadership for vigilant oversight of security protocols; unannounced audits of records and access logs; escorts for non-SRA UMB staff, *i.e.*, maintenance and housekeeping staff; strict intra-University and external transport guidelines; annual reviews; and drills and exercises.[111]

Additionally, UMB has a certified biosafety professional as their biosafety officer.[112] This additional level of training is not mandated of the biosafety officer; however the UMB has chosen to have this additional credentialed professional as the biosafety officer for the team.

IV. Recommendations

1. PROBLEM: The regulatory structure for BSL level 3 and 4 laboratories is fragmented across several federal agencies.

   Recommendation: The PHBPA and the ABPA grant oversight for select agents to the HHS and USDA respectively.[113] Additionally agents, which overlap the human, animal, and plant categories because of their potential to impact each species, can be registered with either agency.[114] Recombinant DNA research is additionally covered by NIH guidelines.[115] Depending on the nature of the action, multiple other agencies and regulations may also be involved.

   One federal agency should provide oversight for laboratories handling BSL-3 and BSL- 4 labs. The CDC and APHIS are tasked with similar oversight responsibilities under the PHBPA; however, it is apparent that the CDC may be in a better position to enforce the Select Agent regulations as primary regulator. In recent testimony to Congress by the Inspector General of the USDA, it was reported that APHIS still had not ensured that entities were fully complying with regulations regarding security plans; restricting access to select agents; training individuals authorized to possess,

[111] BMBL guidelines, *supra* note 42, at 123.

[112] University of Maryland, Baltimore, Environmental Health and Safety, Biosafety, http://www.ehs.umaryland.edu/Biosafety/index.cfm (last accessed Sept. 21, 2009).

[113] PHBPA, *supra* note 5.

[114] ABPA, *supra* note 25.

[115] NIH Guidelines For Research Involving Recombinant DNA Molecules – April 2002, *available at* http://oba.od.nih.gov/oba/index.html (last accessed Sept. 21, 2009).

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use, or transfer the agents; and maintaining current and accurate inventories."[116] The CDC appears to have a more developed Select Agent enforcement program evidenced by thirteen enforcement suits brought between 2004 and 2009.[117]

2. PROBLEM: Incident reporting of biosafety and biosecurity incidents at BSL-3 and BSL-4 laboratories is not centralized.

   Recommendation: Again, oversight for select agents is assigned to the HHS and USDA respectively.[118] Additionally agents that overlap categories can be registered with either agency.[119] Incident reporting for BSL-3 non-Select Agents is not required, though laboratories such as those at UMB do track incidents regarding Non-select agents internally.

   One federal agency, charged with oversight, should receive all reports of incidents of loss, theft, or misuse regarding BSL-3 and 4 labs, regardless of whether a Select or non-select Agent is involved.

3. PROBLEM: Incident review does not produce protocol modification in a timely manner across all laboratories, thereby inhibiting collaboration on best practices.

   Recommendation: Incidents should be reported promptly to one centralized agency for BSL-3 and 4 laboratories. Reports should be regularly reviewed on a timely basis. The review should not be punitive in nature and should be geared towards improving security and safety across labs. The review should be expeditiously shared with all BSL-3 and 4 institutions, so that investigators working with these agents can learn from each other and share solutions in an organized manner.

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[116] U.S. Department of Agriculture, Office of Inspector General, Southeast Region, Audit Report Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations Phase II Report, Report No. 33601-3-AT, at 4 (Washington D.C. January 2006) *available at* http://www.usda.gov/oig/webdocs/33601-3-AT.pdf (last accessed Sept. 21, 2009) (In subsequent audit reports to Congress in fiscal years 2007-2009, the Inspector General did not address the Select Agent Program.).

[117] U.S. Dep't of Health and Human Services, Officer of Inspector General, Select Agents and Toxins, http://oig.hhs.gov/fraud/enforcement/cmp/agents_toxins.asp (last accessed Sept. 21, 2009).

[118] PHBPA, *supra* note 5.

[119] ABPA, *supra* note 25.

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4. PROBLEM: Physical BSL laboratory facilities do not require accreditation.

   Recommendation: Each laboratory is subject to inspection and site visits to assess compliance with the Select Agent regulations.[120] *Surprisingly, facilities no not require accreditation.* The Pirbright incident demonstrated that beyond initial design and construction, ongoing facility maintenance plays a critical role in ensuring the safety and security of high exposure labs over time.[121] This is critical to preventing environmental exposure and disease spread. Each laboratory facility should be accredited to assure uniform standards for biosafety and biosecurity across institutions. Accreditation should require periodic review and assessment.

5. PROBLEM: Protocols that are in place to gauge personnel reliability can be improved. There is great interest in increasing personnel reliability within research laboratories, but to date, some compliance measures may be compromising the efficient production of social benefits gained from investigation of the Select Agents because of overly broad screening measures for personnel and a deterrent effect on potential hires.

   Recommendation:

   1. There is an interest in increasing personnel reliability. There is also reluctance to compromise research efficiency and place additional budgetary strain on BSL research laboratories. Practical improvements to improve personnel reliability should be implemented, including:

      - Improve the SRA to achieve more stringent screening while not imposing the onerous process of a formal PRP. This improvement is aligned with the recommendations of the NSABB.[122]

[120] 42 C.F.R. § 73 (2009) (relating to public health), *See also* 9 C.F.R. § 121 (2009) (relating to animals), *See also* 7 C.F.R. § 331 (2009) (relating to plants).

[121] U.S. Gov't Accountability Office, High-Containment Biosafety Laboratories: Preliminary Observations on the Proliferation of BSL-3 and BSL-4 Laboratories in the United States: Statement of Keith Rhodes (2007), at 23.

[122] NSABB Draft Report, *supra* note 83, at 11-12.

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- The informal practice of checking the names of individuals with favorable SRAs against the Counterterrorism Watchlist and other databases by the FBI that is now occurring about every six months should be formally incorporated into the SRA process.

- All responses, whether affirmative or negative, to questions asking about past criminal conduct, substance abuse and mental illness should precipitate further inquiry through character references or discussion with the prospective employee.

2. The NSABB also identified optimal personnel characteristics that should be considered for candidates for employment in high containment labs.[123] Research on the reliability and practicality of assessing for these characteristics should be undertaken and the accreditation process should be adapted to the results of that research.

6. PROBLEM: The 'one-size fits all' model of compliance is too great a burden on most non-military level laboratories. Military laboratories have heightened security models, but military level security is not practical for university campuses. A private sector model of appropriate and practical biosecurity procedures for those BSL laboratories is needed.

Recommendations:

1. Military institutions have fully developed security models in place that are not practical for the private sector. A non-military model is needed for BSL-3 and 4 biosecurity. An ideal model of this sort would take into account the need for integrating biosecurity measures with the open educational nature of university campuses.

[123] NSABB Draft Report, *supra* note 83, at 8 (The optimal personnel characteristics are: no felony convictions, no domestic or international terrorist ties, no history of scientific or professional misconduct in the workplace, emotional stability and capacity for sound judgment, positive attitude toward safety and security measures, and standard operating procedures, and free of vulnerability to coercion.).

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- The UMB has demonstrated that their system is practical and provides security and safety without compromising the quality of research produced.

- A model, such as that at UMB, would take into account compliance with the BMBL guidelines and provide a standard against which developing programs could achieve compliance. Additionally, UMB employs a certified biosafety professional as their biosafety officer. We believe this additional lever of biosafety training should be required at BSL-3 and 4 laboratories.

- Research is needed to assess what additional steps may be needed to secure private sector BSL-4 laboratories, which are few in number.[124]

- The GAO perimeter report assessed BSL-4 labs based on perimeter security parameters alone. Fifteen parameters were chosen based on 'GAO experience'.[125] Research is necessary to validate the GAO's perimeter security parameters. Additional security parameters should also be assessed and their implementation benefit weighed against additional expense. Validated measures for improving BSL security will help in the development of future security model development.

[124] U.S. Gov't Accountability Office, Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories, (2008), *available at* http://www.gao.gov/new.items/d081092.pdf (last accessed Sept. 21, 2009).

[125] *Id.*

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United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Terrorism and Homeland Security, Committee on the Judiciary, United States Senate

For Release on Delivery
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HIGH-CONTAINMENT LABORATORIES

National Strategy for Oversight Is Needed

Statement of Nancy Kingsbury, Ph.D.
Managing Director
Applied Research and Methods

GAO
Accountability * Integrity * Reliability

GAO-09-1045T

Mr. Chairman and Members of the Subcommittee

We are pleased to be here to discuss our report on a national strategy for high-containment laboratories that deal with dangerous—pathogens also known as biosafety level-3 (BSL-3) laboratories and biosafety level-4 (BSL-4) laboratories—in the United States, which was released yesterday.[1] The number of high-containment laboratories that work with dangerous biological pathogens have proliferated in recent years. In 2007, we reported on several issues associated with the proliferation of high-containment laboratories in the United States, including risks posed by biosafety incidents that have occurred in the past.[2] The Federal Bureau of Investigation's allegation in August 2008 that a scientist at the U.S. Army Medical Research Institute of Infectious Diseases was the sole perpetrator of the 2001 anthrax attacks raised additional concerns about the possibility of insider misuse of high-containment laboratory facilities, material, and technology. The public is concerned about these laboratories because the deliberate or accidental release of biological agents can have disastrous consequences by exposing workers and the public to dangerous pathogens. Highly publicized laboratory errors and controversies about where high-containment laboratories should be located have raised questions about whether the governing framework, oversight, and standards for biosafety and biosecurity measures are adequate.[3] In this context, you asked us to address the following questions:[4]

1. To what extent, and in what areas, has the number of high-containment laboratories increased in the United States?

2. Which federal agency is responsible for tracking the expansion of high-containment laboratories and determining the associated aggregate risks?

[1]GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed.* GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

[2]GAO, *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States,* GAO-08-108T (Washington, D.C.: Oct. 4, 2007).

[3]G.K. Gronvall et. al., "Letter to Senator Edward Kennedy and Senator Richard Burr," Center for Biosecurity, University of Pittsburgh Medical Center, March 3, 2009.

[4]The request letter contained several questions. In agreement with our requester, we revised the questions as stated.

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3. What lessons can be learned from highly publicized incidents at high-containment laboratories and actions taken by the regulatory agencies?

To answer these questions, we interviewed federal agency officials as well as experts in microbiology, reviewed literature, conducted site visits, and surveyed 12 federal agencies to determine if they have a mission to track high-containment laboratories in the United States. We also interviewed officials from relevant intelligence agencies to determine if they have a mission to determine insider risks in high-containment laboratories. The expert panel that reviewed this report was comprised of scientists with substantive expertise in microbiological and select agent research and the operation of high-containment laboratories.

We conducted our work from September 2005 through June 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Number of High-Containment Laboratories Is Increasing in Different Sectors throughout the United States

We found that since 2001, the number of BSL-4 and BSL-3 laboratories in the United States has increased, and this expansion has taken place across federal, state, academic, and private sectors and throughout the United States. Federal officials and experts believe that while the number of BSL-4 laboratories in the United States is known, the number of BSL-3 laboratories is unknown. Information about the number, locations, activities, and ownership is available for high-containment laboratories that are registered with the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) or the United States Department of Agriculture's (USDA) Animal and Plant Health and Inspection Service (APHIS) select agent programs, but not for those outside the program. The recent expansion of high-containment laboratories in the United States began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001. Understandably, the expansion initially lacked a clear, governmentwide coordinated strategy. In that emergency situation, the expansion was based on individual agency perceptions of requirements relative to the capacity their high-containment labs required as well as the availability of congressionally appropriated funding. Decisions to fund the construction of high-containment labs were made by multiple federal

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agencies in multiple budget cycles. Federal and state agencies, academia, and the private sector considered their individual requirements, but an assessment of national needs was lacking. Even now, after more than 7 years, GAO was unable to find any projections based on a governmentwide strategic evaluation of future capacity requirements set in light of existing capacity; the numbers, location, and mission of the laboratories needed to effectively counter biothreats; and national public health goals. Such information is needed to ensure that the United States will have facilities in the right place with the right specifications.

No Federal Agency Has the Mission to Track the Expansion of All High-Containment Laboratories and Regulate Biosafety in the United States

Currently, no executive or legislative mandate directs any federal agency to track the expansion of all high-containment laboratories. Because no federal agency has the mission to track the expansion of BSL-3 and BSL-4 laboratories in the United States, no federal agency knows how many such laboratories exist in the United States. While there is a consensus among federal agency officials and experts that some degree of risk is always associated with high-containment laboratories, no one agency is responsible for determining, or able to determine, the aggregate or cumulative risks associated with the expansion of these high-containment laboratories. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now meet or exceed the national need or is at a level that can be operated safely.

Lessons Learned from Four Incidents Highlight the Risks Inherent in the Expansion of High-Containment Laboratories

Four highly publicized incidents in high-containment laboratories, as well as evidence in the scientific literature, demonstrate that 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. One of the incidents we reviewed involved the allegation that Dr. Bruce Ivins of United States Army Medical Research Institute for Infectious Diseases was the source of the 2001 anthrax attack. This incident highlights two lessons: (1) An ill-intentioned insider can pose a risk not only by passing on confidential information but also by removing dangerous material from a high-containment laboratory, and (2) it is impossible to have completely effective inventory control of biological material with currently available technologies. It is impossible to know the exact number of bacteria or virus in a laboratory's inventory or working stocks at any specific time. At Fort Detrick, ineffective procedures for the control of inventories and the unlimited use of laboratory facilities allegedly allowed Dr. Ivins the opportunity to pursue his own ends. As the number of high-containment laboratories increases, there will be an increase in the pool of scientists with expertise and, thus,

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the corresponding risk from insiders may also increase. It has been suggested that personnel reliability programs would mitigate the insider risk. The National Science Advisory Board for Biosecurity reported that there is little evidence that personnel reliability measures are effective or have predictive value in identifying individuals who may pose an insider risk. Finally, continuity of electrical power is vital for the safe functioning of high-containment laboratories, in particular since maintenance of essential pressure differentials using electrically driven fans provides an important barrier for preventing the uncontrolled release of agents. Lapses in electrical power that occurred at a CDC laboratory raise concerns about standards in high-containment laboratory facility design, management of construction, and operations.

Taken as a whole, these incidents demonstrate failures of systems and procedures meant to maintain biosafety 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.

Conclusions

Oversight plays a critical role in improving biosafety and ensuring that high-containment laboratories comply with regulations. However, some aspects of the current oversight programs provided by the HHS and Agriculture are dependent upon entities monitoring themselves and reporting incidents to federal regulators. Since 2001, personnel reliability programs have been established to counter insider risks, but their cost, effectiveness, and programmatic impact have not been evaluated.

In conclusion, proliferation of high-containment laboratories is taking place in all sectors. Furthermore, since no single agency is in charge of the current expansion, no one is determining the associated aggregate risks posed by the expansion. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now be less than, meet, or exceed the national need or is at a level that can be operated safely.

If an agency were tasked or a mechanism were established with the purpose of overseeing the expansion of high-containment laboratories, it could develop a strategic plan to (1) ensure that the number and capabilities of potentially dangerous high-containment laboratories are no greater or less than necessary, (2) balance the risks and benefits of

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expanding such laboratories, and (3) determine the type of oversight needed.

Such an agency or mechanism could analyze the biothreat problems that need to be addressed by additional BSL-3 and -4 laboratories, the scientific and technical capabilities and containment features that such laboratories need to have, how the laboratories should be distributed geographically, and how the activities of the laboratories would be coordinated to achieve intended goals. The agency or mechanism responsible for overseeing the expansion of high-containment laboratories could also be responsible for coordinating with the scientific community to develop guidelines for high-containment laboratory design, construction, and commissioning and training standards for laboratory workers; providing definitions for exposure; developing appropriate inventory control measures; and providing guidance on the most efficient approach to personnel reliability programs.

Overall, the safety record of high-containment laboratories has been good, although a number of weaknesses have become apparent over time. Consequently, along with expansion there needs to be a commensurate development of both operational and oversight procedures to address known deficiencies and, as far as practicable, proactively evaluate future risks.

Laboratory operators, in collaboration with regulators, need to develop and work through potential failure scenarios and use that information to develop and put in place mechanisms to challenge procedures, systems, and equipment to ensure continuing effectiveness.

Recommendations for Executive Action

To address these issues, we recommended that the National Security Advisor, in consultation with the Secretaries of Health and Human Services (HHS), Agriculture (USDA), Defense (DOD), and Homeland Security (DHS); the National Intelligence Council; and other executive departments as deemed appropriate identify a single entity charged with periodic governmentwide strategic evaluation of high-containment laboratories that will (1) determine

- the number, location, and mission of the laboratories needed to effectively meet national goals to counter biothreats,
- the existing capacity within the United States,
- the aggregate risks associated with the laboratories' expansion, and
- the type of oversight needed

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and (2) develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically including provisions for long-term maintenance.

We recommended that the Secretaries of HHS and USDA develop (1) a clear definition of exposure to select agents and (2) a mechanism for sharing lessons learned from reported laboratory accidents so that best practices—for other operators of high-containment laboratories—can be identified.

Should the Secretaries consider implementing a personnel reliability program for high-containment laboratories to deal with insider risk, we recommended that they evaluate and document the cost, effectiveness, and programmatic impact of such a program.

Recognizing that biological agent inventories cannot be completely controlled at present, we also recommended that the Secretaries of HHS and USDA review existing inventory control systems and invest in and develop appropriate technologies to minimize the potential for insider misuse of biological agents.

Agency Comments and Our Evaluation

We obtained written comments on a draft of our report from the Secretaries of HHS and USDA. The Executive Office of the President: National Security Council did not provide comments. HHS and USDA concurred with our recommendations that were directed to them.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

Contact and Acknowledgments

If you or your staffs have any questions about this report, please contact me at (202) 512-2700 or kingsburyn@gao.gov or Sushil K. Sharma, Ph.D., Dr.PH, at (202) 512-3460 or sharmas@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Amy Bowser, George Depaoli, Terrell Dorn, Jeff McDermott, Jean McSween, Jack Melling, Ph.D., Corey Scherrer, Linda Sellevaag, and Elaine Vaurio made key contributions to this testimony.

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Testimony of:

Brandt Pasco
Compliance Assurance Program Manager
U.S. Department of Homeland Security

Regarding "The Role of the Department of Homeland Security's Science and Technology Directorate in Strengthening Security and Oversight at Biological Research Laboratories"

Before the Senate Committee on the Judiciary
Subcommittee on Terrorism and Homeland Security

September 22, 2009

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Chairman Cardin, Ranking Member Kyl, distinguished Senators, thank you for the opportunity to talk about the good work being done today at the Department of Homeland Security (DHS) related to biosecurity. It is a pleasure to be back in the U.S. Senate, where I started my professional life.

By way of introduction, allow me to explain briefly my role at DHS. I was appointed by the Deputy Secretary to be the Department's Compliance Assurance Program Manager. I am an attorney in the Office of the General Counsel, who supports the Science and Technology Directorate. I manage an office with 14 staff and a FY 2009 budget of approximately $2.8 million, and I oversee compliance efforts for all aspects of the Science and Technology Directorate's $800 million research and development program, including biological safety and security.

The main role of DHS's compliance program in biosecurity is to provide an objective and independent review of all ongoing DHS programs in the life sciences. This rigorous three-pronged review process includes several mutually reinforcing components; the review verifies arms control treaty compliance and regulatory compliance (select agent and toxin security, biosafety, and animal care and use); it further includes classification review.

The process is intended to be a complete programmatic life cycle review; treaty compliance is ensured both at a program's inception and when significant changes are proposed; regulatory compliance is checked throughout the life of project execution; and information generated by the program is continually reviewed for national security concerns. The Department's compliance office includes inspectors who are Ph.D. microbiologists, biosafety experts, animal care and use experts, and experts in national security classification, all supported by a strong professional staff. We have the necessary training to physically inspect Biological Select Agent and Toxin holdings in high containment laboratories.

The cornerstone of the process is the Department's Compliance Review Group, which oversees arms control treaty compliance.

ARMS CONTROL TREATY COMPLIANCE

DHS has a major role in implementing the national biodefense strategy, and it must ensure that its programs comply with all international treaty agreements, including the Biological Weapons Convention and the Chemical Weapons Convention. To accomplish this, DHS has implemented a comprehensive framework for treaty compliance review and certification of all biological and chemical defense projects.

The Compliance Review Group is comprised of the Deputy Secretary, the Under Secretary for Science and Technology, the General Counsel, and the Assistant Secretary for Policy. As a discretionary matter of standing practice, the Deputy Secretary has also included the Under Secretary for Intelligence and Analysis and the Assistant Secretary for Health Affairs. All biological research conducted by the Department must be determined by the Compliance Review Group to be compliant with U.S. law and our international obligations.

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The bulk of the work of the Compliance Review Group revolves around the Biological Weapons Convention. Specifically, the sponsors of each research project must affirmatively demonstrate that:

- the project is clearly for prophylactic, protective or other peaceful purpose; and
- the types and quantities of agents or toxins used in the project are consistent with and justified for the intended prophylactic, protective or other peaceful purpose.

In generating compliance assessments for the Compliance Review Group, projects fall within one of three categories:

Category 1: The project, as presented, does not raise any compliance concern.

- The project does not involve "Research of Concern," as identified by the National Science Advisory Board for Biosecurity, other dual-use issues, or types or quantities of agent that reasonably could raise concerns.
- 368 Category 1 projects have been approved by the Compliance Review Group to date.

Category 2: The project, as presented, might reasonably raise the perception of a compliance issue, but does not involve National Science Advisory Board for Biosecurity "Research of Concern."

- The project has dual use elements, for example, the research may involve aerosols of specific agents are known to have been weaponized by adversaries in the past.
- The project will generate data on threat characterization and specific vulnerabilities.
- 18 Category 2 projects have been approved by the Compliance Review Group to date.

Category 3: The project, as presented, might reasonably raise the perception of a compliance issue and likely does involve National Science Advisory Board for Biosecurity "Research of Concern."

- The project will generate data on threat characterization and specific vulnerabilities.
- 22 Category 3 projects have been approved by the Compliance Review Group to date.

I want to stress that all DHS biological research must go through a comprehensive review and are ultimately signed off on by the Compliance Review Group.

REGULATORY COMPLIANCE

DHS has established a regulatory compliance program to facilitate Department-wide implementation of and compliance with DHS policies for biosafety, select agent and toxin security, and the care and use of animals in research. It is important to remember that DHS is not a regulatory authority for laboratories; we are a funding agency. DHS's select agent and toxin research is subject to regulatory control by the Centers for Disease Control and Prevention (CDC) and the Department of Agriculture Animal and Plant Health Inspection Service. At DHS, we conduct significant additional oversight because of unique sensitivities related to biodefense research, as distinct from conventional public health research, and a desire to ensure complete transparency for senior management of the department about all ongoing biodefense efforts.

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The regulatory compliance program is significantly driven by our treaty compliance efforts. Laboratories conducting Category 2 or 3 projects are subject to an on-site inspection. Other laboratories are visited because we have some indication that there may be problems with non-compliance.

Of the 42 laboratories that are or have recently been working on DHS-funded biological research, we have conducted 23 on-site inspections, covering numerous government, university, private, and not-for-profit laboratories. Once the National Biodefense Analysis and Countermeasures Center at Fort Detrick becomes operational, we will also exercise compliance oversight over that facility.

Importantly, in 2008, we began doing document-based compliance reviews for laboratories conducting lower-priority research. We have completed seven document-based reviews, with five more in progress. This process is quite important for us. DHS requires providers to make available the documentation required by their regulatory agencies. This allows us to verify, for example, that laboratory staff have the appropriate FBI clearances to work with select agents, that training is up to date, and that record-keeping practices are kept to the required standard. Where document-based reviews provide evidence of non-compliance, laboratories are prioritized for onsite inspections.

I want to emphasize that the purpose of compliance inspections is to ensure DHS-funded work is being conducted in a legal and safe manner as well as to assist our providers in remaining compliant with legal requirements. DHS' regulatory compliance inspections identify and address compliance issues with the potential to impact DHS-sponsored programs, and I follow up with detailed guidance to performing organizations on approaches to enhance institutional programs for biosafety and biosecurity. My goal is to correct problems, not to bring scientific endeavors to a halt, barring substantial non-compliance findings. We aspire to eliminate non-compliance so as to help our providers anticipate and address problems proactively with regulatory authorities, and ensure the smooth functioning of the Department's research programs.

CLASSIFICATION REVIEW

To assist the Under Secretary in exercising Original Classification Authority, the Science and Technology Directorate established the Classification Review Panel, which I co-chair with the Directorate's Director of Security.

DHS has a significant priority in maintaining openness in life science research, but the nature of biodefense threat characterization studies requires that some elements remain classified to protect the public from harm. The Classification Review Panel co-chairs are responsible for ensuring all Science and Technology Directorate programs have, and are appropriately applying, classification guidance approved by the Under Secretary in his or his or her role as Original Classification Authority.

CONCLUSION

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In conclusion, DHS has an exceptionally effective record of strengthening biological safety and security in DHS funded laboratories. In rare cases of substantial regulatory non-compliance, DHS has twice issued stop work orders with providers and worked with CDC to address laboratory-wide non-compliance that goes beyond the scope of the DHS-funded work. In one case, the facility lost the ability to work with select agents, and in the other, the facility was placed on a significant performance improvement plan by the CDC. I am particularly proud of this record, because it conclusively demonstrates the value of DHS's efforts in compliance.

Thank you for your attention, and I'd be pleased to answer any questions you may have.

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COMMITTEE**

TESTIMONY OF

JEAN D. REED

DEPUTY ASSISTANT TO THE

SECRETARY OF DEFENSE FOR

NUCLEAR, AND CHEMICAL, AND BIOLOGICAL DEFENSE

PROGRAMS

BEFORE THE UNITED STATES SENATE

JUDICIARY SUBCOMMITTEE ON

TERRORISM AND HOMELAND SECURITY

September 22, 2009

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COMMITTEE**

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Strengthening Security and Oversight at Biological Research Laboratories

Jean D. Reed
Deputy Assistant to the Secretary of Defense
Nuclear, and Chemical, and Biological Defense Programs

Chairman Cardin, Senator Kyl, and distinguished Members of the Committee:

Thank you for the opportunity to discuss with you the safety and security at our nation's biological research laboratories. Our nation's laboratories are a keystone to the life science research, and are essential to developing public health infrastructure and medical countermeasures crucial to protecting U.S. citizens from biological threats, whether as a result of natural or intentional actions.

The purpose of this testimony is to discuss DoD regulations, practices, and procedures put in place since the 2001 Anthrax incidents that can be applied to improved laboratory biosecurity. It's imperative that the implementation of best practices on a national scale optimize the security of biological agents while providing minimal impact to life science research necessary to develop public health and medical countermeasures against these agents.

I will provide an overview of how the DoD regulations came into existence, how they have been implemented, their proposed integration into current national efforts, and a possible way forward to develop best practices and procedures for Biosafety Level (BSL)-4 laboratory safety and security.

The DoD BSL-3 and BSL-4 laboratories operate as a critical element of our biodefense efforts to understand pathogens of concern and to develop medical

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countermeasures to defeat these pathogens, whether they are biological warfare agents or infectious diseases to which our Armed Forces may be exposed.

Following the 2001 Anthrax incidents, Congress passed a series of legislative initiatives to control human, plant, and animal pathogens of concern, this legislation led to the expansion of Select Agent Regulations (42CFR Part 73, 7CFR Part 331, and 9 CFR Part 121). These regulations required each Federal agency to conduct safety and risk assessments, but did not preclude agencies from implementing efforts above and beyond those required by the regulations for safeguarding biological select agents and toxins.

The term "select agent" used in the legislation was used to refer to a specific group of chemical or biological agents that historically have been evaluated and developed for use in weapons. Although the United States does not have a biological weapons program, the use of this term and its historical connotation within the DoD as being associated with weapons programs heavily influenced the direction the Department would take to safeguard its biological agents. Accordingly, the DoD drew from its current chemical and nuclear programs safeguarding measures in developing its regulation for so called biological select agents and toxins, which the Department uses only for basic and applied research in the development of vaccines, therapeutics, and protective countermeasures.

The current DoD risk management framework for safeguarding select agents and toxins consist of a four-fold approach: biosafety, biosecurity, personnel reliability, and agent accountability. Biosafety consists of the application of knowledge, techniques, and

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equipment to prevent personal, laboratory, and environmental exposure to potentially infectious agents or biohazards. Biosecurity refers to the protection, control, and accountability of high consequence biological agents and toxins: critical relevant biological materials; and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release. The Biological Personnel Reliability Program (BPRP) consists of security background investigations as well as medical, mental health, and drug screening. Agent Accountability consists of the registration of agents, personnel, entities and locations, agent inventory control, and limiting access to registered personnel.

All of the above measures implemented by DoD far exceed the prescribed requirements of the Select Agent Rules. This does not mean that the additional measures constitute a series of best practices and procedures, but only represents the extrapolation of the DoD current weapons material safeguarding policies as applied against biological agents. In fact, they highlight the challenges that arise from the direct application of DoD current policies for safeguarding weapons material to the unique situation of defensive research on biological organism. Biological agents differ from nuclear and chemical threats by their nature and by virtue of their context. Nuclear and chemical are entirely manmade. Biological agents are found throughout nature and exist in the context of infectious disease and public health threats, notwithstanding that they can be potentially used for hostile purposes. This is not to say that there are elements of these regulations that could not be incorporated into best practices. However, a series of studies both

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within the DoD and externally suggest that some elements of this program may be too extreme and could not be implemented by other agencies or the civilian sector without severe impact. For example, the use of Single-Scope Background Investigations precludes foreign nationals or personnel having limiting factors, such as financial difficulties or prior non-criminal legal actions, from working with select agents. These background investigations are time intensive and expensive, making it unlikely that academia and industry could support the costs of numerous background investigations. Additionally it would preclude a large segment of exceptionally qualified and talented researchers, particularly foreign national researchers who currently make daily contributions to the advancement of medical and other life science research, from participating in this activity that is so important to the nation. Several recent studies highlight the lack of data to demonstrate such detailed background investigations provide substantial value over the current Department of Justice Security Risk Assessment.

Studies conducted over the past two years by the National Science Advisory Board for Biosecurity, the Defense Science Board, National Academy of Sciences, and the Executive Order 13486, which established the Working Group on Strengthening the Laboratory Biosecurity of the United States, have explored the efficacy and efficiency of current and proposed regulations and policies to strengthen laboratory biosecurity. Reports from the National Science Advisory Board for Biosecurity and the Defense Science Board were submitted to the Executive Branch with a series of recommendations and policy options that can be applied to establishing best practices and procedures for

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the nation. The Executive Order 13486 Working Group and the National Academy of Sciences reports are in their final stage of staffing and will be submitted to the Executive Branch in the very near future. Additionally, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight is soon submitting its report to the Executive Branch.

A potential way forward is to allow the National Security Council to use its Inter-Agency Policy Committee process, in conjunction with input from industry and academia, to review the recommendations and policy options from the collective reports and develop an approach for the nation that optimizes the balance of science and security. Once such an approach is identified, legislative action could be well targeted to ensure the full range of helpful measures needed to enable its implementation.

In summary, the current DoD safety and security measures for safeguarding biological select agents and toxins are derived from its protocols that originally were developed to safeguard its nuclear and chemical weapons materials and not the biological organisms that are critical to developing defenses against our adversaries' biological weapons and naturally-occurring infectious diseases. Although these practices derive from a robust history of security, they most likely would not constitute the basis for best practices and procedures for the nation as they would discourage participation by critical organizations and could be limiting to medical and other life sciences research programs. A more prudent approach would be to exploit the information gathered by the various studies conducted over the past two years and develop a series of appropriately tailored

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policies and practices that maintain a balance between safety and security and the pursuit of a robust biological research and development program to ensure the ability to respond to naturally-occurring pathogens, defense of the U.S. homeland, and protection of our Servicemembers.

Thank you for this opportunity to address you on this matter of national importance as well as your continued support to the Department of Defense. I would be happy to answer any questions you and the Members of the Committee may have.

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Department of Justice

STATEMENT

OF

DANIEL D. ROBERTS
ASSISTANT DIRECTOR
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
FEDERAL BUREAU OF INVESTIGATION

BEFORE THE

SUBCOMMITTEE ON TERRORISM AND HOMELAND SECURITY
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

CONCERNING

"STRENGTHENING SECURITY AND OVERSIGHT OF BIOLOGICAL RESEARCH LABORATORIES"

PRESENTED ON

SEPTEMBER 22, 2009

STATEMENT OF
DANIEL D. ROBERTS
ASSISTANT DIRECTOR
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
FEDERAL BUREAU OF INVESTIGATION

SEPTEMBER 22, 2009

GOOD MORNING CHAIRMAN CARDIN, RANKING MEMBER KYL, AND THE DISTINGUISHED MEMBERS OF THE SUBCOMMITTEE ON TERRORISM AND HOMELAND SECURITY. I AM DANIEL D. ROBERTS, ASSISTANT DIRECTOR OF THE FBI'S CRIMINAL JUSTICE INFORMATION SERVICES DIVISION, OR CJIS, LOCATED IN CLARKSBURG, WEST VIRGINIA. I HAVE SERVED IN THE FBI FOR OVER 22 YEARS, BUT HAVE ONLY HELD MY CURRENT POSITION SINCE JUNE 2009. I THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE THIS SUBCOMMITTEE.

THE CJIS DIVISION MAINTAINS OVERSIGHT OF TWO MAJOR BACKGROUND ASSESSMENT PROGRAMS. THE MORE COMMONLY KNOWN NATIONAL INSTANT CRIMINAL BACKGROUND CHECK SYSTEM ASSESSES A PERSON'S ELIGIBILITY TO POSSESS A FIREARM OR EXPLOSIVE. THE LESSER KNOWN PROGRAM, THE BIOTERRORISM RISK ASSESSMENT GROUP, OR BRAG, IS SIMILAR IN MISSION. BRAG'S ROLE IS TO ENHANCE NATIONAL SECURITY AND PUBLIC SAFETY BY PROVIDING THE TIMELY AND ACCURATE DETERMINATION OF AN INDIVIDUAL'S

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ELIGIBILITY TO USE, POSSESS OR TRANSFER SELECT AGENTS AND TOXINS. CANDIDATES ARE EVALUATED FOR ACCESS TO SELECT AGENTS AND TOXINS AGAINST CRITERIA DELINIATED WITHIN THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002, AND AGAINST PROHIBITIVE CATEGORIES DEFINING A RESTRICTED PERSON WITHIN THE USA PATRIOT ACT.

PURSUANT TO THE BIOTERRORISM ACT, THE ATTORNEY GENERAL OF THE UNITED STATES IS CHARGED WITH USING CRIMINAL, IMMIGRATION, NATIONAL SECURITY, AND OTHER ELECTRONIC DATABASES TO DETERMINE WHETHER AN ENTITY OR AN INDIVIDUAL IS A RESTRICTED PERSON. THE ATTORNEY GENERAL DELEGATED THIS AUTHORITY TO THE DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION IN JANUARY 2003. THE BRAG BEGAN CONDUCTING SECURITY RISK ASSESSMENTS, OR SRAS, IN COLLABORATION WITH OFFICIALS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF AGRICULTURE IN APRIL 2003.

SRAS ARE CONDUCTED ON ENTITIES (EXCEPT FEDERAL, STATE, OR LOCAL GOVERNMENT AGENCIES, INCLUDING PUBLIC ACCREDITED ACADEMIC INSTITUIONS), ANY INDIVIDUAL WHO OWNS OR CONTROLS THE ENTITY, RESPONSIBLE OFFICIALS, AND ALTERNATE RESPONSIBLE OFFICIALS MANAGING ENTITY OPERATIONS EVERY

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THREE YEARS. SRAS ARE CONDUCTED NOT LESS FREQUENTLY THAN ONCE EVERY FIVE YEARS ON INDIVIDUALS REQUIRING ACCESS TO SELECT AGENTS AND TOXINS. A TYPICAL SRA TAKES ABOUT ONE MONTH TO COMPLETE.

THE SRA IS DIFFERENT THAN A FULL BACKGROUND INVESTIGATION SUCH AS THOSE CONDUCTED FOR SECURITY CLEARANCES, AND COMPLIES WITH THE REQUIREMENTS OF THE BIOTERRORISM ACT.

THE SRA COMMENCES WHEN BRAG RECEIVES A CANDIDATE'S FORM FD-961 AND TWO LEGIBLE FINGERPRINT CARDS. THE FINGERPRINT CARDS ARE PROCESSED BY THE FBI'S INTEGRATED AUTOMATED FINGERPRINT IDENTIFICATION SYSTEM AND FLAGGED TO IDENTIFY THE RECORD AS BELONGING TO AN INDIVIDUAL WHO UNDERWENT AN SRA. THE FD-961 DATA SUPPLIED BY THE CANDIDATE IN RESPONSE TO QUESTIONS DIRECTLY CONCERNING EACH PROHIBITOR IS THEN ENTERED INTO BRAG'S STAND-ALONE BIOTERRORISM DATABASE MAINTAINED BY CJIS. THE CANDIDATE'S CASE IS SUBSEQUENTLY ASSIGNED TO A BRAG PERSONNEL SECURITY SPECIALIST FOR RESEARCH.

UPON COMPLETION OF ALL DATABASE SEARCHES, THE CANDIDATE'S STATUS IS DETERMINED AND THE RESULTS SUBMITTED

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TO THE SPONSORING AGENCY. THE SPONSOR PROVIDES, IN WRITING, THE DECISION INDICATING DENIAL OR APPROVAL OF ACCESS TO THE CANDIDATE.

IF ACCESS IS DENIED, THE CANDIDATE IS ADVISED OF THE SPECIFIC PROHIBITING FACTOR APPLIED TO THEM. CANDIDATES MAY APPEAL THE DECISION VIA THEIR SPONSOR WITHIN 30 DAYS OF NOTIFICATION OF DENIAL. THE SPONSOR WILL FORWARD A STATEMENT OF FACTUAL BASIS FOR THE APPEAL AND SUPPORTING DOCUMENTATION PROVIDED BY THE CANDIDATE TO THE FBI FOR RECONSIDERATION. THE FBI WILL REVIEW THE CANDIDATE'S DOCUMENTATION AND RESEARCH THE APPROPRIATE DATABASES. THE FBI WILL EITHER OVERTURN THE RESULTS OF THE ORIGINAL SRA, OR SUSTAIN THE ORIGINAL DETERMINATION OF STATUS. THE SPONSOR IS AGAIN ADVISED OF THE RESULTS AND IN TURN, NOTIFIES THE CANDIDATE IN WRITING OF THE DECISION.

SINCE THE INCEPTION OF THE PROGRAM, THE BRAG HAS COMPLETED 32,742 SRAS. TWO HUNDRED AND EIGHT INDIVIDUALS HAVE BEEN RESTRICTED.

ALTHOUGH SRAS ARE CONDUCTED ON A FIVE-YEAR CYCLE, IF AT ANY TIME AN INDIVIDUAL IS CONVICTED IN ANY COURT OF A CRIME PUNISHABLE BY IMPRISONMENT FOR A TERM EXEEDING ONE

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YEAR, THEN CJIS IS APPRISED OF THIS FACT, AND CJIS INFORMS CDC AND APHIS THAT THE INDIVIDUAL IS CONSIDERED A RESTRICTED PERSON.

THE CJIS DIVISION, IN CLOSE COORDINATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION, AND THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE IS CONTINUALLY SCRUTINIZING AND EVALUATING THE SRA PROCESS. EFFORTS ARE ONGOING TO AUTOMATE THE WORK FLOW, AND IMPROVE INFORMATION SHARING CAPABILITIES.

MR CHAIRMAN, I WOULD LIKE CONCLUDE BY THANKING YOU, RANKING MEMBER KYL, AND THIS SUBCOMMITTEE FOR YOUR SERVICE AND SUPPORT. I LOOK FORWARD TO WORKING WITH YOU IN YEARS TO COME AS WE CONTINUE TO COUNTER BIOSECURITY THREATS OF THE FUTURE.

I WOULD ALSO LIKE TO PERSONALLY THANK THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' CENTERS OF DISEASE CONTROL AND PREVENTION, AND THE DEPARTMENT OF AGRICULTURE'S ANIMAL AND PLANT HEALTH INSPECTION SERVICE FOR YEARS OF UNWAVERING SUPPORT.

THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE YOUR SUBCOMMITTEE. I LOOK FORWARD TO ANSWERING YOUR QUESTIONS.

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