Testimony of

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University of Maryland Center for Health and Homeland Security

and

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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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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 who are developing countermeasures to biopathogens and highly infectious diseases on their emergency operations planning, including those researchers at the Center for Vaccine Development at the University of Maryland of

Medicine 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

Since 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 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

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 HeathDirector; 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. Morland, M.S., R.B.P., C.B.S.P., S.M., Assistant Director and Biosafety Officer 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).

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 drawn widespread attention to the safety and security in university 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)*;* 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); 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).

II. Identified Problems

Based on review of the legislation and Select Agent regulations regarding BSL-3 and BSL-4 laboratories;[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 laboratories. 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; *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).

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

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

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 transport hazardous biological agents.[18]

2. The PATRIOT Act.

The PATRIOT Act, which was passed in October 2001, defines "Restricted Persons" who are statutorily ineligible for clearance from the Department of Justice ("DOJ") to work with Select Agents.[19] A Restricted Person is an individual who is: under

[15] Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, § 511, 110 Stat. 1214 [hereinafter "AEDPA"]. (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; The biological agent provisions of AEDPA were amended by Sec. 351A of the PHBPA, *See* Sec. 201 of Public Law 107-188.)

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

[17] AEDPA, *supra* note 15.

[18] *Id.*

[19] 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

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.[20] 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 asserted 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.[21]

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."[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.")

[20] *Id.*

[21] 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.")

[22] PATRIOT Act, *supra* note 20; *See also* 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 (last accessed Sept. 21, 2009) (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.")

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.[23] 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.[24]

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 imposed 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. [25] When

[23] Agricultural Bioterrorism Protection Act of 2002, Pub. L. No. 107-188, 116 Stat. 647 [hereinafter ABPA].

[24] *Id*; (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).

[25] The Select Agent Regulations are 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) [hereinafter "Select Agent Regulations"]. 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. Department of Agriculture, that personnel who have

adding a biological 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.[26] If denominated as Select Agents, the biological agents must be registered with the National Select Agent Registry.[27] 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.[28]

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access to these materials must undergo a Security Risk Assessment. There are civil and criminal penalties for non-compliance with the Select Agent Rules.

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

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

[28] *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).

There are three sets of relevant regulations: one promulgated by the CDC for the protection of public health;[29] and two promulgated by the Animal and Plant Health Inspection Service ("APHIS") relating to animals[30] and plants.[31] Each set 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 must be restricted; (3) a security plan must be established; (4) a biocontainment and biosafety plan must be established; (5) experiments must be restricted; (6) an incident response plan must be established; (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.[32]

2. Security Risk Assessments

Security Risk Assessments ("SRA") are mandated by the PHBPA, for every individual who seeks to work with Select Agents.[33] Using the criteria from the PATRIOT Act, the SRA is intended to preempt "Restricted Persons" from gaining access to these potentially harmful bioagents.[34] 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.[35] The SRA most notably involves comparing an applicant's fingerprints against criminal and terrorist databases and must be renewed every three or five years.[36]

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

[29] *See* 42 C.F.R. § 73 (2009) (relating to public health).

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

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

[32] Select Agent Regulations, *supra* note 25.

[33] PHBPA, *supra* note 5, Sec. 351A(d).

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

[35] For a list of the steps of the process of applying for a Security Risk Assessment see http://www.selectagents.gov/sra.html (last accessed Sept. 21, 2009).

[36] *Id* (Responsible Officials and Alternate Responsible Officials, as defined by statute, must renew every three years).

have not slid into a restricted category.[37] 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.[38]

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.[39] 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 of openness and inhibit the way university-level research is conducted without sufficient evidence of improved reliability beyond that which is possible from strict enforcement of the SRA process.[40]

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

[37] 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).

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

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

[40] *Id.*

and biosecurity protocols for laboratories depending on the threat posed to laboratory staff and scientists as well as surrounding communities.[41]

a. Biosafety Level Designations:

The BMBL guidelines delineate four biosafety levels ("BSL") in order of ascending levels of containment.[42] 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.[43]

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.[44]

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.[45]

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

[41]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"] (last accessed Sept. 21, 2009) (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.")

[42] *Id*. at 17

[43] 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).

[44] BMBL guidelines, *supra* note 41, at 41.

[45] *Id*. at 44.

inhalation route exposure.[46] Examples of agents handled and stored in BSL-3 laboratories include: Tuberculosis and St. Louis Encephalitis virus.[47] 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.[48]

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.[49] 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.[50]

b. Biosecurity Requirements

Biosecurity has been defined as protection of microbial agents from loss, theft, diversion, or intentional misuse.[51]

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.[52] 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

[46] *Id.* at 49.

[47] 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).

[48] BMBL guidelines, *supra* note 41, at 50-56 (Biological safety cabinets provide personnel, environmental and product protection through air flow management and decontamination techniques).

[49] *Id.* at 56.

[50] *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.")

[51] *Id.* at 118.

[52] Select Agent Regulations, *supra* note 25.

reporting in biomedical and microbiological laboratories are principally governed by the BMBL *advisory guidelines*.[53]

The BMBL guidelines recommend that facilities engage in a two-part approach to biosecurity considerations.[54] 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.[55] 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.[56] The guidelines ultimately establish ten elements that might be incorporated into a biosecurity program, should a facility determine that it is necessary.[57] *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.

[53] BMBL guidelines, *supra* note 41.

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

[55] *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.").

[56] *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.)

[57] *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.).

1. NIH Guidelines For Research Involving Recombinant DNA Molecules – April 2002[58]
2. Hazardous Materials Regulations[59]
3. International transport regulations including those of International Maritime Organization, and the International Maritime Dangerous Goods (IMDG) Code[60]
4. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction[61]

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.[62] 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

[58] 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).

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

[60] 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)).

[61] 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.)

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

Infectious Diseases, Fort Detrick, Maryland ("USAMRIID").[63] 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."[64]

Of note, Dr. Bruce E. Ivins, was cleared for his work with Anthrax at Fort Detrick through though the DOD's more onerous Personnel Reliability Program security process.[65] 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.[66] 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 ("Texas A & M") facilities and safety protocols and found that Texas A & M was guilty of a dozen violations.[67] 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

[63] 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).

[64] *Id.*

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

[66] Kasper, *supra* note 10.

[67] 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).

BSL-3 pathogen.[68] In particular, the exposed lab worker was experienced in handling *M. 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.[69] 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.[70] 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.[71] In 2008, a settlement agreement between Texas A & M and HHS culminated in payment of $1 million. Texas A & M accepted responsibility for the lapses noted in the CDC investigation.[72]

[68] 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, 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).

[69] 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.

[70] 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).

[71] 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).

[72] 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).

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 events occurring between 2000 and 2007.[73] Thirteen laboratory incidents occurred at UT-Austin, including five incidents of exposure to *Shigella,* a BSL-2 agent.[74] All workers recovered without incident.[75] 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.[76]

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[77] and developed an eye infection resulting in her hospitalization.[78] 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.[79]

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[73] 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).

[74] *Id.*

[75] *Id.*

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

[77] 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).

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

[79] *Id.*

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.

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.[80] Investigation into high containment labs at Pirbright found evidence of long term damage and leakage of the drainage system servicing the site. The resulting exposure was suspected to have been caused by contaminated waste water leaching into soil then carried off-site by vehicles via contaminated mud. The event cost taxpayers over £3 billion.[81]

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[82]

In the October of 2008, the White House asked the NSABB[83] to consider whether a national PRP should be mandated for the nation's academic, government and private

[80] 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.

[81] *Id.*

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

[83] 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).

research facilities that handle Select Agents.[84] In April 2009, NSABB produced a draft report recommending security improvements at non-military research facilities whose employees have access to Select Agents, but it explicitly rejected the need for promulgation of a formal, national PRP.[85] 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.[86] 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."[87]

NSABB found that local institutions,[88] 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".[89] NSABB specifically considered the merit of requiring facilities to use personnel reliability assessments commonly used in laboratories affiliated with the Department of Homeland Security and/or funded by the military, including: psychological testing, national security clearances, and medical examinations.[90] 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.[91] NSABB ultimately recommended strengthening the SRA procedure; institutional enhancement of

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

[85] NSABB Report, *supra* at 82 (The final report was issued on May 29, 2009).

[86] *Id.* at 1.

[87] NSABB Report, *supra* note 82, at v.

[88] 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).

[89] NSABB Report, *supra* note 82, at 8.

[90] NSABB Report, *supra* note 82, at 9-10.

[91] *Id*.

a culture of responsibility and accountability; and a reduction or stratification of the list of Select Agents.[92]

2. Commission on the Prevention of WMD Proliferation and Terrorism:[93] World at Risk[94]

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.[95] 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".[96] 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."[97]

[92] NSABB Report, *supra* note 82, at 13-15.

[93] 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.

[94] 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).

[95] *Id.* at xi.

[96] *Id*. at 27.

[97] *Id*. at 25.

3. Government Accountability Office: BIOSAFETY LABORATORIES: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories[98]

This GAO report issued in September 2008, specifically addressed perimeter security of the five operational BSL-4 laboratories. Perimeter security was assessed pursuant to 15 security controls that GAO identified.[99] GAO concluded that two of the five BSL-4 laboratories had significant shortfalls in security controls that could be expected to preclude unauthorized access, loss or theft of select agents.[100] 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.[101]

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[102]

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.[103] 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.[104] This report also emphasizes the critical

[98] 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).

[99] *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 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.

[100] *Id*.

[101] *Id.* at 19.

[102] 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.

[103] *Id.* at 7.

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

importance of facility maintenance in preventing environmental exposure and contamination as clearly demonstrated in the Pirbright exposure.[105]

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.

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 6,000 students and 5,000 staff and faculty on campus. 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.[106] 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.[107]

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

[105] *Id.* at 8.

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

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

containing select agents and toxins.[108] 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.[109] 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 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.[110]

Additionally, UMB has a certified biosafety professional as their biosafety officer.[111] This additional level of training is not mandated of the biosafety officer; however, 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.[112] Additionally agents, which overlap the human, animal, and plant categories because of their potential to impact each species, can be registered with either agency.[113] Recombinant DNA research is additionally

[108] 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).

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

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

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

[112] PHBPA, *supra* note 5.

[113] ABPA, *supra* note 25.

covered by NIH guidelines.[114] 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 DHHS, through 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, use, or transfer the agents; and maintaining current and accurate inventories."[115] The CDC, under DHHS oversight, appears to have a more developed Select Agent enforcement program evidenced by thirteen enforcement suits brought between 2004 and 2009.[116]

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.[117] Additionally agents that overlap categories can be registered with either agency.[118] 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.

[114] 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).

[115] 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.).

[116] 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).

[117] PHBPA, *supra* note 5.

[118] ABPA, *supra* note 25.

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.

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.[119] *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.[120] 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.

[119] 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).

[120] 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.

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.[121]

    - 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.[122] 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.

[121] NSABB Report, *supra* note 82, at 11-12.

[122] NSABB Report, *supra* note 82, 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.).

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.

   - 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.[123]

   - The GAO perimeter report assessed BSL-4 labs based on perimeter security parameters alone. Fifteen parameters were chosen based on 'GAO experience'.[124] Research is necessary

[123] 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).

[124] *Id*.

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.