

Governance and Biosecurity: Strengthening Security and Oversight of the Nation's Biological Agent Laboratories¹

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Abstract

Since the advent of the Anthrax attacks in the fall of 2001, the United States 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 bioterrorist acts themselves. Indeed, the Anthrax attacks that motivated increased funding and research on biopathogens now seems likely to have been caused by research being conducted in the United States on Anthrax, an infectious disease caused by the bacteria *Bacillus anthracis*. Leaving aside which researcher evaded the security measures of the United States Army at its Fort Detrick laboratory facility, the forensic evidence appears very strong that an “insider” obtained the bacteria to perpetrate the 2001 attacks at that facility.

It is the thesis of this article that the United States can improve security measures at those biosafety level (“BSL”) laboratories that handle the most dangerous pathogens (“BSL-3” and “BSL-4” labs), so that laboratories can develop countermeasures to potential bioterror attacks without having that research inherently pose a threat to national security. This article makes recommendations in aid of such a policy. To put the recommendations in context, the article 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; and (3) a brief description of biosafety mishaps at BSL-3 and BSL-4 labs that have provoked the controversy at hand.

We conclude that Congress should enact 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 that ensures 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.

I. Background information

The October 2001 Anthrax attacks resulted in eleven cases of cutaneous anthrax, eleven cases of inhalational anthrax, five deaths and an overwhelming nationwide fear about public safety and the threat of biological attacks.² These deadly exposures 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 Since the anthrax attacks, 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.⁴ The increased funding directly correlates to an increased number of researchers and laboratories working with deadly biological agents.⁵

Prior to the 2001 Anthrax incidents, concerns in the scientific and regulatory community about improper handling of the biological agents that are used for research focused on the possession, use, and transport of those agents. However, as awareness grew of the highly dangerous and potentially lethal threats that these agents posed, 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.⁶ The Secretary of the United States Department of Health and Human Services (“HHS”) and the Secretary of the USDA chose “Select Agents” using statutory criteria.⁷ The identified Select Agents pose high threats to human, plant and animal life because of their methods of transmission, potential for misuse, and toxicity.⁸ Upon the heels of this new legislation and regulation, numerous studies have been conducted on the issue of biosecurity. The National Science Advisory Board on Biosecurity (“NSABB”), The Commission on the

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 Atlas, *supra* note 2, at 16.

⁵ *Id.* at 15.

⁶ Caitriona McLeish & Paul Nightingale, *Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy*, 36 RESEARCH POLICY 1635, 1639 (2007), available at www.sciencedirect.com (last accessed Sept. 21, 2009).

⁷ 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).

⁸ *Id.*

Prevention of WMD Proliferation and Terrorism (“The Commission”), and the Government Accountability Office (“GAO”) have each been independently charged with investigating different aspects of biosecurity at BSL laboratories.⁹ 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.¹⁰

II. Identified Problems

Based on review of the legislation and Select Agent regulations regarding BSL-3 and BSL-4 laboratories,¹¹ the NSABB, Commission, and GAO reports,¹² and reports of incidents and accidental exposures,¹³ the following problems in biosafety and biosecurity persist:

- The regulatory structure for BSL-3 and BSL-4 laboratories is fragmented across several federal agencies.
- Incident reporting of biosafety and biosecurity incidents at BSL- 3 and BSL-4 laboratories is not centralized.
- Incident review does not produce protocol modification in a timely manner across all laboratories, thereby inhibiting collaboration on best practices.
- Physical BSL laboratory facilities do not require accreditation.
- 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

⁹Dennis 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).

¹⁰ 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).

¹¹ PHBPA, *supra* note 7; *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).

¹² Kasper, *supra* note 9; BSL-4, *supra* note 9.

¹³ Texas A&M, *supra* note 10.

benefits gained from investigation of the Select Agents because of overly broad screening measures for personnel and a deterrent effect on potential hires.

- 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 vital.

III. Supporting Material

A. Pertinent Statutory Review: Oversight of BSL laboratories is fragmented across multiple agencies. The following statutory framework provides an overview of BSL regulation.

1. Antiterrorism and Effective Death Penalty Act of 1996

The Antiterrorism and Effective Death Penalty Act of 1996 (“AEDPA”) required 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.¹⁴ The resultant regulations established the Center for Disease Control and Prevention (“CDC”) Laboratory Registration/Select Agent Transfer Program.¹⁵ The regulations included six essential provisions: (1) a list of select agents that posed a severe threat to public health and safety; (2) required registration of facilities prior to any domestic transfer of named agents; (3) transfer documentation; (4) accountability mechanisms; (5) disposal requirements; and (6) exemptions.

The AEDPA explicitly addressed the possibility of weaponization of biological agents.¹⁶ The promulgated 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.¹⁷

¹⁴ 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.)

¹⁵ *See* 42 C.F.R. § 72 (2002). (The regulations became effective on April 15, 1997.)

¹⁶ AEDPA, *supra* note 14.

¹⁷ *Id.*

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.¹⁸ 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; a person who has been dishonorably discharged from the military; or one who has been committed to a mental institution.¹⁹ 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, who might be precluded by this DOJ investigation, on a case-by-case basis has dramatically impeded the development of medical countermeasures necessary to combat bioterrorist attacks.²⁰

Additionally, 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 ten 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.”²¹

¹⁸ 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) [hereinafter 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 Section 6(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 Section 40(d) of Chapter 3 of the Arms Export Control Act (22 U.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.”)

¹⁹ *Id.*

²⁰ McLeish & Nightingale, *supra* note 6 at 1641. (“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.”).

²¹ PATRIOT Act, *supra* note 18; *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,

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. This statute expanded the scope of the AEDPA provisions on biological agents. The Select Agent regulations that both HHS and USDA promulgate (as PHBPA requires) 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.²² 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.²³

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) (“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.’”)

²² Agricultural Bioterrorism Protection Act of 2002, Pub. L. No. 107-188, 116 Stat. 647 [hereinafter ABPA].

²³ *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.

B. Regulations and Advisory Guidelines

1. Select Agent regulations

As the PHBPA directs, HHS and USDA have expanded the Select Agent regulations to encompass possession and use of Select Agents.²⁴ There are three sets of relevant regulations: one promulgated by the CDC for the protection of public health²⁵ and two promulgated by the Animal and Plant Health Inspection Service (“APHIS”) relating to animals²⁶ and plants.²⁷ 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.²⁸

When 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.²⁹ If denominated as Select Agents, the biological agents must be registered with the National Select Agent Registry.³⁰ As of the last biennial review in November of 2008 there were thirty-six Selected Agents listed by HHS, twenty-four by USDA, seven

²⁴ The Select Agent Regulations are 42 C.F.R. § 73 (2009) (relating to public health), 9 C.F.R. § 121 (2009) (relating to animals), and 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 Center for Disease Control and Prevention or the U.S. Department of Agriculture. Also, 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.

²⁵ See 42 C.F.R. § 73 (2009) (relating to public health).

²⁶ See 9 C.F.R. § 121 (2009) (relating to animals).

²⁷ See 7 C.F.R. § 331 (2009) (relating to plants).

²⁸ Select Agent Regulations, *supra* note 24.

²⁹ PHBRA, *supra* note 7. (criteria for placing an agent or toxin on the Select Agent Registry).

³⁰ National Select Agent Registry, <http://www.selectagents.gov/index.html> (last accessed Sept. 21, 2009).

USDA Plant Protection and Quarantine (“PPQ”) agents, and ten overlapping agents where oversight authority and responsibility is shared between the two agencies.³¹

2. Security Risk Assessments

Security Risk Assessments (“SRA”) are mandated by the PHBPA for every individual who seeks to work with Select Agents.³² Using the criteria from the PATRIOT Act, the SRA is intended to preempt “Restricted Persons” from gaining access to these potentially harmful biological agents.³³ APHIS and CDC work with the Criminal Justice Information System (“CJIS”) at the Federal Bureau of Investigation (“FBI”) to identify individuals who should be

³¹ See <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html> (last visited 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 (Reconstructed 1918 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; 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 zea, Synchytrium endobioticum, Xanthomonas oryzae, Xylella fastidiosa (citrus variegated chlorosis strain); 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.

³² Public Health Service Act, 42 U.S.C. § 262, et seq., amended by PHBPA, *supra* note 7, to include § Sec. 351A (d). (The PHBPA amended the Public Health Service Act to enumerate the registration requirements for persons working with Select Agents.)

³³ PATRIOT Act, *supra* note 18.

precluded from gaining access to select agents and toxins.³⁴ The SRA most notably involves comparing an applicant's fingerprints against criminal and terrorist databases and must be renewed every three or five years.³⁵

Recently, the CDC notified the NSABB that 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.³⁶ 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 the baseline, mandatory 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.

One reason for the marked difference between the personnel screening measures used at 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.³⁷ A culture of strict security has always been the norm in these facilities and so the more invasive PRP procedures are not generally considered to be an extreme 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

³⁴ For a list of the steps in applying for a Security Risk Assessment, see <http://www.selectagents.gov/sra.html> (last visited Sept. 21, 2009).

³⁵ *Id.* (Responsible Officials and Alternate Responsible Officials, as defined by statute, must renew every three years. All other laboratory scientists must renew every five years.).

³⁶ NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *Enhancing Personnel Reliability among Individuals with Access to Select Agents* 7 (2009), available at <http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf>.

³⁷ *Enhancing Personnel Reliability Among Individuals with Access to Select Agents*, Report of the National Science Advisory Board for Biosecurity, May 2009, at 5 available at <http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf>

research is conducted without sufficient evidence of improved reliability beyond that which is possible from strict enforcement of the SRA process.³⁸

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

Advisory guidelines published by CDC and the NIH, *Biosafety in Microbiological and Biomedical Laboratories* (“BMBL guidelines”) delineate biosafety and biosecurity protocols for laboratories depending on the threat posed to laboratory staff and scientists as well as surrounding communities.³⁹

- a. Biosafety Level Designations:

The BMBL guidelines delineate four biosafety levels (“BSL”) in order of ascending levels of required containment.⁴⁰ 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.⁴¹

1. Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and those which present a minimal potential hazard to laboratory personnel and the environment.⁴²

³⁸ *Id.*

³⁹ U.S. DEP’T OF HEALTH AND HUMAN SERVICES, CTRS. FOR DISEASE CONTROL AND PREVENTION, THE NAT’L INSTS. OF HEALTH, *Biosafety in Microbiological and Biomedical Laboratories* (final printing forthcoming 5th ed., U. S. Gov’t Printing Office, 2007) <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.”

⁴⁰ *Id.* at 17.

⁴¹ 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 2009 available at: http://www.popularmechanics.com/science/health_medicine/4315093.html?page=1 (“The outer area is the medical research equivalent of a maximum-security prison- Biosafety Level 3. The inner sanctum is supermax or BSL-4.”).

⁴² BMBL guidelines, *supra* note 40, at 41.

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.⁴³
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.⁴⁴ Examples of agents handled and stored in BSL-3 laboratories include Tuberculosis and St. Louis Encephalitis virus.⁴⁵ 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 the laboratory.⁴⁶
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.⁴⁷ 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.⁴⁸

b. Biosecurity Requirements

Biosecurity has been defined as protection of microbial agents from loss, theft, diversion, or intentional misuse.⁴⁹

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

⁴³ *Id.* at 44.

⁴⁴ *Id.* at 49.

⁴⁵ *Id.* at 37.

⁴⁶ *Id.* at 50-56. Biological safety cabinets provide personnel, environmental and product protection through air flow management and decontamination techniques.

⁴⁷ *Id.* at 56.

⁴⁸ *Id.* at 57. In a “Cabinet Laboratory” all handling of agents must be performed in a Class III BSC whereas in a “Suit Laboratory” personnel must wear a positive pressure protective suit.*

⁴⁹ *Id.* at 118.

through BSL-4 laboratories.⁵⁰ 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 reporting in biomedical and microbiological laboratories are principally governed by the BMBL *advisory guidelines*.⁵¹

The BMBL guidelines recommend that facilities engage in a two-part approach to biosecurity considerations.⁵² 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.⁵³ 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.⁵⁴ The guidelines ultimately establish ten elements that might be incorporated into a biosecurity program, should a facility determine that it is necessary.⁵⁵ *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 statutes are involved in oversight of Select Agents. This is 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. In addition to the agencies aforementioned including DHS, DOD, HHS, USDA, NIH, and the CDC, other federal agencies also have some part in oversight of the movement and use of biological agents in the U.S. or

⁵⁰ Select Agent Regulations, *supra* note 24.

⁵¹ BMBL GUIDELINES, *supra* note 40.

⁵² *See id.* at 120. (stating “A risk management approach to laboratory biosecurity 1) establishes which, if any, agents require biosecurity measures to prevent loss, theft, diversion, or intentional misuse, and 2) ensures that the protective measures provided, and the costs associated with that protection, are proportional to the risk”).

⁵³ *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 biologicals 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.”).

⁵⁴ *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.”)

⁵⁵ *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, transport of biological agents, accident response plans, reporting and communication procedures, training and practice drills, and security updates.

have BSL labs themselves. These include the Food and Drug Administration, the Department of Commerce, the Department of State, the Department of Labor, the Department of the Interior, the Environmental Protection Agency, and the Department of Veterans' Affairs.⁵⁶ While a comprehensive listing and review of each applicable statute, regulation, and guidelines would be outside the scope of this article, a few are listed below to illustrate the broad nature of potentially applicable law and practice.

1. NIH Guidelines For Research Involving Recombinant DNA Molecules – April 2002⁵⁷
2. Hazardous Materials Regulations⁵⁸
3. International transport regulations including those of International Maritime Organization, and the International Maritime Dangerous Goods (IMDG) Code⁵⁹
4. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction⁶⁰

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

Select events are discussed below for illustrative purposes.

⁵⁶ GOVERNMENT ACCOUNTABILITY OFFICE, GAO-09-574, HIGH-CONTAINMENT LABORATORIES: NATIONAL STRATEGY FOR OVERSIGHT IS NEEDED, 9-10 (2009).

⁵⁷ DEP'T OF HEALTH AND HUMAN SERV'S, NAT'L INST. OF HEALTH, GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (2002) [hereinafter NIH GUIDELINES], *available at* http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf.

⁵⁸ Hazardous Material Regulations, 49 C.F.R. §§171-180 (2009) (relating to the safe and secure transportation of hazardous materials in commerce).

⁵⁹ INTERNATIONAL MARITIME ORGANIZATION, INTERNATIONAL MARITIME DANGEROUS GOODS CODE, (2004), *available at* http://www.imo.org/Safety/mainframe.asp?topic_id=158#1. 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).

⁶⁰ 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.

1. Anthrax: Fort Detrick

Bacillus anthracis (“Anthrax”), designated alternately as a BSL-2 or 3 agent depending on application, was the biopathogen responsible for five deaths and increased fear regarding public safety when it was dispersed through the United States Postal Service (“USPS”) in 2001.⁶¹ 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 Infectious Diseases, Fort Detrick, Maryland (“USAMRIID”).⁶² Dr. Bruce Ivins, an Army researcher at USAMRIID, suspected in the attacks, committed suicide before officially being 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.”⁶³ There has been substantial debate whether Dr. Ivins was the perpetrator. Irrespective of the guilt or innocence of Dr. Ivins, strong scientific evidence has come forth that the Anthrax strain used in the attacks came from the laboratory.

Of note, Dr. Bruce E. Ivins was cleared for his work with Anthrax at Fort Detrick through the DOD’s more onerous Personnel Reliability Program security process.⁶⁴ A 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.⁶⁵ 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.⁶⁶ The review

⁶¹ Atlas, *supra* note 2, at 17.

⁶² Press Release, Federal Bureau of Investigation, Anthrax Investigation: Closing a Chapter (Aug. 6, 2008), *available at* <http://www.fbi.gov/page2/august08/amerithrax080608a.html>; 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.

⁶³ *Id.*

⁶⁴ Bhattacharjee, *supra* note 3, at 1283.

⁶⁵ Kasper, *supra* note 9.

⁶⁶ *See e.g.* 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) (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.) *availabl at* <http://www.sunshine->

was conducted after notification from a source outside the university regarding a February 2006 occupational exposure to *Brucella*, a BSL-3 pathogen.⁶⁷ The exposed lab worker was experienced in handling *M. tuberculosis* (“TB”) and had been trained to work safely with that agent. The 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.⁶⁸ Texas A & M violations included broad access to Select Agents by employees who were not authorized to work with the agents, multiple biosafety infractions, and inadequate record keeping.⁶⁹ 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.⁷⁰ In 2008, a settlement agreement between the university and HHS culminated in payment of \$1 million. Texas A & M ultimately accepted responsibility for the lapses noted in the CDC investigation.⁷¹

project.org/TAMU/CDCTAMURreport.pdf. See also 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) (on file with authors).

⁶⁷ 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) (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.) (on file with authors).

⁶⁸ U.S. GOV’T ACCOUNTABILITY OFF., 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.

⁶⁹ See e.g. Jennifer Couzin, *Texas University Responds to Biosafety Complaints*, SCIENCE NOW DAILY NEWS, Sept. 6, 2007, available at <http://sciencenow.sciencemag.org/cgi/content/short/2007/906/1> (last accessed Sept. 21, 2009); U.S. Gov’t Accountability Off., 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).

⁷⁰ See e.g. 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).

⁷¹ Press Release, Texas A&M University, Vaccine Research Update (Feb. 20, 2008), available at <http://vaccineresearch.tamu.edu/news-release.html>.

3. *Shigella*: University of Texas at Austin

As a result of inquiry from NIH, University of Texas at Austin (“UT-Austin”) began to systematically review all laboratory incidents occurring between 2000 and 2007.⁷² Thirteen laboratory incidents were assessed, including five incidents of exposure to *Shigella*, a BSL-2 agent.⁷³ All workers recovered without incident.⁷⁴ As a result, UT-Austin thoroughly revised laboratory policies and procedures, notably those relating to surveillance, inspection, training, incident reporting and incident response. The university also developed and implemented additional safety and laboratory procedures.⁷⁵

4. *Vaccinia* virus in Smallpox Research: Philadelphia

In Philadelphia, at an unnamed research institution, an immunology graduate student was exposed to *Vaccinia*, a BSL-2 agent⁷⁶ and developed an eye infection resulting in her hospitalization.⁷⁷ 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.⁷⁸

⁷² 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).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *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.

⁷⁶ The *Vaccinia* virus is the "live virus" used in the smallpox vaccine. Dep’t of Health and Human Serv’s: 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).

⁷⁷ 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).

⁷⁸ *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, were discovered at several local farms near Pirbright in the UK.⁷⁹ Investigation into high containment labs found evidence of long term damage and leakage of the drainage system servicing the site. Contaminated waste water leaching into soil then carried off-site by vehicles via contaminated mud probably caused the resulting exposure. The event cost taxpayers over £3 billion.⁸⁰

E. Government Sponsored Reports:

As a result of one or more of the episodes described above, several institutions conducted investigative studies 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 article 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*⁸¹

In the October of 2008, the White House asked the NSABB⁸² to consider whether a national Personnel Reliability Program (“PRP”) should be mandated for the nation’s academic,

⁷⁹ U.S. GOV’T ACCOUNTABILITY OFF., HIGH-CONTAINMENT BIOSAFETY LABORATORIES: PRELIMINARY OBSERVATIONS ON THE OVERSIGHT OF THE PROLIFERATION OF BSL-3 AND BSL-4 LABORATORIES IN THE UNITED STATES: STATEMENT OF KEITH RHODES (2007), at 22.

⁸⁰ *Id.*

⁸¹ Nat’l Sci. Advisory Bd. 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).

⁸² 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 Report, *supra* note 82, at 1. 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. *See* 42 U.S.C. § 217a. The NSABB is governed by the provisions of the Federal Advisory Committee Act, *amended by* Pub. L. 92-463, 5

government, and private research facilities that handle Select Agents.⁸³ A PRP typically requires, at a minimum, psychological testing, a national security clearance, and medical testing.⁸⁴ In May 2009, NSABB produced a 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 mandate.⁸⁵ The challenge before regulators, as NSABB identified, 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 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.”⁸⁸ 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.⁸⁹ 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.⁹⁰ 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.⁹¹

U.S.C. 552(b)(C), which sets forth standards for the formation and use of advisory committees. Information about NSABB is available at http://oba.od.nih.gov/biosecurity/about_nsabb.html.

⁸³ Bhattacharjee, *supra* note 3, at 1283.

⁸⁴ NSABB Report, *supra* note 82, at 10-11.

⁸⁵ *Id.* at 9. The final report was issued on May 29, 2009. (“Furthermore, as it considered the potential utility of the various assessments commonly utilized in PRPs, it found little evidence to suggest that personnel reliability assessments going beyond the SRA and other institutional background checks that are already in place would correlate with, or effectively identify, an insider threat.”).

⁸⁶ *Id.* at 1.

⁸⁷ *Id.* at v.

⁸⁸ NSABB Report, *supra* note 82, at 8.

⁸⁹ *Id.* at 9-10

⁹⁰ *Id.*

⁹¹ NSABB Report, *supra* note 82, at 13-15.

2. Commission on the Prevention of WMD Proliferation and Terrorism: World at Risk⁹²

Congress tasked The Commission on the Prevention of WMD Proliferation and Terrorism (“The Commission”) with assessing the Nation’s activities, initiatives and programs to prevent the proliferation weapons of mass destruction and terrorism.⁹³ The Commission focused its study on those dangers that have been perceived as the greatest threats to national security, namely 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.”⁹⁴ 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.”⁹⁵

3. Government Accountability Office: *BIOSAFETY LABORATORIES: Perimeter Security Assessment of the Nation’s Five BSL-4 Laboratories*⁹⁶

This GAO report issued in September 2008 specifically addressed perimeter security of five operational BSL-4 laboratories. Perimeter security was assessed pursuant to fifteen security controls that GAO identified.⁹⁷ GAO concluded that two of the five BSL-4 laboratories had

⁹² 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) (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, Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110-53, §1851, 121 Stat. 266, 502. 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.).

⁹³ *Id.* at xi.

⁹⁴ *Id.* at 27-28.

⁹⁵ *Id.* at 25.

⁹⁶ U.S. GOV’T ACCOUNTABILITY OFF., *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).

⁹⁷ U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 98, at 14. (“(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

significant shortfalls in security controls that if operating as expected could preclude unauthorized access, loss, or theft of select agents.⁹⁸ HHS commented on this report noting that the CDC, in coordination with APHIS, will seek input from relevant stakeholders about the need and advisability of Federal regulation regarding specific perimeter controls.⁹⁹

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*¹⁰⁰

This preliminary GAO report identifies lessons learned from past exposure events and specifically raises the issue that no single federal agency has an oversight mission; therefore, no single agency is accountable for biosafety and biosecurity at all BSL labs.¹⁰¹ The GAO concludes that reporting barriers must be overcome in order to enhance biosafety through shared learning from past mistakes and to assure the public that accidents are examined and contained.¹⁰² This report also emphasizes the critical importance of facility maintenance in preventing environmental exposure and contamination as clearly demonstrated in the Pirbright exposure.¹⁰³ This report was followed by the recently released report summarized below.

5. Government Accountability Office: *HIGH-CONTAINMENT LABORATORIES: National Strategy for Oversight is Needed*¹⁰⁴

In its most recent report on the issue of biosecurity at BSL laboratories, GAO was asked to address the proliferation of high-containment laboratories, to describe which federal agency was tracking and overseeing this expansion, and to comment on lessons learned from highly

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.”)

⁹⁸ *Id.*

⁹⁹ *Id.* at 19.

¹⁰⁰ U.S. GOV'T ACCOUNTABILITY OFF., *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).

¹⁰¹ *Id.* at 7.

¹⁰² *Id.* at 7-8.

¹⁰³ *Id.* at 23.

¹⁰⁴ U.S. GOV'T ACCOUNTABILITY OFF., *HIGH-CONTAINMENT LABORATORIES: NATIONAL STRATEGY FOR OVERSIGHT IS NEEDED*, GAO-09-574 (September 21, 2009).

publicized incidents involving bioagents.¹⁰⁵ The report concludes that because no single federal agency has the authority or the mandate to track the expansion of all high-containment laboratories, no agency knows the precise number of high-containment labs currently in the United States or under development.¹⁰⁶

IV. Recommendations

The regulatory structure for BSL level 3 and 4 laboratories is fragmented across several federal agencies. The PHBPA and the ABPA grant oversight for Select Agents to the HHS and USDA respectively.¹⁰⁷ Additionally Select Agents, which overlap the human, animal, and plant categories because of their potential to impact various species, can be registered with either agency.¹⁰⁸ Recombinant DNA research is additionally covered by NIH guidelines.¹⁰⁹ Depending on the nature of the research or use of the agent, 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 given 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, the Inspector General of the USDA, 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, or maintaining current and accurate inventories.¹¹⁰ The CDC, under DHHS oversight, appears to have a more developed Select Agent enforcement program, as evidenced by thirteen enforcement suits brought between 2004

¹⁰⁵ *Id.* at 1

¹⁰⁶ *Id.* at 2.

¹⁰⁷ PHBPA, *supra* note 7.

¹⁰⁸ ABPA, *supra* note 22.

¹⁰⁹ 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).

¹¹⁰ U.S. DEP'T OF AGRIC., OFF. OF INSPECTOR GEN., 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 (Wash. D.C. Jan. 2006), at 4, *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.

and 2009.¹¹¹ Consolidating oversight into one federal agency does not necessarily preclude the beneficial collaboration that is now in place. For example, the FBI, through CJIS, should still be integrally involved in performing the background check component of the Security Risk Assessment because that is within its field of expertise and is more efficient than another federal agency independently developing those procedures.

Incident reporting of biosafety and biosecurity incidents at BSL-3 and BSL-4 laboratories is not centralized. Again, oversight for select agents is assigned to the HHS and USDA respectively.¹¹² Additionally agents that overlap categories can be registered with either agency.¹¹³ 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.

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

Physical BSL laboratory facilities do not require accreditation. Each laboratory is subject to inspection and site visits to assess compliance with the Select Agent regulations.¹¹⁴ 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.¹¹⁵ This is critical to preventing environmental exposure and the spread of disease. Each laboratory facility should be accredited to assure uniform standards for biosafety and biosecurity across institutions. Accreditation should require periodic review and assessment.

¹¹¹ U.S. DEP'T OF HEALTH AND HUMAN SERV'S, OFF. OF INSPECTOR GEN., SELECT AGENTS AND TOXINS, http://oig.hhs.gov/fraud/enforcement/cmp/agents_toxins.asp (last accessed Sept. 21, 2009).

¹¹² PHBPA, *supra* note 7.

¹¹³ ABPA, *supra* note 22.

¹¹⁴ 42 C.F.R. § 73.18 (2009) (relating to public health); *See also* 9 C.F.R. § 121.16 (2009) (relating to animals); *See also* 7 C.F.R. § 331.18 (2009) (relating to plants).

¹¹⁵ U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 102, at 23.

Protocols that are in place to gauge personnel reliability can be improved. There is great interest in increasing personnel reliability within research laboratories. However, some current compliance measures may be compromising the social benefits gained from investigation of the Select Agents because of onerous screening measures for personnel. This may have a deterrent effect on potential hires. Practical improvements to improve personnel reliability should be implemented.

For instance, the oversight agency might focus on improving 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.¹¹⁶ The informal practice of checking the names of individuals with favorable SRAs against the Counterterrorism Watchlist and other FBI databases, already occurring about every six months, should be formally incorporated into the SRA process through regulation. The oversight agency should insist that 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.

The NSABB also identified optimal personnel characteristics that should be considered for candidates for employment in high containment labs.¹¹⁷ 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.

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.

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

¹¹⁶ NSABB Report, *supra* note 82, at 11-12.

¹¹⁷ *Id.* 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.).

open educational nature of university campuses. Research is needed to assess what additional steps may be needed to secure private sector BSL-4 laboratories, which are few in number.¹¹⁸

The GAO perimeter report assessed BSL-4 labs based on perimeter security parameters alone. Fifteen parameters were chosen based on “GAO experience.”¹¹⁹ 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.

Conclusion

We conclude that Congress should enact 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 that 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.

The task at hand is sweeping as it requires reorganization of a regulatory scheme that involves almost a dozen federal agencies. However, it is crucial that this important scientific research be conducted in the safest and most secure manner possible.

¹¹⁸ U.S. GOV’T ACCOUNTABILITY OFF., BIOSAFETY LABORATORIES: PERIMETER SECURITY ASSESSMENT OF THE NATION’S FIVE BSL-4 LABORATORIES (2008), at 4, *available at* <http://www.gao.gov/new.items/d081092.pdf> (last accessed Sept. 21, 2009).

¹¹⁹ *Id.* at 7.