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Competing Responsibilities?:

Addressing the Security Risks of Biological Research in Academia

Report of a meeting on January 20-21, 2010

ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES

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Disclaimer
The concerns or recommendations outlined in this report reflect the discussions at the workshop and do not necessarily represent the views of the AAAS Board of Directors, its Council, or membership; AAU Board of Directors or membership; or APLU Board of Directors or membership.

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About AAU
The Association of American Universities (AAU) is a nonprofit association of 60 U.S. and two Canadian preeminent public and private research universities. Founded in 1900, AAU focuses on national and institutional issues that are important to research-intensive universities, including funding for research, research and education policy, and graduate and undergraduate education.

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The Association of Public and Land-grant Universities (A·P·L·U) is a non-profit association of public research universities, land-grant institutions, and many state university systems and has member campuses in all 50 states and the U.S. territories. The nation's oldest higher education association, APLU is dedicated to advancing research, learning and engagement. Current initiatives include efforts in math and science teacher preparation; international development; institutional accountability; online education; and more.

Executive Summary:
Introduction and Key Suggestions

New discoveries in the biological sciences and new applications of biotechnology offer the potential for vast societal benefits but also have led to increased national security concerns. In 2001, concerns over bioterrorism resulted in significant increases in funding for basic and applied biodefense research – for example, pathogenicity studies and vaccine and drug development – which prompted increased investments in the construction of high-containment facilities to address the biosafety risks associated with that research. At the same time, concerns about the potential exploitation of emerging biotechnologies and the risk of possible theft of dangerous pathogens initiated policy debates on how to minimize security risks.

A few highly publicized cases of accidental exposures of laboratory researchers to harmful pathogens as well as the accusation of a researcher from the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) as the perpetrator of the 2001 anthrax attacks prompted additional review of biosafety and biosecurity[1] initiatives in the United States. While strategies to address biosafety and biosecurity may differ, there are a few parallel concepts that may achieve both safety and security. Current policy debates center around issues common to both safety and security. Two examples of common issues include good research practices and vetting of personnel. The Appendix provides a brief background of current biosecurity policy debates and additional information.

Efforts have been made by the federal government to engage stakeholders in discussions of proposed policy actions. The National Science Advisory Board for Biosecurity (NSABB), the National Security Council (NSC), and interagency policy groups have reached out to the scientific community to raise awareness of biosecurity concerns and seek input on ongoing policy activities. The Office of Science and Technology Policy of the White House (OSTP), Federal Bureau of Investigation (FBI), and Office of the Director of National Intelligence (ODNI) have initiated a few specific biosecurity outreach activities. Similarly, the academic community has taken steps to address security concerns within their institutions and have contributed to discussions and other outreach activities to engage stakeholders, like local law enforcement and the public. Despite these efforts, more needs to be done to facilitate communication and engagement among the scientific community, security community and law enforcement, and policy-makers that benefit both the conduct and advancement of science and national security interests. While the security and scientific communities understand the importance of advancing research, assessing risks associated with that research, and implementing good research practices, there are differing perspectives on what constitutes a proper balance between these activities.

[1] Biosafety refers to the prevention of accidental exposures to laboratory biological agents whereas biosecurity refers to prevention of intentional exploitation, theft, and/or release of biological agents. These terms are often described as separate concepts with distinct mitigating activities in the U.S. however, many countries describe biosecurity and biosafety as a single concept. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines has added a section on biosecurity and the World Health Organization publishes a Laboratory Biosecurity Manual.

On January 21 and 22, 2010, the American Association for the Advancement of Science (AAAS), the Association of American Universities (AAU), and the Association of Public and Land-grant Universities (APLU) hosted a meeting with university leadership, scientists, representatives of the security community, and policy-makers to explore the perceptions of risk held by different communities, review current policy discussions to minimize those risks, address potential barriers and challenges academic institutions face in dealing with national security requirements, and suggest actions to improve the collaborative environment to promote research and education in the biological sciences while minimizing potential national security risks. This meeting was supported by the Alfred P. Sloan Foundation.

Emerging Themes and Suggested Policy Actions:

Several overarching themes emerged from the meeting: 1) the scientific and security communities share the same goal – ensuring public safety – giving them a common base on which to build relationships to address security concerns; 2) promoting and maintaining mutual trust among the scientific community, security community, policy-makers, and the public is critical to addressing potential security risks associated with advancing research; 3) safety and security measures must be addressed at the institutional level in order to best reflect internal structure and policies and local laws; and 4) leadership is important in fostering a safe, ethical, and secure research environment. The federal government and security community should work with the academic community to develop national policies, provide specific guidance on laboratory biosecurity that builds on existing programs, and learn how to interact effectively with university leadership and scientists. Correspondingly, the scientific community has a responsibility to continue to address biosecurity concerns by taking action to promote good practices in biological research, improve communication with the security community, and actively engage the policy process.

Listed below are policy options and actions that were suggested by meeting participants to minimize security risks while promoting education and research. Implementation of and detailed guidance for the suggested policy actions may be difficult to achieve but may allow institutions to best address critical national security concerns. The meeting sponsors made no attempt during the meeting to have participants reach a consensus on these suggestions although participants reviewing the report indicated their support for them. In addition, the suggested recommendations do not necessarily reflect the views of AAAS, AAU, or APLU.

Suggestion 1: ***Communication between Academia and the Public:*** **The biological sciences community should continue to foster communication and build trust with the public, particularly those living in the vicinity of research institutions.**

Suggestion 2: ***Communication between the Scientific and Security Communities*****: The security and scientific communities should continue to work together to foster relationships, improve communication, and build trust.**

Suggestion 3: ***High-level Support for Good Research Practices at Academic Institutions*****: Research institutions should provide high-level support and attention to ensure that effective processes are in place to secure laboratories that are conducting research with pathogens and toxins posing the highest safety and**

security concerns. This level of support should be provided regardless of whether regulations are imposed by the government.

Suggestion 4: ***Sustainable Guidance for Securing Select Agents*****: Government regulators should provide flexible and adaptable guidance to ensure that select agent regulations can be implemented effectively and appropriately over time.**

Suggestion 5: ***Harmonization of Common Science and Security Requirements:*** **The federal government should reduce financial and administrative burdens on research institutions and increase the use of good safety and security practices by harmonizing select agent policies across all relevant agencies, and by building a common regulatory structure for safety and security of laboratory hazards, such as radioactive materials, harmful chemicals, and dangerous biological agents.**

Suggestion 6: ***Scientific Input in the Policy Process*****: Policy-makers should enhance efforts to incorporate input from the scientific community during the policy development process to effectively address security concerns while minimizing associated administrative burdens and consequent missed research opportunities, and to ensure buy-in for the policies.**

Suggestion 7: ***Scientific Input in Expanding and Promoting Good Research Practices*****: Universities and non-governmental organizations should enhance their existing programs and increase the involvement of scientists in developing and promoting good practices in ethics, safety, and security.**

Suggestion 8: ***University-based Threat Assessment Teams:*** **Universities should establish or expand threat and/or risk assessment and management teams to address different hazards experienced on their campuses.**

Meeting Summary

Perceptions of Risk

In order to create effective policies that promote scientific inquiry while minimizing any potential security risks, it is important to engage the scientific community, federal and state regulators, policy-makers, and intelligence and security officials in developing local and national policies in a deliberate and transparent manner. Although the federal government has engaged the scientific community on critical policy issues, many national security requirements developed to prevent exploitation or theft of biological equipment and materials still do not necessarily contribute to either enhanced security or the progress of research. Some of these requirements, such as requiring security clearances for equipment that poses minimal threat of misuse, may have reduced the credibility of regulators and policy-makers. Facilitating engagement and interaction between the scientific and security communities requires that each community familiarize itself with the other's culture and daily experiences to promote understanding of the rationale, perception, and implementation of policies.[2] The language used by different stakeholders is an important contributing factor in any discussions between technical and security experts about risks and threats.

The Security Community's Perceptions

The law enforcement, intelligence, and security communities have information that malicious actors have expressed an interest in using chemical, biological, and/or radiological agents to inflict harm, and that these individuals and groups seek to acquire the requisite knowledge, materials, and/or agents from legitimate facilities.[3] When interacting with the scientific community or the public, the security community often uses messages (e.g., 'we are at war with Al Qaeda' or 'war on terrorism') or images (e.g., the 9/11 World Trade Center attacks or the 2001 anthrax laced letters) to present a compelling case for increased security at research facilities. The security community has to take into account the national security concerns they routinely face with possible consequences of a deliberate attack as well as provide the appropriate information to prevent or promote preparedness for an attack. To facilitate these activities, the security community tries to find ways to continually monitor the situation, for example, by examining openly published scientific literature to stay current with technological advances and identify research activities that may have the potential to be exploited maliciously. However, approaching the scientific community with general threats rather than acknowledging or addressing the more tangible threats that research institutions routinely face (e.g., cyber crimes, eco-terrorism, campus shootings), can make the security community be perceived as insensitive to the conduct and governance of science. This can result in scientists fearing that

[2] In some states, requirements to disclose information requirements may contribute to less secure research environments.

[3] The definitions of threat and risk are important in these conversations. Often, the term "threat" is used to refer to tools, agents, and technologies that could potentially be used for harm, but the term should be used to represent an entity that has the intent and the capability to do harm. Scientific tools, techniques, agents, knowledge, experience, and other similar factors contribute to the actor's capability. Since biotechnology is expanding globally, penetrating markets in a wide range of industrial sectors, and advancing rapidly for fully legitimate commercial and scientific reasons, the intelligence community cannot solely rely on assessing access to tools, agents, technologies, and/or knowledge to understand the bioterrorism threat. Instead, it must determine intent of potential adversaries. A more complete picture of the impact of a deliberate biological attack includes assessments of a population's vulnerability and the consequences of a successful attack.

proposed remedies would unduly hamper the advancement of life sciences research and biotechnology.[4] These attitudes can be detrimental to building relationships with the scientific community.

The Scientific Community's Perceptions

The biological sciences community is diverse, and scientists can be grouped into several categories based on their discipline, educational background, research area, and work experiences. These categories contribute heavily to a scientist's perception of risk. In general, scientists do not necessarily perceive that harmful organisms by themselves make effective biological weapons or that basic research confers knowledge and tools that could contribute to the successful development of biological weapons. If scientists have experience working with a particular microorganism or technology, they may not share the perception of risk that security officials or intelligence experts have regarding the same agent or technology. Further influencing the way the scientific community perceives risk is that they do not equate increased paperwork with enhanced security or safety. In addition, the international scientific community may not share the same perspective about weapons of mass destruction (WMD) risks and potentially overall risks (ethical, environmental, safety, and security risks) as the American security community and may not necessarily agree with U.S. policies on biosecurity.

Open Communication, Trust, and the Policy Process

Fostering relationships among these disparate groups as well as with the public was repeatedly raised by meeting participants as critical to advancing scientific research and addressing issues of accountability. Demonstrating to the public, policy-makers, and security experts that universities take national security concerns and requirements seriously, that their scientists act responsibly, and that mechanisms are in place to oversee the universities' research activities is absolutely critical to build trust among the communities. Scientists who engage in and are committed to promoting trust and building relationships with the security community, public, and policy-makers can act as role models and leaders to the rest of the scientific community.

Promoting Communication between the Scientific Community and the Public

Fostering relationships with the public is absolutely critical to the conduct of science in the 21st century because the entire operation and success of the biological enterprise is heavily dependent on public trust. Some scientists perceive that the public does not have trust in the scientific community's ability to act responsibly to address risks associated with biological research. There is no evidence that public opinion on this issue has been systematically assessed. There is evidence however, that members of the security and policy-making communities doubt whether the scientists can act responsibly.[5] To address this issue, scientific societies and the federal

[4] For additional information about scientists' views regarding law enforcement, see Hafer N, Vos CJ, McAllister M, Lorenzi G, Moore C, Berger KM, Stebbins M. How Scientists View Law Enforcement. Science Progress. Feb 2009. (http://www.scienceprogress.org/wp-content/uploads/2009/02/how_scientists_view_law_enforcement.pdf).

[5] At a December, 2008 hearing of the Senate Homeland Security and Governmental Affairs Committee, witness Robin Cleveland, a member of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, testified that scientists do not act responsibly and mandatory education should be required to educate scientists about security risks of their research. (see http://hsgac.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=d0d0b4c1-d1d1-4b7a-9c16-fd9af22d97e0) This hearing resulted in the writing of the WMD Prevention and Preparedness Act (S.1649, 111th Congress).

government have developed educational programs to assist scientists in becoming effective communicators about their research, including research-associated risks and how those risks are addressed.[6] Similarly, research institutions have administrative staff and faculty that oversee biological research[7] and screen personnel. However, these programs are not marketed or described using terms familiar to the security community, leading the security community and the public to believe that adequate procedures are not in place to address current or emerging biosecurity concerns.

To promote transparency and communication with the public, many universities have actively engaged with residents in their neighboring communities about the types of research they conduct and the measures they have in place to protect their employees, students, animals used in research, and the general public. Some institutions, for example, conduct tours of their facilities.[8] Recognizing that communication is an important part of building public trust about biodefense research, universities have begun to issue press releases that highlight the research being conducted on campus and its societal benefit. Opportunities to foster relationships between the scientific community and public do not stop at the local level, and it is incumbent upon the research community to expand that dialogue to the global level. There are also numerous opportunities to address public trust issues in science locally and globally via scientific collaborations and scholarly meetings.

Promoting Communication among Scientists, Policy-makers, and the Security Community

Policy-makers and the security community must demonstrate to the academic community that their guidance, regulations, and statutes are reasonable, based on evidence that such measures are necessary (i.e. the threat is real), and can have a measurable impact at reducing emerging threats and potential risks associated with scientific research. The increased attention given to biosecurity in 2009 – eight years after 9/11 and the anthrax mailings – leads many in the scientific community to ask, "why the urgency?" The issue of urgency affects the type, process, and quality of policies being developed. Moving past general urgency to immediate threats would provide critical opportunities to foster dialogue and a deliberative policy discussion that includes all relevant stakeholders and ultimately results in the development of more effective policies. The security community and policy-makers need to acquaint themselves with university organization and governance as well as interact with scientists on tangible threats (e.g., animal rights incidents and campus violence) rather than simply addressing amorphous national security threats.

Most of the recent policy discussions have been driven by a few discrete incidents – the 2001 anthrax attacks and the fear of insider threats, and a small number of recent accidental exposures

[6] The current Responsible Conduct of Research (RCR) training in the U.S. provides educational topics and tools to address ethical and safe laboratory practices. American graduate students supported by the National Institutes of Health and the National Science Foundation are required to be trained in RCR. See http://ori.dhhs.gov/education/, http://www.nsf.gov/pubs/policydocs/rcr/faqs_mar10.pdf, for additional information.

[7] Examples include biosafety professionals, Institutional Biosafety Committees (, Institutional Animal Care and Use Committees, and Institutional Review Bodies.

[8] There is concern from members of the scientific community that wide-spread implementation of tours of laboratory and/or animal facilities may not be feasible as they may make research institutions more vulnerable to threats, such as eco-terrorism.

to select agents.[9] Developing policies in response to rare occurrences may result in greater vulnerability and increased unintended consequences in the longer term. Some university administrators believe that the National Science Advisory Board for Biosecurity (NSABB) has been very responsive and thoughtful, but that its approach to address the dual use life sciences issues[10] reflects today's political concerns rather than an interest in creating a sustainable mechanism that helps scientists and university leadership to understand how to deal with the dual use potential of current and future technologies. Since laboratory biosecurity policies and the dual use dilemma will affect the scientific and academic community broadly, policy discussions need to be deliberate and rational, include all stakeholders as active participants in the policy-making process, articulate the risks clearly, develop policies that are adaptable to evolving risks, and incorporate regulatory measures or guidance based on their efficacy for minimizing potential risks. This continued and expanded engagement could help identify solutions for pressing security concerns that can be easily implemented in academia and impart confidence in the policies with scientific leaders.

Accountability, Audits, and Metrics

Currently, the executive branch of the U.S. government prefers to develop guidance rather than additional regulation or statute to address biosecurity concerns in an attempt to avoid increasing the burden on research institutions and provide sufficient flexibility for the guidance to adapt to emerging biotechnologies. Even so, the pace of science, especially in the biological arena, is advancing very rapidly, and federal oversight bodies may not be nimble enough to respond accordingly. Guidance is considered by university administrators as *de facto* regulation, and requisite administrative and financial resources must be dedicated for compliance with guidance. However, in the absence of evidence identifying security measures that could be uniformly and effectively implemented, laboratory biosafety and biosecurity, including physical and personnel security, may be best addressed by the research institutions themselves and by using a combination of guidance and regulation. These policy actions would be most effective if they had a demonstrable impact on minimizing the risks of biological research while also minimizing the administrative burden already felt by principal investigators (PIs) and laboratory heads or managers.[11] Much of the current policy discussions about laboratory biosecurity and misuse of biological research relies on personal responsibility among individual researchers and perceptive laboratory heads to identify suspicious behaviors or activities, but provides little guidance on the roles and responsibilities of scientists and institutional administrators in these matters.

Metrics

Research institutions recognize that compliance with regulations and guidelines is one critical component of effective research and laboratory management. However, the existing Select Agent Program and the agencies that support select agent research as well as other agencies and organizations that oversee aspects of biological research promote a culture of compliance instead of cultivating a culture of safety and security. Checklists used for compliance purposes tend to

[9] Kaiser, J. *Accidents Spur a Closer Look at Risks at Biodefense Labs*. Science., 28 Sept 2007; 317: 1852-1854.
[10] The term dual use is used to describe the misapplication of legitimate biological research for harmful purposes.
[11] Currently, PIs spend about 42% of their time dealing with administrative tasks associated with their research and institutional responsibilities. See Federal Demonstration Partnership's (FDP) Faculty Burden Survey Paper at http://sites.nationalacademies.org/PGA/fdp/. For additional information, see Leshner, A. Reduce Administrative Burdens. *Science*. 12 Dec 2008; 322(5908): 1609.

include tangible or quantifiable measures such as physical barriers, databases, inventory controls, and lists of personnel rather than addressing the potentially more effective, qualitative security measures, such as building trust and relationships among scientists, institutional administrators, local law enforcement, and/or the public. Fostering communication and trust is critical to the implementation of effective security measures, raising awareness of the biosecurity problem, and promoting a cultural change within the scientific community that stresses personal responsibility and facility security.[12] However, cultural changes (for example, a culture of security awareness) cannot be captured by current audit mechanisms – i.e., checking boxes. Instead, a system based on performance may be more effective at achieving a cultural shift that is more sensitive to biosecurity risks and concerns. Several universities consider the real audits to be the less-regimented and more free-flowing exchanges between compliance inspectors or law enforcement - including DHS and the FBI – and the researchers and administrators under review. As policies are being developed to address laboratory biosecurity and the dual use dilemma and as more infectious agents are characterized, there is a need to develop compliance and inspection mechanisms that stress safety awareness and a security mindset over mere compliance.[13]

Inspections

Another troublesome issue is the multiple yet uncoordinated inspections to which institutions performing select agent research are subject. The Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and/or Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) have an integrated inspection program and conduct periodic inspections to review compliance with the Select Agent Program requirements, which includes principles prescribed in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual.[14] This system improves as more information about effective security measures and corrective actions to mitigate risks at research institutions are identified. The Department of Defense (DoD) and the Department of Homeland Security (DHS) may conduct separate inspections of the select agent research they fund at associated facilities in order to assess compliance with agency-specific requirements. Currently, these inspections are not conducted jointly with the CDC and/or APHIS and some of these agency-specific requirements may conflict with the requirements of the Select Agent Program. The CDC is open to integrating inspections with DoD and DHS, and the *Report of the Working Group on Strengthening Laboratory Biosecurity in United States*[15] recommended that the federal government establish a system to coordinate oversight and inspection of select agent laboratories. However, if the contractual requirements still differ among agencies and programs, even joint inspections may not alleviate the burdens associated with these inspections.

Moreover, institutions conducting research involving select agents may be subject to a wide variety of other audits and inspections, each of which can be costly and time-intensive. The inspecting agencies may differ based on the type of laboratory – hospital, basic research, private industry/manufacturing, or vivarium – and may include the funding agency, the Occupational

[12] The scientific community became more accepting of personal and facility security as a result of animal terrorism.
[13] These types of policies would promote safety and security as complementary objectives with a common basis.
[14] Center for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition.* See http://www.cdc.gov/od/OHS/biosfty/bmbl5/bmbl5toc.htm for more information.
[15] See http://www.hhs.gov/aspr/omsph/biosecurity/biosecurity-report.pdf for more information.

Health and Safety Administration, the Association for Assessment and Accreditation of Laboratory Animal Care International, the Environmental Protection Agency, state departments of health, the Food and Drug Administration, the Federal Aviation Administration, the Department of Transportation, the National Institute for Occupational Safety and Health, the Nuclear Regulatory Commission, the Centers for Medicare and Medicaid Services (Clinical Laboratory Improvement Amendments), or the Joint Commission.[16] An audit is conducted for each inspection to ensure that the research institution is in full compliance with the inspection agency's requirements; each audit is time-intensive and costly.

Costs of Laboratory Biosecurity Requirements

Compliance with the Select Agent Program is quite costly and burdensome for many research institutions, particularly given that they are currently subject to many different regulatory requirements. In addition to the requirements of their funding agencies, research institutions often must implement procedures to minimize the security risks associated with other laboratory activities or functions as well as university-wide functions. Universities must make a commitment to provide substantial administrative and financial resources if their researchers want to work on select agents. University research programs already face over 30 unfunded research compliance mandates[17] and adding more will stretch the finite human and financial resources even thinner. Except for the National Biocontainment Laboratories,[18] costs for compliance cannot be funded from direct costs of research. Although the National Institute of Allergy and Infectious Diseases (NIAID) biodefense budget increased dramatically after 2001 stimulating scientists to seek biodefense funding, many scientists who worked with human, animal, or plant microorganisms that were placed on the select agent list consequently abandoned their research and pathogen or toxin collections for less restrictive work. This may have been due to the financial and administrative burdens imposed on laboratories conducting work with pathogens and toxins on the select agent list.

The unintended consequences of current and proposed policies and opportunity costs must also be factored into the overall burden of regulations, laws, and guidance and acknowledged in any trust-building exercises or policymaking activities. These opportunity costs are very difficult to quantify. All U.S. biodefense priorities are interconnected and measures for select agents could negatively affect medical countermeasure development and infectious disease surveillance, and could also have a negative impact on other sectors, like energy (e.g., biofuels), public health, and agriculture. Adverse effects may be experienced if research is temporarily halted because of audits or inventorying agents, or if collections are destroyed when entire research portfolios are abandoned due to associated burdens or retirement (with no continuation of the work).

Animal disease laboratories find conducting research with infectious agents in natural animal hosts difficult and costly under existing select agent regulations. In addition, few facilities exist for conducting animal studies using zoonotic select agent pathogens. Many researchers study diseases in surrogate animals rather than the natural animal host, which can reduce the administrative and financial burdens associated with the research. However, the use of animal surrogates to study animal pathogens is scientifically less robust than conducting the research in

[16] See http://www.jointcommission.org/ for more information.
[17] Council on Government Regulations, *Federal Regulatory Changes, Since 1991*. Accessed April 9, 2010.
[18] See http://grants1.nih.gov/grants/guide/notice-files/NOT-AI-02-038.html for additional information.

the natural animal host. This problem is further complicated by the lack of financial resources and guidance provided by the USDA.

The Select Agent Program and Personnel Security

Since the alleged perpetrator of the 2001 anthrax letters was a government researcher at the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), the bio- and homeland security communities have been very involved in policy discussions on preventing the 'insider threat' and have been exploring ways to strengthen methods for screening personnel and ensuring they can be trusted to work with select agents.[19] Researchers and institutional administrators, professional relationships, and professional responsibility are critical for personnel security and can be more effective than physical security measures or background checks.[20] For example, one university experienced a situation in which an animal rights activist, dressed as a researcher, tried to gain access to an animal housing facility without proper key card access. The attempt failed only because an approved employee noticed the person was wearing jewelry, which is not allowed in that animal research laboratory according to university policy. Another university experienced an animal rights attack that was believed to have been carried out by an insider, but for which the FBI has yet to catch the perpetrator. Security procedures therefore had to be developed under the assumption that the perpetrator may still be working in the facility. This incident also prompted the university to consider characteristics contributing to inappropriate behavior. These incidents support the involvement of the scientific community in setting the boundaries for acceptable and unacceptable laboratory behavior.

Screening and Monitoring Employees

Universities are interested in having employee evaluation systems in place to prevent tangible safety and security concerns. They see the value in having institutions take responsibility for their employees. However, universities face legal barriers, such as privacy and antidiscrimination laws, when attempting to acquire potentially derogatory information about prospective employees from former employers and other references. This becomes an even more delicate balancing act if an institution seeks to remove an employee who has acted suspiciously or unsafely from the laboratory environment, and to get a better understanding of any potential impacts on safety and security posed by an employee in counseling. Although universities informally communicate with each other to learn more about prospective employees and almost every university has a faculty and staff evaluation system, these systems are not thought of as adequately addressing the 'insider threat' because they are not widely publicized or cohesive. In addition, the recent shooting at Fort Hood demonstrated the difficulties of identifying problematic behavior when relevant and revealing information is not integrated into a single system, when people are reluctant to report problems, and when no mechanisms exist to prevent rehiring of individuals with a prior history of problematic behavior.

Select Agent Approval of Graduate Students

Personnel security programs are particularly challenging to implement in institutions, such as universities, whose missions include educating undergraduate and graduate students. Graduate

[19] All personnel with access to select agents have to be approved and registered by the CDC and/or APHIS, a process that requires security risk assessments by the FBI, which is comprised of database checks.

[20] See also National Research Council. Responsible Research with Biological Select Agents and Toxins. National Academy Press. (Washington, DC, 2009).

students choose their thesis laboratory by rotating through a few laboratories for a few months during the beginning of their graduate studies. These rotations are not very compatible with the lengthy and costly security risk assessment process currently required to grant access to select agents. This limits the pool of students available to work in select agent laboratories because in the absence of rotations, the students do not have an opportunity to gain awareness of the laboratory environment as well as available research and training opportunities in select agent laboratories. Universities would have to approve all graduate students who might have any interest in working in a select agent laboratory, provide students with an escort during their time in a select agent laboratory, or expect students to assess the working environment and possible thesis projects in select agent laboratories without having actually worked in one. An alternative solution of streamlining the security risk assessment process to expedite approval for incoming graduate students would be problematic, since the public and policy-makers may view granting select agent access to relatively unknown individuals – i.e., new graduate or undergraduate students – as irresponsible.

Responsible Conduct of Research

Personal responsibility and research integrity are critical aspects of current biosecurity discussions. The NSABB, scientific societies, and the international biosecurity community have advocated for codes of conduct for all life scientists that would make exploitation of biological research for malicious purposes taboo. Some believe that codes of conduct could address concerns about unsafe and suspicious behavior and bypass legislative measures for regulating behavior but may not sufficiently address concerns from the homeland security community. However, others, including some bioethicists, are skeptical about the use of codes of conduct to change behavior because the biological sciences community is very heterogeneous. Codes of conduct are effective for people with a common sense of research conduct, but the behaviors of researchers working in the biological sciences may vary by fields of study, disciplines, facility, and laboratory management and make it difficult to achieve a common sense of conduct. This challenge is exacerbated at the global level. In addition, demonstrating to senior scientists the need for codes of conduct or other methods to raise awareness of biosecurity issues is difficult because mid- to late-career scientists tend to think they have a deeper understanding of the applications of their research and responsible conduct in science than the security community, and because there have been very few cases of misuse of biological research.

Training Scientists about Biosecurity Issues

Training can be thought to induce a cultural change in the scientific community by raising awareness of important issues. The NSABB, a number of scientific societies, and the international biosecurity community are currently investigating programs that train scientists about the dual use dilemma. Though a few academic programs address the dual use dilemma in biosafety training programs,[21] more have addressed this issue within the broader context of responsible conduct of research (RCR).[22] One institution educates its American and foreign graduate students and post-doctoral fellows about the dual use dilemma in one lecture of the responsible conduct of research program using simulations and small group discussions. The Regional Biocontainment Laboratories and National Biocontainment Laboratories are required to

[21] See http://cstsp.aaas.org/dualuse.html for more information.

[22] The RCR system is a conceptual framework used to engage students on issues, such as social responsibility, mentoring or role modeling.

provide biosafety and biosecurity training.[23] The Federation of American Scientists,[24] Southeastern Regional Center of Excellence of Emerging Infections and Biodefense,[25] the Center for Arms Control and Nonproliferation,[26] and the University of Bradford, UK[27] have developed online training modules to introduce scientists to broader biosecurity issues and the dual use dilemma. The National Institutes of Health and the National Science Foundation require RCR training for certain grant awardees. Much like audits for the Select Agent Program, the RCR system is more of a "check-the-box" requirement rather than a system that trains scientists to identify lapses in responsible behavior and act accordingly. Very recently, RCR training has included biosafety,[28] and there are currently discussions about including the dual use dilemma and possibly other biosecurity topics as well. Scientists already take biosafety training very seriously, having every incentive to conduct their research safely to protect themselves, co-workers, their neighbors, and the surrounding environment from accidental exposure.

Implementation of biosafety measures and training programs is both a contractual and a regulatory requirement for select agent laboratories. Unlike biosafety training, biosecurity training is considerably more difficult to develop. Very little guidance has been provided to the scientific community for characterizing the dual use potential of research activities, weighing the risks and benefits of research activities, determining suspicious behavior, and communicating research methods and findings that have the potential for exploitation.

Communication of Research[29]

To allow science to advance and for experiments to be reproduced, basic and applied research and their methods are published in open literature. However, open literature can be used for both legitimate and malicious purposes. Quite a few university leaders are aware that terrorists look at the open scientific literature, but this level of awareness is not necessarily representative of the entire scientific community. With concerns over exploitation of legitimate biological research for malicious purposes, communication of research methods, findings, and potential applications has

[23] The Regional and National Biocontainment Laboratories were established but the National Institute of Allergy and Infectious Diseases to perform research focused on identifying strategies for prevention, detection, diagnosis, and treatment of dangerous pathogens and toxins. See http://grants1.nih.gov/grants/guide/notice-files/NOT-AI-02-038.html for more information.

[24] See http://www.fas.org/biosecurity/education/dualuse/index.html for more information.

[25] See http://sercebtraining.duhs.duke.edu/Demographics.asp for more information.

[26] See http://www.politicsandthelifesciences.org/Biosecurity_course_folder/base.html for more information.

[27] See http://www.brad.ac.uk/acad/sbtwc/dube/resource/index.html for more information.

[28] The National Institute of Health. Update on the Requirement for Instruction in the Responsible Conduct of Research. NOT-OD-10-019. November 24, 2009.

[29] In 1995, President Reagan issued National Security Decision Directive 189 (NSDD-189), which states that publication of basic, fundamental research that is not determined to be classified should not be otherwise restricted. NSDD-189 was reiterated in 2001 by Condeleezza Rice, then National Security Advisor. However, this Directive is not self-enforcing, and many universities report that their research funding instruments contain restrictions on their treatment of "sensitive but unclassified" information. These "troublesome clauses" have so far primarily affected physical science and engineering research, particularly those done under subcontract to private firms, but universities are concerned that this practice will transfer to life science grants as well. This may not become a wide-spread practice in biological research because the National Institutes of Health and National Science Foundation, the primary U.S. government funding agencies of life science research, cannot utilize such restrictions. The Bush administration issued a Presidential Memorandum (Designation and Sharing of Controlled Unclassified Information) asking federal agencies to use the term Confidential Unclassified Information (CUI) instead of Sensitive but Unclassified (SBU).

been an important part of biosecurity policy discussions. In 2003, policy-makers, editors of premier scientific and medical journals, and scientists issued a statement about responsible communication of life science research at the time of publication or earlier.[30] The NSABB has developed a series of tools for communicating research with dual use potential. The NSABB noted that all communications should be considered for their dual use potential but that only those manuscripts deemed to be of concern should be more thoroughly assessed by reviewers.[31] Currently, the journals *Science*, *Nature*, *Bioterrorism and Biosecurity,* and those published by the American Society of Microbiology ask reviewers of manuscripts to assess the dual use potential of the research. Very few papers have been flagged or elicited discussion as a result of this process, and all were eventually published with supporting commentary or modification of the manuscript. Authors have been willing to cooperate if revisions to manuscripts do not affect the scientific content or conclusions. At the same time, leaders in the scientific community are quick to caution that communication strategies and policies should be developed and implemented very carefully so they do not set a bad precedent of modifying manuscripts in ways that eliminate the reproducibility of experiments (i.e., by abbreviating descriptions of research methods). The issue of communication of dual use life science research will be complicated by increasing knowledge about infectious agents and emerging biotechnologies, and the risks they may pose.

Information Sharing of Best Practices and Isolating Scientists

Development of best practices in biosafety and biosecurity benefits greatly from the sharing of problems and corrective actions among appropriate stakeholders. While there was support for a more formal mechanism to share best practices at the Competing Responsibilities meeting, there was concern that sharing this information with the general public or the news media could impede these efforts. New safety and security measures may not necessarily be incorporated into best practices in the absence of protected peer-to-peer communication, existing measures may not improve without peer review or additional information, and biosafety or biosecurity measures, if not shared, would not necessarily evolve with the risks posed by new technologies or biological research.[32] Sharing of best practices in biosafety and biosecurity with other research institutions may be jeopardized as select agent policies become more restrictive and consequently, select agent laboratories become more isolated from the rest of the academic and institutional communities. Isolation may compromise the quality of the research by limiting peer review, collaboration, intellectual contributions from outside colleagues, or innovative ideas. This isolation also may affect education and laboratory training and could negatively impact the overall conduct of research and employee morale.

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[30] Journal Editors and Authors Group. *Statement on Scientific Publication and Security*. Science., 2003 Feb 21; 299(5610): 1149.

[31] National Science Advisory Board for Biosecurity. *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information.* 2007. See http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf for more information.

[32] Prior to 1969 when the U.S. had an offensive biological weapons program, the laboratories at Fort Detrick developed a system of biosafety that used risk assessments to identify risky agents and appropriate containment measures that addressed those risks. The classified environment of the former U.S. offensive biological weapons program imposed barriers to sharing biosafey information with the civilian population. After the U.S. offensive program was dissolved in 1969, the biosafety practices were complied in the BMBL and made available to all research facilities housing infectious agents. The guidance for assessing the level of risk posed by an agent has been made more prominent in the 5th Edition of the BMBL.

Emerging Themes and Suggested Policy Actions

Although efforts have been made to promote communication and trust between the scientific and security communities, more can be done to ensure that institutions can most efficiently and effectively use their limited resources to minimize national security concerns while promoting beneficial science. Listed below are policy options and actions that were suggested by meeting participants to minimize security risks while promoting education and research. Implementation of and detailed guidance for the suggested policy actions may be difficult to achieve but may allow institutions to best address critical national security concerns. The meeting sponsors made no attempt during the meeting to have participants reach a consensus on these suggestions although participants reviewing the report indicated their support for them. In addition, the suggested recommendations do not necessarily reflect the views of AAAS, AAU, or APLU.

Suggestion 1: ***Communication between Academia and the Public:*** **The biological sciences community should continue to foster communication and build trust with public, particularly those living in the vicinity of research institutions.**

To alleviate the public's distrust of scientists and biomedical research, some universities have engaged their local communities to address key ethical and security concerns. One university included stakeholders in an all-hazards discussion after the institution was awarded a U.S. government contract for a biosafety level 3 laboratory. They worked through three scenarios with community stakeholders, which included law enforcement. The major challenge is to find productive lines of communication with the public to change their perception about the benefits and risks of research.

Specific suggestions:

1) Institutions should expand current efforts to inform the public that procedures are in place to prevent unsafe, unethical, or insecure research.
2) The scientific community should use the media to promote the beneficial uses of laboratories and research activities.
3) Universities, the public, the security community, and policy-makers should reconcile issues associated with information sharing and the public's need for greater transparency. Greater transparency may mean greater vulnerability to the institution and possibly to national security.

Suggestion 2: ***Communication between the Scientific and Security Communities*****: The security and scientific communities should continue to work together to foster relationships, improve communication, and build trust.**

General threats used to increase awareness of national security concerns do very little to build the trust and understanding between these disparate communities that is essential if they are to work together to address security risks. These messages may imply that scientists are either unaware of or indifferent to the September 11 attacks, or that they are somehow directly culpable for terrorist interest in biological weapons. More effective methods of communicating and cultivating trust include understanding university practices, acknowledging the benefits of

scientific research and education, promoting the continuation of good research practices within the scientific community, and using tangible examples of the misuse of science, such as showing specific scientific papers that have been found in terrorist manuals. The security and scientific communities need to foster mutual communication and trust if any existing or future policies on laboratory biosecurity, the dual use dilemma, or other national security issues are to be successfully addressed.

Specific suggestions:

1) The security community should use better examples of the risks. These examples could include unwitting cooptation of a scientist or inappropriate activities undertaken by a disgruntled individual.
2) The FBI Weapons of Mass Destruction (WMD) Directorate should continue its dialogue with the scientific community, and field WMD Coordinators should become involved in institutional exercises to raise the level of trust and familiarity between members of the scientific community and their local FBI officials.
3) The scientific and security communities should work together to identify solutions to current problems. Forums like the AAAS-AAU-APLU 'Competing Responsibilities' meeting should be continued and expanded to form smaller, multi-disciplinary 'task forces' to address the evolving biosecurity and national security concerns with university and scientific leadership.

Suggestion 3: ***High-level Support for Good Research Practices at Academic Institutions*****: Research institutions should provide high-level support and attention to ensure that effective processes are in place to secure laboratories that are conducting research with pathogens and toxins posing the highest safety and security concerns. This level of support should be provided regardless of whether regulations are imposed by the government.**

The unreported, accidental exposure of a laboratory researcher with the causative agent of brucellosis, a select agent, at Texas A&M University in 2006 resulted in significant changes by the university and the CDC. This incident prompted the CDC to continually improve inspections and guidance for compliance with the Select Agent Program (see **Suggestion 4**). The university reorganized its governance structure by elevating the level of the official who oversees select agent research and compliance with select agent regulations so that this position reports directly to the Vice President of Research. The oversight staff has financial and administrative support from university leadership to make all necessary improvements to laboratory security.

These changes require significant financial and administrative support from university leadership. At Texas A&M University, a university president promoted transparency, education of safe and secure conduct, and a higher level of safety and security for select agent laboratories. Not every institution can make equivalent changes, but movement in this direction can help to address competing, and sometimes conflicting, requirements. With limited resources, convincing institutional leaders that they should heavily invest in safeguards to prevent exploitation or theft of biological research and/or select agents may be very difficult. This is especially true if institutional leaders believe existing mechanisms for securing laboratories from cyber crimes, eco-terrorism, and other tangible threats will contribute to compliance with requirements for

minimizing national security risks. Further, institutional leaders, faculty, and other scientists may question the rationale for imposing costly and/or cumbersome laboratory biosecurity policies if malicious individuals can readily evade them by going to other countries or research facilities.

Specific suggestions:

1) Institutions should seek champions within the university administration and faculty for biosecurity. In some cases, the additional investments needed to implement biosecurity measures can be minimal or non-existent.
2) Universities should institutionalize risk management. Additional mechanisms may be needed to evaluate the efficacy of measures used to secure laboratories.
3) Mechanisms should be developed to standardize the education and qualifications of people who can handle the biosecurity and biosafety of select agent laboratories.
4) Institutional leaders should engage scientists in their institution on safety and security issues.
5) Some universities have established centralized research oversight offices. All universities should consider having a similar office.

Suggestion 4: *Sustainable Guidance for Securing Select Agents*: Government regulators should provide flexible and adaptable guidance to ensure that select agent regulations effectively and appropriately over time.

The Texas A&M University incident was reported to the CDC public health system but not directly to the CDC Select Agent Program because the exposed researcher was treated with readily available therapeutics and did not pose a public health risk to the community. Lack of guidance for what constitutes "exposure" and "release" of a biological agent is a major problem that needs defining, especially when corrective actions could be taken. There is no clear guidance for what constitutes acceptable facility and personnel security. The CDC cited unauthorized access to select agents for the exposed individual who was escorted by an approved individual. In general, universities have, on their own, required mandatory laboratory registration for all biosafety level 3 and 4 laboratories on their campuses. At one university, registration includes application, permitting, and approval of research proposals by the Institutional Biosafety Committee and local public health commission.

Specific suggestions:

1) Because relationships are critical to the success of personnel security, scientists should promote regular interaction among their colleagues about research and security, safety, and ethical concerns.
2) Any biosecurity guidance provided by the federal government has to be holistic, sustainable, reasonable relative to the actual risks of the research, and done in collaboration with universities. The guidance should provide a mechanism by which university leadership can report if there is a problem.
3) The U.S. government should provide specific guidance based on community input for personnel security and identifying suspicious behavior. Systems should be developed through which universities can check background information about candidate employees. There needs to be a mechanism to share good practices in personnel security.

Guidance needs to be provided for requesting approval for rotating graduate students, visiting faculty, and hiring new personnel to work in select agent laboratories.

4) To improve efficiency, guidance should leverage existing infrastructure to address tangible and national security concerns, and to minimize costs where appropriate.
5) To promote compliance and prevent unfunded security mandates from diverting resources from other research activities, the U.S. government should provide dedicated funds for select agent security.
6) Inspectors should be knowledgeable about effective biosafety and biosecurity measures, and be educated about university practices.
7) The U.S. government should ensure that select agent requirements are implemented consistently across government agencies and research institutions.
8) Examples of real situations should be used to raise awareness of biosecurity issues with all scientists, not just those working with select agents. While the use of specific national security examples for raising awareness may not be appropriate if they are not publicly known, examples described in public sources can be used.[33]
9) More guidance should be provided to develop educational programs to teach scientists about the dual use dilemma and laboratory biosecurity issues.
10) The U.S. government should develop separate reporting mechanisms for occupational exposures to dangerous pathogens and for actual releases into the environment or surrounding population, and these mechanisms should incorporate a system to stratify incidents based on risk. Universities should be afforded more autonomy to categorize exposures and appropriately report them. Universities can engage the FBI in this assessment to help determine whether an exposure is intentional or accidental. This reporting system and guidance should be also developed for animal exposures.
11) The scientific and security communities should work together to develop appropriate and suitable mechanisms for screening and monitoring personnel. The scientific community should be receptive to continually monitoring personnel for unsafe and/or suspicious behavior. The security community needs to recognize that policing colleagues could have a chilling effect on collaborations and the culture of science.
12) Universities should be encouraged to inform local public health and law enforcement about the potential risks associated with the biological research conducted on the campus.

Suggestion 5: ***Harmonization of Common Science and Security Requirements:*** **The federal government should reduce financial and administrative burdens on research institutions and increase the use of good safety and security practices by harmonizing select agent policies across all relevant agencies, and by building a common regulatory structure for safety and security of laboratory hazards, such as radioactive materials, harmful chemicals, and dangerous biological agents.**

[33] A recent individual, who was educated at American universities (undergraduate and graduate), was suspected of considering exploitation of biology for malicious purposes. Hughes, CJ. *Pakistani Scientist Found Guilty of Shootings*. NY Times. 3 Feb 2010. See http://www.nytimes.com/2010/02/04/nyregion/04siddiqui.html for more information. Global Security Newswire. *Suspected Al-Qaeda Member Convicted in Shooting Attempt.* 4 Feb 2010. See http://www.globalsecuritynewswire.org/gsn/nw_20100204_4160.php for more information.

At the meeting, biosecurity policies were described as a "wonderful patchwork of regulatory oversight that is unrelated to other regulatory oversight activities." Universities must comply with numerous requirements to secure radioactive materials, restrict access to irradiators, secure chemical laboratories, secure and restrict access to select agents, track foreign visa holders, and implement increasingly more complex export control and deemed export policies. These requirements impose significant financial and administrative burdens on institutions, and some require redundant functions.[34] Some examples where harmonizing requirements across agencies include: 1) the CDC and NIH have worked together to develop and periodically update the BMBL guidelines; 2) the CDC and APHIS work together to regulate the Select Agent Program and associated inspections and audits; 3) the CDC, APHIS and FBI coordinate their efforts to screen individuals and facilities prior to select agent approval; and 4) the Executive Branch of the U.S. government has and continues to undergo several interagency policy development activities on a variety of biosecurity-related issues.

Specific suggestion:

1) The security and policymaking communities should stop looking at biosecurity as a singular problem and take a more integrated approach to security.
2) The federal government should thoughtfully integrate the requirements and oversight of the Select Agent Program across all agencies with the input of the research community. Extrapolating from how facilities and administrative costs/indirect rates are negotiated, oversight of select agents could be the responsibility of the primary funder of research at the institution, to which all other relevant funding agencies would defer their responsibilities. Such an approach could only work if security policies are harmonized across all relevant agencies, and if all agencies agreed with this "leader/follower" approach. At the very least, there should be a mechanism allowing universities to cross-reference their audits across agencies that fund or conduct select agent research.
3) Common requirements and oversight should be developed for redundant elements that cut across many different national security requirements and integrated into a single security framework. A mechanism should be developed to allow universities to cross-reference audits across several national security requirements.
4) Federal agencies should share information with each other and should work in a unified structure or team.
5) The U.S. government should ensure that strategic federal policy actions are being implemented as intended.
6) Universities should be allowed to directly recover their costs for compliance with select agent regulations.

Suggestion 6: *Scientific Input in the Policy Process*: Policy-makers should enhance efforts to incorporate input from the scientific community during the policy development process to effectively address security concerns while minimizing associated administrative burdens and consequent missed research opportunities, and to ensure buy-in for the policies.

After the 2001 anthrax mailings, one state's governor sent armed National Guardsmen to secure a laboratory that housed the vaccine (harmless) strain of anthrax. Meeting attendees described

[34] The European Union has developed an integrated risk management system that attempts to address several risks.

the different perceptions of this action by different communities: the governor considered his action to be decisive and successful; the public was shocked and angry that the university had been allowed to house pathogens that were dangerous; scientists found little value added by the extreme measures for securing a nonpathogenic organism.[35] To inspire confidence and buy-in among scientists, policies and consequences have to be reasonable and reflect the risks of the incident in question, and they should not appear to be motivated by alternative security or political agendas. Inclusion of all stakeholders in the policy-making process can inform the development of laws, regulations, and guidance that can be effective at minimizing biosecurity risks while maximizing available resources and promoting scientific research and education.

Specific suggestions:

1) The scientific community, security community, policy-makers, and the public should engage each other to discuss current biosecurity risks and consider how to manage them.
2) The policy process for addressing biosecurity concerns should include significant input from the scientific community (practitioners and administrators) and should be sustainable. The scientific community should contribute more to policy initiatives that impact their discipline and this contribution should be rewarded by institutional administrators.
3) The scientific and security communities should determine the total cost of compliance with security policies, including costs associated with missed research opportunities. They also should assess the degree to which current policies mitigate biosecurity risks and whether the security benefit is worth the aggregate cost.
4) Scientists should be involved in determining how to define dual use and how to develop risk assessment tools for teaching students how to identify contentious experiments.

Suggestion 7: *Scientific Input in Expanding and Promoting Good Research Practices*: Universities and scientific professional societies should enhance their existing programs and increase the involvement of scientists in developing and promoting good practices in ethics, safety, and security.

Senior scientists play a key role in promoting cultural change within the scientific community by setting an example with their own behavior and by teaching younger scientists about best practices and the responsible conduct of science. To get scientists involved in biosecurity issues, one university asked faculty to help set up the new biosafety level 3 laboratory. The faculty recognized associated biosecurity concerns and promoted safe and secure conduct. The Texas A&M University incident highlighted the need to share good practices among the scientific community and to put mechanisms in place to prevent adverse incidents from occurring. However, methods for addressing biological risks may be difficult to generalize across different institutions.

Specific suggestions:

1) An information system should be established to allow the scientific community to share good practices while keeping it out of the public domain.

[35] A guard was stationed outside the laboratory for seven years until the laboratory experienced an attack by an animal rights organization and installed cameras. See Yardley J and Caney D. *Anxiety Grows as Anthrax Mystery Lingers*. NY Times. 12 Oct 2001 for additional information.

2) Scientists should be vested in a culture of personal and scientific responsibility which is supported by university leadership. Other instances in which the culture of the scientific community has been changed, such as human subject experimentation and recombinant DNA research, should be evaluated for useful information regarding current issues with biosecurity.
3) The scientific community should help identify appropriate risk prevention and mitigation strategies as well as alert the security community of potential emerging risks.
4) Universities should evaluate all biological containment laboratory personnel for their ability to work safely and securely with select agents before gaining access to them. These evaluations may exceed existing biosafety training programs that assess an individual's ability to reliably perform under the stressful conditions of high containment laboratories.
5) All scientists should be trained and re-trained periodically on core ethical, safety, and security principles. Biological risks should be rationally articulated to promote buy-in from younger scientists. The objective should be to convey that since science can be used for good and bad, taking precautions is acting responsibly. Scientific societies should promote mentoring on good research and scientific practices.
6) The scientific community should inform the security community and policy-makers about existing best practices in place to ensure research with dangerous pathogens and toxins is safe and secure.

Suggestion 8: ***University-based Threat Assessment Teams:*** **Universities should establish or expand threat and/or risk assessment and management teams to address different hazards experienced on their campuses.**

Campus shootings prompted several universities to establish threat assessment teams on their campuses. Members of these teams come from multiple disciplines and provide various functions to the universities. One university has had a great experience with teams assessing and identifying solutions to complex threats. Because the teams are made up of community residents as well as university members, assessments and potential solutions can address community - or institution - specific issues and provide institution-specific guidance.

Specific suggestions:
1) The U.S. government needs to standardize methods for laboratory risk assessments.
2) The security community has to realistically consider the threats at a university and address more tangible threats in ways that could help address national security threats.
3) The security community needs to clearly articulate to the scientific community the differences between risk and threat, and biosafety and biosecurity.

Conclusions

In 2009, many biosecurity concerns became prominent in the policy community. These included development of recommendations for strengthening laboratory biosecurity; introduction of legislation proposing improvements in laboratory biosecurity, international engagement, and global health; and the U.S. *National Strategy for Countering Biological Threats*. This U.S. strategy lists goals that span responsible conduct in science, malicious exploitation of biological

research and materials, and global health security. Following the Competing Responsibilities meeting, the congressionally mandated Commission on the Prevention of WMD Proliferation and Terrorism released a report card scoring the federal government's response to the Commission's initial recommendations in *World at Risk* (2008).[36] Of note, they claimed that prolonged policy discussions are forcing us to lose ground against adversaries that are moving at a faster pace. They urged congressional action to address laboratory biosecurity concerns, and they gave the federal government a barely passing grade for improving the security of high containment laboratories. On the same day, the White House publicly stated that it did not agree with the conclusions of the report card.[37] Unfounded perceptions of inadequate security could be detrimental to research and education at universities that support select agent research. However, acting hastily to improve security could compromise U.S. biodefense goals by over-regulating and restricting necessary research. This meeting summary hopefully has demonstrated the progress that has been made at universities and in the federal government to minimize the risks of biological research. It also relays specific challenges that were identified at the meeting and provides suggestions for remedying those challenges. Meeting participants were interested in continuing dialogues similar to the one described here. Implementation of the suggested policy options and actions may be difficult but with continued efforts by the academic and security community to discuss critical science and security matters, policies may be developed that promote scientific inquiry and minimize national security concerns.

[36] Commission on the Prevention of WMD Proliferation and Terrorism. *Prevention of WMD Proliferation and Terrorism Report Card*. 2010. See http://www.preventwmd.gov/prevention_of_wmd_proliferation_and_terrorism_report_card/ for more information.
[37] Emanuel, M. *WH Responds to WMD Report.* Fox News.com. 26 Jan 2010. See http://whitehouse.blogs.foxnews.com/2010/01/26/wh-responds-to-wmd-report/ for more information.

Appendix

Background and Additional Discussion

Malicious exploitation of the biological sciences is a relatively new concept to most scientists. After the U.S. ended its offensive biological weapons program in 1969 and the Biological Weapons Convention was signed in 1972 (ratified by the U.S. in 1975), generations of biologists have been trained without specific education about the exploitation of biological research to create biological weapons. In the academic setting, biosecurity referred to protecting research animals from infections; in agriculture, to the protection of livestock; in environmental policy, to protection against invasive species. Biological, chemical, or radiation safety were taught, as appropriate, to scientists working with hazardous biological, chemical, or radiological materials, respectively, to protect themselves, co-workers, and surrounding population and environment. As violent animal rights activists started targeting researchers and facilities, universities started to implement physical security measures to minimize the risks posed by animal rights activists. Since 2001, the sharp increase in civilian biodefense funding for priority threat agents, the extension of the Select Agent Program to regulate possession of select agents, and the increased attention given by the security community to the exploitation of biological research, knowledge, and materials by malicious individuals have all contributed to redefining of the term "biosecurity" to mean the protection of society against the deliberate use of biological agents to inflict harm. In practice, some universities have already started to educate students about the dual use dilemma and have established programs for vetting personnel with access to select agents.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002[38] - a bill that expanded the Select Agent Program[39] - required that security measures employed for select agents be commensurate with the risks those agents pose and complement the procedures prescribed in the *Biosafety for Microbiological and Biomedical Laboratories* (BMBL) manual. This manual was initially written in the early 1980's by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) to ensure safe laboratory operation, and has undergone four major revisions since then. The fifth edition, which was released in 2007, prominently addresses risk assessment and includes a section on biosecurity.[40] The World Health Organization also publishes a laboratory biosecurity guidance document.[41] Biosafety and biosecurity are complementary and overlapping disciplines, and both are necessary to address complex national security concerns about exploitation of biological research for malicious purposes.

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[38] Public Law 107-188.

[39] The Select Agent Program was initially created to restrict transfer of pathogens and toxins that could pose severe public health risks. In 2002, the Public Health Security and Bioterrorism Preparedness and Response Act expanded the program to include animal and plant pathogen and toxins that pose severs risks to animal and plant health and products and to restrict possession of all agents on the select agent list. See http://www.selectagents.gov/ for more information.

[40] Center for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition.* See http://www.cdc.gov/od/OHS/biosfty/bmbl5/bmbl5toc.htm for more information.

[41] World Health Organization, *Laboratory Biosecurity Guidance*. See http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf for more information.

Dual Use Dilemma

Within the last few years, increased scrutiny has been placed on biological research, especially that of infectious diseases. Prompted by a National Research Council Report *Biotechnology Research in an Age of Terrorism*,[42] the U.S. government established the National Science Advisory Board for Biosecurity (NSABB) to develop recommendations for oversight and education of legitimate biological research that could be misapplied for malicious purposes, termed "dual use" research.[43] The NSABB – made up life scientists, security experts, intelligence experts, and lawyers – developed criteria for identifying dual use experiments, overseeing and communicating such research, and raising the awareness of dual use issues within the scientific community. The NSABB also provided recommendations to minimize security risks associated with synthesizing select agent genomes. The federal government is currently reviewing the oversight recommendations and has already issued draft *Screening Framework Guidance for Synthetic Double-Stranded DNA Providers*.[44] In addition, it has issued draft language adding synthetic nucleic acids to the recombinant DNA guidelines.[45]

Identifying the dual use potential of immediate concern of basic research experiments can be very difficult. However, recognizing the dual use potential of experiments is easier as the research becomes more applied or more closely resembles engineering systems. Very little guidance is available to help scientists determine how to mitigate the risks of an experiment found to have dual use potential. Scientific societies can play a major role in raising awareness and educating scientists about dual use life sciences research and current policy debates on the issue. A few academic institutions have programs that educate students about the dual use dilemma.[46] There have been efforts to educate biosafety professionals on biosecurity concepts. While many of these individuals may have received basic training about the dual use dilemma, they may struggle with identifying and/or characterizing research activities as having dual use potential, especially if the experiments are not necessarily described by the criteria identified by the NSABB as "dual-use research of concern." Though the Southeastern Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB) has developed an online training module[47] that was given to research personnel, including faculty funded by SERCEB grants, there has been no wide-spread effort to proactively address this issue with faculty members. No standard curriculum exists to educate and/or train individuals about the dual use dilemma but there are efforts within the U.S. and globally to catalogue existing education programs to inform development of standardized curricula. While the NSABB has not produced curricula, its report proposing an oversight regime for "dual use research of concern" has been used as educational material in the university setting. One university that educates its younger graduate students and post-doctoral fellows on dual use issues has found that these scientists are more interested and responsive to such discussions than more senior faculty or scientists. There have been some misconceptions by foreign students who think they may be prohibited from participating in research that has dual use potential. Educational modules must not only address such

[42] National Research Council. Biotechnology Research in an Age of Terrorism. Nat Acad Press, 2004. See http://www.nap.edu/catalog.php?record_id=10827 for more information.
[43] See http://oba.od.nih.gov/biosecurity/biosecurity.html for more information.
[44] See http://www.thefederalregister.com/d.p/2009-11-27-E9-28328 for more information.
[45] See http://oba.od.nih.gov/oba/RAC/meetings/jun2009/Final%20Published%20FRN.pdf for more information.
[46] See http://cstsp.aaas.org/dualuse.html for more information.
[47] See http://sercebtraining.duhs.duke.edu/Demographics.asp for more information.

misconceptions and serve to make students aware of biosecurity issues, but they must also allow students to understand stakeholder perspectives and foster trust among all stakeholders.

Laboratory Biosecurity

In December 2008, the congressionally mandated Commission on the Prevention of WMD Proliferation and Terrorism (WMD Commission) asserted that a WMD attack is more likely than not to occur by 2013, and that a biological attack is more likely to occur than nuclear attack.[48] The WMD Commission's report, *World at Risk*, cited the globalization and increased availability of biotechnology and the emergence of ever more advanced biotechnologies on the horizon as contributing to the perception that advancing biotechnology is a national security concern. The report and subsequent Congressional testimony by some of the commissioners prompted Senators Lieberman and Collins, chair and ranking members of the Senate Homeland Security and Governmental Affairs Committee (HSGAC), to announce their intent to draft legislation that would address the concerns highlighted in the report and hearing, and to request input from stakeholders following introduction of that bill.[49] The WMD Prevention and Preparedness Act[50] was introduced in September 2009 and was reported favorably out of the HSGAC in November 2009. Title I of this legislation addresses laboratory biosecurity by creating a Tier I list of biological agents that pose the greatest security risks to the U.S. and assigning the development and oversight of appropriate measures to secure those agents to the Department of Homeland Security (DHS). In crafting Title I of the bill, the HSGAC recognized that placing uniform security measures on agents with varying risks can dilute regulatory resources. The scientific community, which is generally in favor of stratifying the select agent list, nevertheless cautioned that lists of harmful pathogens and toxins are rigid and less likely to adapt to evolving biological risks. Scientific societies have expressed concerns over assigning DHS, an agency with limited experience working with the biological sciences community, as the lead oversight agency for securing personnel working with and laboratories housing Tier I agents. Developing and applying security measures for a heterogeneous population – i.e., academic researchers – is more difficult than applying such measures at organizations whose personnel are more uniform, like the military or law enforcement. Title II of the legislation addresses distribution of medical interventions, microbial forensics, and risk communication; Title III provides the Department of State with the authority to engage the international scientific community on security issues, addresses international public health workforce shortages, and attempts to improve international infectious disease surveillance; Title IV addresses government organization; and Title V addresses citizen engagement. The White House has expressed their support for Titles II-V but at the time of this writing has not issued a position on Title I. In April 2010, the WMD Prevention and Preparedness Act was introduced in the House of Representatives.[51]

In early 2009, the White House issued Executive Order (EO) 13486, *Strengthening Laboratory Biosecurity in the United States*, to address security concerns associated with the Select Agent

[48] Commission on the Prevention of WMD Proliferation and Terrorism. World At Risk. 2008. See http://www.preventwmd.gov/report/ for more information.
[49] See http://hsgac.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=d0d0b4c1-d1d1-4b7a-9c16-fd9af22d97e0 and http://hsgac.senate.gov/public/index.cfm?FuseAction=Press.MajorityNews&ContentRecord_id=6664d8e5-7e9c-9af9-730a-0e660c7adf40&Region_id=&Issue_id= for more information.
[50] S.1649
[51] H.R.5057.

Program and personnel security.[52] This EO was issued at the end of the Bush Administration and was supported by the Obama Administration. The EO established an interagency working group to review the Select Agent Program, laboratory biosecurity, and personnel security.[53] The White House asked the NSABB[54] and the National Academy of Sciences[55] to provide independent assessments of personnel assurance and the Select Agent Program. The Defense Science Board[56] also reviewed select agent oversight within the Department of Defense; its report contributed to the interagency working group report. The interagency working group report was submitted to the White House in July 2009 and publicly released in January 2010.[57] This report recommended improvements to the Select Agent Program, particularly personnel security and physical security, but it recommended leaving full oversight over the Select Agent Program to the agencies currently having that responsibility: the CDC, within the Department of Health and Human Services, and the Animal and Plant Health Inspection Service (APHIS), within the Department of Agriculture. The report called for stratification of the select agent list, with security measures commensurate with the risks for each tier. Recommendations for enhancing existing policies regarding secure transportation of select agents were also included in the report. The White House is currently reviewing the recommendations and has initiated a policy process to consider implementation of them.

As the federal government was reviewing the Select Agent Program, the National Security Council was developing an overall strategy for countering biological threats. The White House released the resulting strategy, titled *National Strategy for Countering Biological Threats,*[58] in December 2009 at the Biological Weapons Convention 2009 Meeting of States Parties.[59] The strategy listed seven strategic objectives designed to protect the U.S. against misapplication of the biological sciences for malicious purposes: 1) promote global health security; 2) reinforce norms of safe and responsible conduct; 3) obtain timely and accurate insight on current and emerging risks; 4) take reasonable steps to reduce the potential for exploitation of the life sciences; 5) expand our capability to prevent, attribute, and apprehend individuals with ill-intent; 6) communicate effectively with all stakeholders; and 7) transform the international dialogue on biological threats. With a commitment to biosecurity from the Obama Administration, these

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[52] See http://georgewbush-whitehouse.archives.gov/news/releases/2009/01/20090109-6.html for more information.
[53] Personnel reliability programs (PRP) were initially developed to ensure the reliability of personnel working with nuclear weapons. Some of these programs have been modified to apply to personnel working with select agents. The accusation of Bruce Ivins, a researcher at USAMRIID, as the 2001 anthrax perpetrator prompted current policy discussions on personnel security, which has also been referred to as "personnel assurance" or "personnel reliability."
[54] National Science Advisory Board for Biosecurity. *Enhancing Personnel Reliability among Individuals with Access to Select Agents*. 2009. See http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf for more information.
[55] National Research Council. *Responsible Research with Biological Agents and Toxins*. Nat Acad Press, 2009. See http://books.nap.edu/catalog.php?record_id=12774 for more information.
[56] Defense Science Board. *Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program*. 2009. See http://www.stormingmedia.us/69/6941/A694105.html for more information.
[57] U.S. Department of Health and Human Services. *Report on the Working Group on Strengthening Laboratory Biosecurity in the United States*. 2009. See http://www.hhs.gov/aspr/omsph/biosecurity/biosecurity-report.pdf for more information.
[58] See http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf for more information.
[59] See http://geneva.usmission.gov/2009/12/09/tauscher-bwc/ for more information.

objectives form the basis for existing and future policies and investments in preventing deliberate biological incidents, and the U.S. government has already started taking steps to implement them. The objectives of stakeholder engagement, reinforcement of norms, and minimizing the potential for misusing the biological sciences were of greatest relevance to the AAAS-AAU-APLU Competing Responsibilities meeting. Other than regulating biological select agents and toxins, the federal government favors issuing guidance rather than regulation or statute to achieve many these objectives.

Biosecurity Outreach

With strong support from the administration, the U.S. government has initiated outreach activities to improve engagement and communication with the scientific community on biosecurity issues. The White House Office of Science and Technology Policy (OSTP) is creating a single, authoritative website that highlights ongoing biosecurity policy and program activities. This website is not yet publicly available but seeks to inform the scientific community about ongoing policy debates and programmatic activities in biodefense and provide a mechanism where scientists can contribute to the policy debates and voice their concerns. OSTP has also started using social media tools to engage younger scientists to raise awareness of biosecurity issues and to contribute to policy discussions. The Office of the Director of National Intelligence has initiated a fully transparent initiative to raise awareness within the scientific community about biosecurity concerns regarding personnel and research activities. The Federal Bureau of Investigation's Weapons of Mass Destruction (WMD) Directorate has been very active in reaching out to academic and other research institutions on laboratory biosecurity issues. WMD Coordinators in each FBI field office are required to interact with local research institutions, raise awareness of biosecurity issues, and provide a point of contact for institutional administrators in case of a suspicious incident. The FBI WMD Outreach Program has also engaged in interacting with amateur scientists, students and mentors of the iGEM (International Genetically Engineered Machines) competition, and synthetic DNA manufacturers. The FBI is planning meetings to build relationships and raise awareness of biosecurity issues with biosafety professionals, and Institutional Biosafety Committees, Institutional Animal and Care and Use Committees, and Institutional Review Boards. These outreach activities have generated interest in hosting a meeting on various aspects of laboratory biosecurity by the Department of Health and Human Services' Office of Research Integrity, which will be held in November 2010.[60] The FBI points to its interactions with synthetic DNA manufacturers and the draft *Screening Framework Guidance for Synthetic Double-Stranded DNA Providers*[61] as a success story for its outreach efforts and its ability to narrow the gap in policymaking between the U.S. government and the industry stakeholders.

[60] Some of these meetings are being organized in cooperation with HHS, the Department of State, and AAAS Center for Science, Technology and Security Policy.

[61] See http://www.thefederalregister.com/d.p/2009-11-27-E9-28328 for more information.