

**National Institutes of Health (NIH)
Office of the Director
Office of Science Policy
Office of Biotechnology Activities (OBA)**

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY (NSABB)

June 23, 2011
NIH Campus
9000 Rockville Pike
Building 31, Room 6C
Bethesda, MD

MINUTES of MEETING

NSABB VOTING MEMBERS

Paul S. Keim, Ph.D., *NSABB Acting Chair*
Kenneth I. Berns, M.D., Ph.D.
Arturo Casadevall, M.D., Ph.D.
Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Susan A. Ehrlich, J.D., LL.M.
Lynn W. Enquist, Ph.D.
David R. Franz, D.V.M., Ph.D.
Christine M. Grant, J.D., M.B.A.
Michael J. Imperiale, Ph.D.
Joseph Kanabrocki, Ph.D., C.B.S.P.
Jeffery F. Miller, Ph.D.
Randall S. Murch, Ph.D. (by phone)
Michael T. Osterholm, Ph.D., M.P.H.
James A. Roth, D.V.M., Ph.D., D.A.C.V.M.
Anne K. Vidaver, Ph.D.

NSABB *EX OFFICIOS*/FEDERAL AGENCY DESIGNEES

Kay M. Briggs, Ph.D., U.S. Department of the Interior (DOI)
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Diseases (NIH)
Brendan Doyle, Ph.D., U.S. Environmental Protection Agency (EPA)
Daniel W. Drell, U.S. Department of Energy (DOE)
Lisa Kaplowitz, M.D., M.S.H.A., Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS)
Lawrence Kerr, Ph.D., Office of the Director of National Intelligence (ODNI)
Jane Knisely, Ph.D. (NIH)
Laura Kwinn, Ph.D. (HHS)
Theresa Lawrence, Ph.D. (HHS)
David R. Liskowsky, Ph.D., National Aeronautics and Space Administration (NASA)
CDR Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration (FDA)

Donald Malinowski, Ph.D. (ODNI)

Janet K. A. Nicholson, Ph.D., Centers for Disease Control and Prevention (CDC)

Christopher J. Park, Bureau of International Security and Nonproliferation, U.S.

Department of State

Eileen Thacker, D.V.M., Ph.D., Agricultural Research Service, U.S. Department of

Agriculture (USDA)

Robbin S. Weyant, Ph.D. CDC

Edward H. You, Federal Bureau of Investigation (FBI)

Call to Order and Review of Conflict of Interest Rules

Paul S. Keim, Ph.D., NSABB Acting Chair, and Paul L. Lewis, Ph.D., NSABB Executive Director

Dr. Lewis called the meeting to order at 8:30 a.m. He welcomed members and public participants to the meeting. Dr. Lewis noted the passing of NSABB member Andrew Sorenson, Ph.D., M.P.H., who died unexpectedly on April 17, 2011. Dr. Sorenson contributed greatly to the deliberations and work products of the NSABB, said Dr. Lewis. He was thoughtful, personable, accessible, and statesmanlike, and he was greatly admired by his peers. His death is a great loss, Dr. Lewis noted.

Dr. Lewis reviewed the rules of conduct and conflict of interest for NSABB members, as described in the document *Standards of Ethical Conduct for Employees of the Executive Branch*. Members of the NSABB are considered Special Government Employees and are asked to provide information before every meeting to identify any conflicts of interest. Members are required to recuse themselves in advance of any discussion in which they believe they have a conflict of interest. Questions about potential conflicts of interest should be brought to the attention of Ms. Lisa Rustin in the Office of Committee Management.

Introductions and Approval of October 2010 Meeting Minutes

Paul S. Keim, Ph.D., NSABB Acting Chair

Dr. Keim noted that Dr. Sorenson was a great committee member who would be missed by all. Voting board members and *ex officio* members introduced themselves. Dr. Keim asked for comments on the minutes of the October 2010 NSABB meeting.

NSABB Motion 1

Moved by Dr. Kanabrocki, and seconded by Ms. Judge Ehrlich, the NSABB members voted unanimously by voice vote to accept the October 19, 2010 NSABB meeting minutes as written.

Update of Relevant Federal Activities: Federal Experts Security Advisory Panel (FESAP)

Laura A. Kwinn, Ph.D., Science Policy Advisor, Office of Policy and Planning, ASPR, HHS

Dr. Kwinn explained that FESAP includes representatives of 15 federal departments and agencies who were convened by Executive Order to develop consensus recommendations regarding biological select agents and toxins (BSATs). She outlined the composition and progress to date of FESAP's three working groups.

The Tiering Working Group reviewed the current list of 82 select agents to identify those BSATs with a documented risk of causing a high-consequence event, so that they could be designated as Tier 1 select agents. The group also identified those that have little or no potential to be used in a high consequence event so they could be considered for removal from the list. In designating the following Tier 1 BSATs, the Tiering Working Group considered the agents' ability to produce a mass casualty event or devastating effects to the economy, communicability, infectious dose, and history of or current interest in weaponization based on threat reporting:

- *Bacillus anthracis*
- Botulinum toxin and toxin-producing strains of *Clostridium botulinum*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

Dr. Kwinn noted that some agents, such as the variola viruses and foot-and-mouth disease virus, have their own security requirements. Even within Tier 1, FESAP recognizes that not all select agents require the same level of security. Dr. Kwinn emphasized that not every Tier 1 laboratory will be required to have the same level of security as, for example, a smallpox facility.

The working group also recommended the following agents for removal, including several animal agents that are endemic to the United States, some agents that are not shown to cause disease in humans, and some that have low potential for causing a high-consequence event:

Human and Overlap Agents

- Cercopithecine herpesvirus 1 (herpes B virus)
- *Coccidioides immitis*
- *Coccidioides posadasii*
- Eastern equine encephalitis virus, South American genotypes
- Flexal virus
- Tick-borne encephalitis viruses, European subtypes

- Venezuelan equine encephalitis virus, enzootic subtypes ID and IE

Animal Agents

- Akabane virus
- Bluetongue virus
- Bovine spongiform encephalitis
- Camelpox virus
- *Ehrlichia ruminantium*
- Goat pox virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus
- Menangle virus
- *Mycoplasma capricolum*, subsp. *capripneumoniae*
- Sheep pox virus
- Vesicular stomatitis virus

The Personnel Reliability Working Group addressed current policies for determining security, suitability, and reliability of personnel at the local and federal level. The Working Group proposed a statement defining the key characteristics of suitability that does not discriminate against any group of people, such as foreign nationals. Dr. Kwinn pointed out that the FBI conducts the security risk assessment (SRA) required at the federal level by consulting a database; it is neither a full background check nor a security clearance process. Some barriers to a more efficient SRA could be easily addressed, said Dr. Kwinn; for example, FBI staffers who perform SRAs should have access to other relevant FBI databases to better assess disqualifying factors, which is not the case now.

Other recommendations to strengthen the SRA include simplifying the language of the questionnaires that candidates complete to start the risk assessment process, improving access to information to vet foreign nationals, and ensuring that the Secretaries of HHS and USDA have more consistent statutory authority to address personnel security questions. As an example of the latter, Dr. Kwinn noted that an individual may have been “adjudicated a mental defective” (a disqualifier) in an effort to receive treatment for anorexia through his or her health insurance. The HHS Secretary does not have the authority to waive a disqualification, although the USDA Secretary does.

The Personnel Reliability Working Group sought to provide more guidance and tools to responsible officials at the local level to better understand who is employed at their facilities and who should not have access to BSATs. The Working Group recommended investigating suitability before access is granted by, for example, conducting credit checks, criminal background checks, and credential verification. Dr. Kwinn stressed that the recommendations do not seek to dictate how local entities determine personnel suitability, but rather to suggest mechanisms for those entities to comply with the requirement to have a security plan in place. The Working Group continues to explore the utility of behavioral assessments in identifying the potential for violent behavior.

Ongoing monitoring and evaluation are critical to assessing an employee's reliability. At the local level, employees should have clear mechanisms for self-reporting and reporting about peers regarding safety or security concerns. Dr. Kwinn said the Working Group recommended that responsible officials have more guidance and tools to assess reliability, remove personnel temporarily or permanently, and access the local FBI Weapons of Mass Destruction (WMD) coordinator.

The Physical Security and Cybersecurity Working Group recommended creating a risk management tool for all facilities that enables uniform, comprehensive risk assessment and development of cybersecurity standards. The Working Group also suggested that existing guidance on securing items received should be codified in regulations, and current security and intelligence threats should be communicated to laboratory managers when applicable.

In addition, the Working Group proposed some security standards for regulation of Tier 1 BSATs that both are more prescriptive than previous guidelines and allow for a more flexible approach to protecting assets. The Working Group recognized that smaller laboratories—such as diagnostic, public health, animal health, and environmental laboratories—may not meet all of the physical security requirements. In such cases, a facility may be able to boost personnel reliability efforts to maintain a consistent level of security, Dr. Kwinn suggested.

Two other FESAP Working Groups are evaluating behavioral assessment approaches and risk assessment tools. In addition, FESAP is assisting in the development of guidance on suitability and reliability assessments, particularly credit checks, reference vetting, and self- and peer reporting mechanisms. The recommendations of FESAP informed a proposed rule that will be published in October 2011 for public comment. The final rule will be published in November 2012.

NSABB Discussion

Dr. Casadevall said he appreciated FESAP's recommendation to reduce the BSAT list, but Tier 1 still groups high- and low-virulence strains together. As a result, although the list includes fewer agents, it may be even harder for researchers to work on those agents. The more restrictions that exist for a given agent, the less research will be performed using those agents. Therefore, he suggested that FESAP could maintain security without limiting research by eliminating low-virulence strains of BSATs from Tier 1. Dr. Kwinn responded that FESAP grappled with the question of when an agent is modified enough to either become, or no longer be considered, a select agent. She said that, for now, from a security standpoint, FESAP is comfortable leaving all the relevant strains on the Tier 1 list and excluding some as possible. Dr. Roth and Dr. Casadevall both suggested that vaccine strains that are available either inside or outside the United States in particular should be considered exempt. Dr. Kwinn said she could not comment on specific pathogens, but that the public comment period for the proposed rule would allow another opportunity to raise such issues.

Members debated the validity and utility of credit checks as an assessment of reliability. Dr. Imperiale said credit reports often contain inaccurate information that is difficult to correct. He questioned where to draw the line between minor credit issues, such as late payments, and major concerns. Judge Ehrlich supported the use of credit checks, saying the responsible official uses his or her discretion to evaluate an individual's relationship to debt and can distinguish between a late payment and, for example, large casino debts. Dr. Roth noted that some responsible officials are highly risk-averse and may over-interpret the guidance, although he agreed with the importance of allowing flexibility at the local level. There was some disagreement over whether credit checks are a good predictor of future behavior. Dr. Osterholm said that guidance should identify more specificity on what steps are necessary to prevent violent acts but also allow responsible officials to use their judgment and make decisions that they can defend.

In response to Board members' questions, Dr. Kwinn clarified that the security requirements for all Tier 1 BSATs will be uniform, but individual facilities may interpret them differently. She said FESAP is conducting a cost-benefit analysis of implementation of its recommendations, and it sought to make recommendations that were reasonable for all types of laboratories. Dr. Kwinn said a subgroup evaluated plant pathogens but made no recommendations that any be included in Tier 1 in response to a question from Dr. Vidaver. Dr. Vidaver felt that decision should be reconsidered and that plant pathogens should be included when thinking about small laboratories. Dr. Kwinn said, in response to Dr. Franz, that when the definition of suitability is finalized, FESAP will seek to harmonize the definition with other federal regulations, such as those of the Department of Homeland Security, while ensuring it remains applicable to non-federal entities. She added that the recommendations focus on domestic regulations, but international biosecurity entities are aware of the work of the FESAP and its recommendations.

Dr. Kwinn emphasized that the recommendations are intended to raise awareness about how to identify security concerns, not to discourage facilities from pursuing legitimate research. She added that in developing its recommendations, FESAP heard presentations and input from scientists, public health officials, animal research societies, and many others who would be affected by new regulations, as well as many of the same *ex officio*s who serve on the NSABB. She anticipated additional discussion on the impact of recommendations, which are open to comment via the ASPR's Public Health Emergency website (<http://www.phe.gov/preparedness/pages/default.aspx>).

Dr. Enquist pointed out that the Tier 1 list raises the fundamental problem of classifying agents by names, including historical names, which are not always biologically based and often refer to phenotypes, not genotypes. Dr. Kwinn wondered whether classifying by genotype would make it easier or harder for laboratories to comply with the recommendations.

Dr. Berns suggested FESAP consider in more detail practical approaches that address the differences in how diagnostic and research laboratories operate and security requirements between these two types of labs. He questioned whether research laboratories that cannot meet sophisticated security requirements should be allowed to use BSATs.

Dr. Weyant noted that the list of select agents already excludes many vaccine strains, and individuals are invited to propose other strains for consideration for removal.

Overview of NSABB Draft Report *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility*

Paul S. Keim, Ph.D., Division Director, Pathogen Genomics, The Translational Genomics Research Institute, Cowden Endowed Chair in Microbiology, Northern Arizona University, Flagstaff, AZ and NSABB Acting Chair; Judge Susan A. Ehrlich, J.D., LL.M., (biotechnology & genomics), Judge(ret.), Arizona Court of Appeals, Adjunct Professor, Department of Microbiology & Immunology, University of Texas Medical Branch– Galveston, Galveston National Laboratory, Galveston, TX and Member, NSABB Working Group on Culture of Responsibility

Judge Ehrlich explained that the Working Group on Culture of Responsibility sought to identify strategies and guidance for enhancing the culture of responsibility for people working with select agents. A 2009 NSABB report, “Enhancing Personnel Reliability Among Individuals with Access to Select Agents,” concluded that a formal, national personnel reliability program is unnecessary, but local institutions should enhance efforts to promote a culture of responsibility as the best defense against an insider threat. The Working Group developed guidance to assist institutions and laboratories in enhancing their culture of responsibility. The guidance elaborates on recommendations made in the 2009 report to make hiring practices more rigorous, raise awareness about biosecurity and risk, enhance understanding of responsibility for reporting concerns, build a strong sense of team, and allow individuals to temporarily opt out of select agent research. Improving the culture of responsibility helps the entire scientific community build and maintain public trust by demonstrating that it is working responsibly to protect public welfare and security.

To inform its deliberations, the Working Group sought input from researchers and institutions in two roundtables, convened several panel discussions with experts in human resources and law, and spoke with representatives of Institutional Biosafety Committees (IBCs). The Working Group also held a public consultation on January 5, 2011 with panels on promoting biosecurity, personnel reliability, and a culture of responsibility; encouraging biosecurity awareness and responsible conduct; peer reporting; disclosure of negative information about job candidates; and assessing effectiveness and impact of strengthening personnel reliability and the culture of responsibility.

Judge Ehrlich summarized the messages of the public consultation, which are reflected in the draft working group report:

- **Culture of responsibility starts at the top.** Leaders should clarify expectations, empower individuals to make good decisions, and demand accountability. Visible champions are important. Build trust among all personnel.
- **Reliable references are critical to a culture of responsibility.** Hiring decisions should be adequately informed.

- **Lead by example.** The principal investigator sets the tone. Be open and consider the input of others.
- **Foster strong working relationships** through training, respect, and building rapport.
- **Enable reporting about concerning behavior of peers, supervisors, and staff.** Multiple, transparent, confidential avenues for reporting are critical. In some cases, a problem can be addressed before the issue escalates.
- **Provide rigorous education programs on the culture of responsibility,** especially for new staff, institutional biosafety committee (IBC) members, and all laboratory personnel. Build education into existing programs (e.g., ethics).
- **Consider the burden** of existing requirements and make compliance easy.
- **Biosecurity is multidimensional** and should involve a wide range of experts. One option is a biosecurity task force that convenes as needed to address issues as they arise.
- **IBCs are key to a culture of responsibility.** Participation should be framed as an honor with adequate and appropriate expertise represented.
- **Biosecurity champions are needed,** but they must be credible, visible, and influential.

Dr. Keim summarized the contents of the draft report *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* (Attachment A), acknowledging the contributions of OBA staff member Allison Mistry in preparing the report. The report background considers the definition of a Culture of Responsibility and calls on all scientists to cultivate such as a culture of responsibility by acknowledging the implications of their research, including any potential for deliberate misuse of their research. Scientists must hold themselves and their peers responsible for advancing science and maintaining public trust. The draft report is intended for members of the life sciences who work with BSAT; it notes that all those involved in life science research must be aware of activities around them and understand the individual and collective responsibilities for reporting concerning behaviors.

Dual use research (DUR) and dual use research of concern (DURC) in the life sciences are not limited to BSATs. Moreover, an insider threat could involve someone who does not have direct access to BSATs, so a culture of responsibility must extend beyond those directly involved.

The draft report includes nine recommendations on good hiring and employment practices:

- **References:** obtain accurate, candid references and put in place policies for providing references. Seek information from current employers (including the current supervisor) about work performance, conduct follow-up inquiries, and go beyond verifying the candidate's education and credentials to explore past performance issues related to reliability.
- **Criminal background checks:** conduct criminal background checks of potential and current employees with access to BSATs.

- **Institutional expectations:** ensure that new personnel understand the risks and responsibilities involved with BSAT research.
- **Performance reviews:** institute and document achievement or goal focused periodic performance reviews. Obtain performance review results from previous employers and institute a policy for sharing performance review results with prospective employers for those candidates or employees who have access to BSATs.

The next nine recommendations focus on encouraging biosecurity awareness and promoting responsible conduct in six areas:

- **Leadership:** communicate the institution's expectations that researchers will be treated with respect, especially those involved with BSATs, understand and comply with all applicable rules and regulations, acknowledge their responsibilities to report activities that are inconsistent with these laws, and handle confidential information appropriately. Institutions are to provide information and tools to meet those expectations. Identify champions (i.e., individuals who serve as mentors and who promote adoption of DUR awareness), and ensure these champions have credibility and the support of their institutions.
- **Education and training:** incorporate biosecurity and dual use research and dual use research of concern implications in research ethics courses.
- **Codes of conduct:** incorporate discussion of codes of conduct into educational programs to address the issues of biosecurity and the dual use implications of life sciences research.
- **Reporting concerning behavior:** ensure that reporting mechanisms allow for reporting in a respectful, responsible manner.
- **Opting out of BSAT research:** provide mechanisms for employees to temporarily opt out of BSAT research. The decision to opt out should not be stigmatized.
- **Institutional and local peer review:** risk assessment of laboratory protocols for BSATs should take place before a given research project begins and throughout the research project.

The report covers two approaches that are potentially useful but do not merit widespread implementation. The first, video monitoring, is costly to implement, and its utility varies. Therefore, use of cameras should be determined by a local risk assessment. The second, the two-person rule, can be useful in protecting the safety of personnel in high-risk situations, but implementation can affect work flow, work time and may unintentionally increase safety risks.

Dr. Keim noted that a number of practices were specifically *not* recommended for broad implementation, especially at academic institutions, because of privacy concerns or because they are costly and of unproven benefit. Such practices include credit checks, mental health assessments, drug and alcohol screenings, and polygraph (i.e., lie detector) tests.

Finally, the draft guidance discusses the need to assess the effectiveness of personnel reliability processes and culture of responsibility improvements. The practices recommended reflect successful strategies already being used in BSAT research, and that affect the day-to-day conduct and cost of research. Evaluating the success of such efforts is difficult, because it is impossible to measure the absence of a threat. Yet, assessing prevention efforts and an institution's ethical climate can provide some insight on effectiveness and unintended consequences.

The public consultation identified several measures to evaluate. Assessments should consider the desired end-state, e.g., a strong culture of responsibility. Intermediate outcomes should be identified, and effectiveness—not just implementation—should be evaluated. Assessment should capture unintended consequences, such as mechanisms that affect work processes. Other fields can provide valuable insight into the assessment of the culture of responsibility, which should begin early and continue periodically. The final recommendation of the report stresses the need to assess the effectiveness, potential impacts, and unintended consequences of any measures implemented in light of the costs and the burden they impose.

Public Comments

Jacqueline Edwards, Branch Chief of Personnel Security/Suitability, CDC, sent written comments in her personal capacity asking that the NSABB reconsider its findings and recommend the use of some or all of the components of formal personnel reliability programs, such as mental health assessments, drug and alcohol testings, credit checks, and polygraph tests. Ms. Edwards wrote that there should be evidence that academic institutions are at risk because of their lack of formal procedures for determining personnel reliability, and she believes that case studies support the value of longstanding formal programs. She suggested the NSABB recommendations should highlight concerns about the costs and resources, as well as the privacy issues and legal concerns involved but recognize the cost of implementation as the cost of doing business.

Dr. Keim noted that NSABB member David A. Relman, M.D., (who was not at the meeting) provided written remarks in response to Ms. Edwards' comments. Dr. Relman noted that formal personnel reliability programs may be highly counterproductive to science; there is no clear documented value of such programs, whereas there is some evidence of the burden they pose. Dr. Relman wrote that such programs may instill a false sense of security and also alienate those in the scientific community whose help and buy-in are needed to ensure the success of efforts to strengthen security.

Gregory D. Koblentz, Ph.D., Assistant Professor and Deputy Director of the Biodefense Program, Department of Public and International Affairs, George Mason University said the report offers many suggestions about what institutions should do to achieve personnel reliability and a culture of responsibility, but it does not discuss the opportunity costs, incentives, and disincentives. Because personnel reliability and a culture of responsibility are not part of the traditional mission of laboratories, the NSABB should recommend

some way to ensure its suggestions are implemented, such as:

- requiring that a small percentage of an institution's federal grant funding for BSAT research be dedicated to strengthening its personnel reliability and the culture of responsibility;
- making such efforts a requirement for working with select agents;
- imposing a penalty for not adopting security measures; and
- applying incentives to assessment.

Gerald Epstein, Ph.D., Director, Center for Science, Technology & Security Policy, American Association for the Advancement of Science (AAAS), said polygraph tests have limited scientific validity but are widely used. He suggested the report emphasize that the value of polygraph tests does not warrant the massive disruption that implementing them would cause. He hoped the NSABB would recognize that some institutions do not allow employers to give out any information about current or past employees beyond their dates of employment and salary, which prohibits potential employers from gathering reliable reference information. Finally, he said public trust in scientific research can be measured; for example, surveys can determine whether the public recognizes the benefit of certain research despite the risks involved.

Janet Peterson, Assistant Director and Biological Safety Officer, Compliance Officer Program, University of Maryland, said credit checks may not be a good method for determining who should have access to BSATs, noting that some young researchers may lack fiscal responsibility but that may not necessarily translate into irresponsibility in their scientific work. She also asked the NSABB to recognize the additional burden on responsible officials and institutions that the recommendations pose.

Larry Cereghino, Project Manager, Science Application Interaction Corporation, said the report did not cite the good, usable evidence available on the predictive value of drug testing, which represents a rare example of an objective, biological marker that can predict human behavior. Furthermore, a robust body of knowledge by research psychologists and criminologists describes the predictive value of personal financial behavior, and there are tools to improve decision-making when using such information. Mr. Cereghino recommended reviewing the evidence from the Department of Defense Personnel Security Research Center in Monterey, California.

NSABB Discussion of Draft Report

Dr. Vidaver said the report focuses on life scientists working with BSATs and leaves out scientists in other fields and amateur or do-it-yourself (DIY) biologists who may inadvertently work with BSATs or other dangerous substances. Ms. Grant noted that another NSABB Working Group is addressing the need to educate amateur biologists, who often work in separate realms, although Dr. Vidaver believes the professional life scientists and amateur biologists could intersect. Dr. Keim responded that the guidance addresses the charge of focusing on life science researchers, but he hoped the concept of a culture of responsibility becomes widespread.

Dr. Miller said many fields bring in young researchers and train them to work safely in their disciplines, despite the barriers. Members agreed that the report should acknowledge the difficulty of evaluating the skills and performance of an incoming employee who recently graduated from college and has little laboratory experience, much less a history of well-documented performance evaluations. It should offer some ways to facilitate personnel reliability assessment of, for example, a recent graduate working with BSATs.

Dr. Osterholm suggested delving deeper into the problem of institutions that refuse to provide significant information about an employee and the barriers to getting useful information. Judge Ehrlich explained that the Working Group chose not to address in detail how to gather references on a prospective employee given the complexity of policies, regulations, and federal and state laws. Dr. Keim noted that the Working Group tried to address the issue to some extent, because there is a lot of misunderstanding about what information can be passed on, and a lot of people are more conservative than they need to be. He added that institutions should consider the potential liability of not reporting concerning information. Dr. Kanabrocki suggested that employees could sign a consent form authorizing employers to discuss their history. Ms. Grant noted that outside recruiting firms and other entities may be conducting assessments but not be aware of the BSAT security risk assessment.

Dr. Franz said the report addresses the need for leadership that supports a culture of responsibility, but with so many services contracted out, it's difficult to cultivate leadership skills in the current work environment. Academic research laboratories have both more freedom and more control over their environment than, for example, government-run laboratories, which rely more on regulations than a culture of leadership to ensure that goals are met.

Dr. Casadevall said the recommendations may discourage the best and brightest from working on BSATs—especially when combined with the FESAP recommendations, which may make it harder to work on select agents in the future. He expressed concern about the long-term future of laboratories. Dr. Keim responded that he believes the recommendations are reasonable and reflect efforts already in place to some degree in many laboratories. Dr. Franz reiterated his point that not every laboratory has significant freedom to implement policies, and Dr. Osterholm added that some federally funded research involves international laboratories, and it may be difficult to hold such laboratories to U.S. biosecurity standards.

Dr. Miller suggested adding an appendix of case studies or more detailed recommendations on integrating a culture of responsibility into courses on ethical conduct of science that are already taught as part of NIH training grants. Dr. Kanabrocki pointed to the importance of balancing decision-making authority and leadership with strong relationships and team building in the laboratory. He added that a strong biosafety culture likely fosters good biosecurity.

Dr. Murch, who served on the Working Group that drafted the guidance, suggested that

the recommendations on exploring a potential candidate's previous work performance and suitability be more specific. He noted that the recommendation to implement performance reviews sounds patronizing and should be reworded to suggest institutions incorporate biosecurity/biosafety issues into program reviews. He suggested clarifying that requesting a candidate's performance evaluation reports from prior employers applies to specific disciplines and not, for example, to taxonomic botanists who can be considered to "work with BSAT."

Dr. Murch said that the recommendation to conduct criminal background checks should acknowledge the resources required to do so. The report should include some examples of, or links to, model codes of conduct, such as the American Society for Microbiology (ASM). Finally, research ethics training should incorporate biosafety and biosecurity issues as relevant to the specific disciplines.

NSABB Motion 2

Dr. Imperiale moved to approve the draft report *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* with the addition of language that acknowledges the unique situation of some young employees, such as students and trainees, who may not have a well-documented history on which to base decisions about suitability and reliability. Judge Ehrlich seconded the motion. Fourteen members voted in favor of the motion, one voted against, and there were no abstentions. The motion passed.

Overview of NSABB Draft Report *Strategies to Educate Amateur Biologists and Scientists in Non-Life-Science Disciplines about Dual Use Research in the Life Sciences*

Michael J. Imperiale, Ph.D., Professor, Department of Microbiology and Immunology University of Michigan Medical School and Co-Chair, NSABB Working Group on Outreach and Education

Dr. Imperiale explained that the NSABB was originally tasked with developing strategies to educate the scientific community and the public about DUR. In fulfillment of that task, the Working Group developed, and the Board adapted in December 2008, as strategic plan for outreach and education, which the US government has been following since. That effort notwithstanding, the nature of biotechnology research is changing: (1) amateur (or hobbyist or DIY) biologists have the capacity to conduct research easily and inexpensively outside the reach of institutional oversight, and (2) multidisciplinary teams of scientists bring researchers from other fields into life science research. Understanding how to educate these two communities entails better understanding who they are, how they see themselves, and how they work.

Amateur biologists may not have formal training in science, biosafety, or biosecurity. They tend to conduct low-risk experiments and are interested in learning about biosafety. They are likely to be young, creative, curious, and early adopters of new technology. Some amateur biologists assemble into groups—physical or virtual. They often seek to educate the general public about science.

Scientists from other disciplines are diverse and comprise engineers, mathematicians, chemists, physicists, and computer scientists, among others, working directly or indirectly in life science research. Typically, they do not have training in biosecurity or biosafety. They may not be subject to institutional oversight committees, and they may not be familiar with relevant oversight requirements.

The Working Group interviewed members of both communities. Dr. Imperiale summarized the Working Group's observations and recommendations, which are detailed in the draft report *Strategies to Educate Amateur Biologists and Scientists in Non-Life-Science Disciplines About Dual Use Research in the Life Sciences* (Attachment B). For example, outreach efforts should target organizations of amateur biologists and encourage interaction between professional and amateur scientists. Messages should be embedded into broader concepts about personal and societal responsibility and should include the importance of taking measures to prevent others from misusing materials with dual use potential. Communications should explore novel mechanisms and utilize new media to reach young, tech-savvy amateurs. Outreach efforts to non-life-science researchers should exploit institutional mechanisms of reaching scientists across department and disciplines and should leverage the experience of other fields with potential DUR.

The report recognizes that amateur biologists and non-life-science researchers have some special educational needs to consider, but the approaches described in the NSABBs earlier strategic plan to educate about DUR remain valid, said Dr. Imperiale. As these two communities are very interested in learning about DUR, biosecurity, and biosafety, education efforts should take advantage of the many ways to reach out to them, he concluded.

NSABB Discussion of Draft Report

To improve outreach to amateur biologists, members suggested engaging influential individuals (e.g., Rob Carlson, one of the original developers of the amateur biology community) and the amateur biology groups such as DIY Bio, BioCurious, and genSpace; using novel mechanisms to raise awareness, such as comic books and trading cards; and communicating through such venues as science fairs.

Some mainstream science organizations are reaching out to amateurs, for example, through student competitions. Dr. Jessica Tucker, (HHS) said DIY biologists have collaborated with the American Biological Safety Association and with AAAS. Mr. Ed You, (FBI), noted that his organization is engaged in community outreach to amateur biologists (e.g., through WMD coordinators), and that the DIY community is very receptive. He noted that outreach could also target public members of IBCs. Mr. You said the FBI wants amateur biologists to have situational awareness so they can identify suspicious activity.

Members offered suggestions for disseminating the recommendations, noting that high school science teachers may be very receptive, because they recognize that students are

doing cutting-edge science with potential safety concerns. The report does not mention home-schooled students, who should be considered a target audience for outreach. Mr. Chris Park (Department of State) said there are formal and informal channels for reaching students even before high school, such as national science fairs and the national Science Olympiad, which reach home-schooled and traditional students. He added that the recommendations in the report should be communicated to university education departments to reach future teachers. Ms. Grant, Co-Chair of the Working Group, said the federal government will decide how it wants to proceed in light of the recommendations, which will inform the next steps, such as dissemination.

Public Comments

Lorna Weir, Ph.D., York University, made the suggestion that the Working Group consider using the term “popular” instead of “amateur.” She noted a long history of popular participation in science—for example, in natural history (birding, insect collecting)—that is welcomed by professional scientists. “Popular” gives more significance to the work and creates a bridge from local and historical biological endeavors to professional ones. Dr. Weir further suggested that the Working Group might have benefitted from having a historical consultant on the significance of popular science in professional science and its historic place in American culture. Recognizing the historic role of popular science would lead to a less defensive relation to DIY biology, she said.

Dr. Koblenz, George Mason University, pointed out that there seems to be a disconnect among the NSABB Working Groups. The draft guidance on personnel reliability and culture of responsibility emphasizes peer reporting of unusual or suspicious behavior, which was specifically excluded from previous NSABB recommendations on developing a code of conduct. The current draft report does not describe a mechanism for addressing conduct among amateur biologists. As a result, the burden of dealing with scientific conduct falls entirely on professional scientists and laboratories, he said. Dr. Koblenz called for more cooperation among Working Groups around the issues of conduct.

NSABB Motion 3

Dr. Cohen moved that the draft report *Strategies to Educate Amateur Biologists and Scientists in Non-Life-Science Disciplines About Dual Use Research in the Life Sciences* be approved as written. The motion was seconded and the members voted unanimously in favor, and the motion passed.

Update on NSABB Journal Review Policies Working Group Activities

Arturo Casadevall, M.D., Ph.D., Professor and Chairman, Division of Infectious Diseases, Albert Einstein School of Medicine and Jeffery F. Miller, Ph.D., Professor and Chair, Department of Microbiology, Immunology & Molecular Genetics, David Geffen School of Medicine, University of California - Los Angeles and Co-Chairs, NSABB Working Group on Journal Review Policies

Dr. Casadevall described the aims of the Working Group: raising awareness about DURC

in the scientific publishing community, engaging scientific editors and publishers about their policies for, and experiences with, DURC publishing, and gathering insight to improve current NSABB guidance. Members of the Working Group conducted individual interviews with editors and held a roundtable with editors on January 13, 2011.

The interviews revealed that all the journals have their own approaches. The ASM journals have procedures in place for identifying DURC. In other cases, simply engaging editors in discussion led them to decide to establish policies, said Dr. Casadevall, and they were directed to the NSABB recommendations on Responsible Communication of Life Sciences Research with Dual Use Potential.

The roundtable addressed best practices and models for screening submissions for DURC. Many journals use the select agent list to flag manuscripts for review; if that list is pared down, journals may have more difficulty identifying manuscripts that require closer attention, and other methods are needed. Editors agreed that the materials and methods sections of a manuscript should be sufficient to allow for reproduction of the experiment—even if it may provide a recipe for DURC. In addition, highlighting concerns in a commentary may have the effect of raising the potential for harm.

The roundtable offered some suggestions for educating reviewers and using existing tools, such as seeking out specific expertise when needed. The many opportunities for disseminating information, including self-publishing, make it impossible to ensure that a rejected manuscript will not be disseminated.

The Working Group is planning to bring together journal editors and intelligence community representatives this fall to facilitate discussion and forge links. It is hoped that participants will discuss policies and procedures for managing manuscripts when DURC is identified. The Working Group is also considering a public consultation and hopes to have a draft document with recommendations for NSABB review in February 2012. Dr. Miller added that he sees increased acceptance and awareness of the NSABB's efforts among the scientific publishing community.

NSABB Discussion

Editors are uncomfortable with being the final checkpoint for the dissemination of DURC, said Dr. Miller. They would prefer to see many checks and balances along the research continuum prior to publishing research—for example, by the funding agency or the institution where the research is conducted. When a manuscript can be modified, however, editors are enthusiastic about explaining the issues and working with authors.

Dr. Osterholm wondered to whom an editor would report an identified concern, especially without clear evidence of a potential crime or damage. Dr. Miller responded that the Working Group will include in its report links to sources that can address some questions. Some journals would like access to a panel of experts for consultation, which the Working Group is considering. Drs. Enquist and Casadevall agreed that more mechanisms are needed to address the substantial workload of identifying manuscripts

and potentially adding another layer of review.

Update on NSABB Codes of Conduct Working Group Activities

Kenneth I. Berns, M.D., Ph.D., Director of Genetics Institute, University of Florida and Chair, NSABB Working Group on Codes of Conduct

Dr. Berns said the passing of Dr. Sorenson leaves a large hole in the Code of Conduct Working Group because he was Co-Chair. Dr. Berns described the charge to the NSABB to advise on development, use, and promotion of codes of conduct for life science and the aims of the Working Group to promote awareness, dissemination, and adoption of codes of conduct. Dr. Berns suggested revising the aims to go beyond academic institutions, professional societies, and individuals engaged in DUR to include those in life science who may inadvertently be involved with DUR and government and industry laboratories.

The Working Group began from the premises that (1) development and implementation of codes should be voluntary and (2) codes are optimal for educating and raising awareness among scientists. By thinking about the issues, scientists may avoid inadvertently inappropriate behavior. The Working Group is tasked with providing guidance on how to maintain living codes that reflect changes in DUR. Dr. Berns said more input is needed to better understand this task.

In October 20, 2010, the Working Group hosted a roundtable of experts including representatives of academic institutions, scientific associations, and an official from the Office of Research Integrity at HHS. There was consensus among the Roundtable participants that codes of conduct can be effective in raising awareness and that the process of developing a code is a key opportunity for education; thus, it should involve as many stakeholders as possible. Other lessons learned from the Roundtable included:

- The importance of strong institutional commitment, resources, and a champion to develop and disseminate a code.
- People from all levels of the organization should be involved, and dissemination should occur through multiple venues to reach multiple audiences.
- Codes of conduct should incorporate real-world examples to make the issues more real.

The Working Group plans to provide a draft report to the NSABB at the next NSABB meeting. Stakeholders in the life sciences community have noted the need for guidance in this area. Thus, the report will feature a toolkit and an educational resource on developing, disseminating, and—notably—evaluating codes of conduct. The educational resource will target leadership, researchers, and students and can be used as part of a course on the responsible conduct of research or as an individual, self-guided learning tool. It will include background on DUR and provide cases for discussion.

NSABB Discussion

Dr. Berns said that the proposed section of the report describing the NSABB's previous efforts around codes of conduct addresses model codes to some extent. He agreed with Dr. Keim that it would be appropriate to test the educational resource to determine its usefulness before widespread dissemination—perhaps using his own students. Dr. Imperiale offered to help with the educational resources, saying that he had incorporated the concept into his own research ethics courses.

Dr. Imperiale questioned the premise that a code of conduct should be voluntary. He said everyone involved in life science research should commit to abiding by a code of conduct. Making it voluntary seems to suggest that it is not necessary. Dr. Berns pointed out that some researchers are subject to multiple codes, and some are subject to none (e.g., amateur biologists). Dr. Casadevall noted that all medical students take the Hippocratic Oath, although Dr. Berns pointed out that it is voluntary. Dr. Osterholm added that the Hippocratic Oath does not stop doctors from making preventable errors and that regulations that include penalties and peer pressure are more likely to have an effect.

The overarching issue is to define the accepted norm for conduct, Dr. Osterholm continued. He felt strongly that the NSABB should take a stand on an effective and appropriate code of conduct relating to dual use research and educate all those affected by it of its importance. If this is done, when the next biological event occurs, the scientific community will not see a Draconian response that sends all life science research back into the Dark Ages, he said. Dr. Berns agreed on the need to communicate expectations for conduct, but he believes the issue is identifying the appropriate format in which a code is promoted to achieve the best result .

Some discussion focused on whether the definition of DURC should be clarified, and Dr. Berns pointed out that, as with the select agent list, problems arise as soon as you start trying to pin down the specifics. Dr. Berns said he would be happy raising general awareness among people involved in life science about DURC and codes of conduct. Dr. Keim felt that institutions should be required to update their own codes of conduct periodically, because the process itself raises awareness, which may be more important than getting the code exactly right. Dr. Kanabrocki noted that consistency is a concern, as codes of conduct go well beyond DURC, Dr. Berns replied that he was struck by the potential for fusion among the various NSABB Working Groups as the notion of separating development of a code from the culture of responsibility was rather artificial.

Update on NSABB International Engagement Working Group Activities

David R. Franz, D.V.M., Ph.D., Vice President and Chief Biological Scientist, Midwest Research Institute, Frederick, MD/ Director, National Agricultural Biosecurity Center, Kansas State University and Co-Chair, NSABB Working Group on International Engagement

Dr. Franz echoed the previous comments that the process of engagement is as important as the product, both domestically and internationally, and that perspective informs the efforts of the International Engagement Working Group. He explained that the Working

Group seeks to raise awareness, gain perspectives, and expand the international network around biosecurity issues, DUR, and NSABB efforts. Because large, in-person meetings have become so expensive, the Working Group has taken advantage of video teleconference opportunities, piggybacking onto other international meetings when possible.

The Working Group sponsored a video teleconference on strengthening the culture of responsibility with respect to DUR and biosecurity in November 2010 as a satellite session of the international workshop *Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention* held in Beijing, China. The one-hour presentation and participant discussion is available http://oba.od.nih.gov/biosecurity/bio_video_teleconference_Nov2010.html. The event was successful and provided some insights into logistical planning for future efforts, said Dr. Franz. Many participants were very knowledgeable about DUR, but some knew very little.

A second video teleconference on RCR took place in Kuwait in March 16, 2011. The two-hour panel session was organized as part of an AAAS International Engagement Meeting entitled “Responsible Bioscience for a Safe and Secure Society Seminar Series” and included breakout groups and a general discussion among a panel and audience in Kuwait, and an NIH/NSABB panel in Washington, DC. Dr. Franz said establishing a workshop or panel as part of a larger meeting is a more effective method for engaging an international audience than a stand-alone webinar. He praised the enthusiasm of the participants and said a video of the Kuwait event would be posted online once it is edited.

The Working Group is organizing a workshop on December 9, 2011, to raise awareness about DUR in the Asia/Western Pacific region. It will use as a case study the controversial paper on mousepox published in 2001 by Australian researchers. The event will take place on the NIH campus, with co-moderators representing the United States and the Asia/Western Pacific region. An expert panel will include Ian Ramshaw, Ph.D., National Center for Biosecurity, The University of Sydney, a co-author of the mousepox paper.

Moving forward another in-person international roundtable meeting would be valuable to identify thought leaders, discuss what has changed in recent years, and map out next steps. The Working Group is also considering arranging and filming more seminars and expert presentations, more bilateral video teleconferences, and regional webcasts. Dr. Franz noted the Working Group outreach efforts have not included Africa so that might be a likely region for the Working Group’s next effort.

NSABB Discussion

In response to an inquiry from the Board, Dr. Franz said that the United States engages more regularly with Europe than other regions, and there was a webcast focused on Europe about a year ago, so there are no other plans to reach out to Europe right now. Dr. Berns said the NSABB should take advantage of international meetings related to

virology, bacteriology, etc. as an efficient way to get the message about DUR out to the target audience. Dr. Franz was surprised to learn that the issue of DUR was novel to bioethicists attending a meeting in Singapore; bioethicists represent another target population that should be informed about DUR.

Dr. Miller suggested that the NSABB's Recommendations on Responsible Communication of Life Sciences Research with Dual Use Potential be sent in advance to participants in the next international video teleconference on DUR. Judge Ehrlich said she would like to see more women involved on the expert panels. She also suggested including food and plant researchers and public health professionals in future events. Dr. Osterholm recommended addressing the intentional use of chemicals for harm (although it falls outside the purview of the NSABB), because recent events of intentional food contamination demonstrate a threat of great concern to many Asians. Dr. Lewis noted that an upcoming American Phytopathology Society annual meeting in Honolulu will include a session on agriculture and food security that will cover DUR, representing an opportunity to reach out to the Asian research community.

In response to a request for more details about the Kuwait video teleconference, Dr. Gerald Epstein (AAAS) said a report is in development, and video will be posted. Dr. Epstein invited additional comments on the meeting from Gwenaele Coat, the meeting organizer, who noted that engaging women in some areas, such as the Middle East, is difficult. At the Kuwait panel, for example, none of the women in the room would speak on camera.

Mr. You said he is organizing a biosecurity workshop in August. He advised the NSABB to take advantage of opportunities to learn from partners in the Middle East—for example, how real-life situations have affected their culture and what efforts have been implemented.

Mr. You said he believes advocates of open science (e.g., DIY biology) will push to put more information online, including, for example, results of clinical trials without institutional review board (IRB) oversight. He asked how the editors of the Public Library of Science (PLoS) journals responded to the discussion about reviewing manuscripts for DURC. Dr. Casadevall said the PLoS journals tend to be fairly mainstream, and Dr. Keim noted they have rigorous IRB review requirements. However, Dr. Casadevall agreed that patients may organize their own trials, subverting standard oversight methods, and publish their findings online.

Public Comments

Dr. Weir, York University, suggested contacting the Australian Center for Biosecurity to establish a dialogue with the Asia/Western Pacific Region. She added that young people and non-scientists can be stimulated to care about DUR with interesting examples of famous DUR experiments. For example, she cited her own article (with Dr. Michael Selgelid)—an interview with Dr. Ramshaw and his co-author Dr. Ronald Jackson about how the mousepox publication experience affected their careers and the science.

Member Activities Updates

Dr. Kwinn said ASPR held a session about applying security at an ASM meeting that included policymakers, nonprofit organizations (including the Virtual Biosecurity Center of the Federation of American Scientists), and researchers working in laboratories. The session was well received with good questions and dialogue, and Dr. Kwinn hoped to organize such sessions at larger meetings in the future.

Dr. Casadevall said he presented at a meeting last April, promoting safe and responsible science in the conduct of biomedical research involving high-risk pathogens.

Mr. You said the FBI acted on the NSABB's recommendations on outreach and partnered with the Massachusetts Society for Medical Research for a national conference in California on institutional animal care and use committees, IRBs, IBCs, to discuss biosecurity. The FBI has also held workshops regionally with industry representatives and provided biosecurity lessons at academic institutions. The workshop included tabletop exercises and group discussion; those efforts have had very positive results, said Mr. You. Dr. Keim said he took part in such a presentation recently at Tempe (Arizona State University), and the audience was very engaged. Mr. You explained that Dr. Keim described the NSABB recommendations and challenges, and then the FBI presented its security perspective. Case studies provided real-world examples (beyond DUR) that illustrated the issues in terms of domestic terrorism and even workplace violence. Dr. Keim said the NSABB has been talking about outreach for seven years, and Mr. You brings proof of the FBI's effective outreach efforts.

Murray L. Cohen, Ph.D., M.P.H., C.I.H., said he attended the reincarnation of the International Federation of Biosafety Associations in Bangkok in February. He was pleasantly surprised to find that 170 delegates from 33 countries attended. Materials from the NSABB were provided at the meeting (e.g., DVDs, links to online reports). Captain Theresa Lawrence, Ph.D., Office of Medicine, Science and Public Health, ASPR, HHS, said the meeting offered a good networking opportunity around biosafety and biosecurity issues, including dual use. Of particular interest to the International Engagement Working Group, the incoming chair of the Federation is from the Kenyan National Research Institute, and the Federation's next meeting in June 2012 takes place in Johannesburg, South Africa, in collaboration with the African Biosafety Association. Within one year, the African Biosafety Association has signed up approximately 300 members from 15 African countries, which Dr. Cohen found surprising given the range of development of laboratory science in Africa.

Dr. Kanabrocki said he took part in the AAAS Conference as described earlier. He and Dr. Gerald Epstein, AAAS, said there generally was good discussion at the conference until the videoconference began (and the women participants stopped speaking), so he agreed that having more women from the United States participate would be helpful. In a breakout session on publishing DUR, he was told that such results would not be published in the Middle East because of the fear of terrorism. Dr. Kanabrocki also

attended a conference sponsored by NIH on institutional biosafety committees and oversight of recombinant DNA research, which included much content on DUR. .

Dr. Franz said he will be speaking at two meetings in Brazil, one sponsored by ANBio (the National Biosafety Association of Brazil) and another related to biosecurity. Judge Ehrlich said she was the inaugural speaker for the biosecurity symposium series at the University of Texas Medical Branch at Galveston, and she is planning to bring in additional speakers. She is also designing a biosecurity education module that will be a requirement at the Medical Branch.

Mr. Park said that on December 5–22, 2011, he will be attending the Seventh Review Conference of the Biological Weapons Convention meeting in Geneva. The meeting topics will include extensive discussions of laboratory biosafety/biosecurity and national regulations as well as discussion of codes of conduct, education, outreach, and building a culture of responsibility. The meeting outcomes will shape the activities of the Department of State for the next five years. In a series of workshops leading up to the Geneva meeting, there will be opportunities for civilian society to weigh in. For example, next week in Manila, Mr. Park will talk about going beyond regulations and legislation, emphasizing the importance of a bottom-up approach to biosafety and biosecurity. In addition, between sessions at the Geneva meeting, there will be other opportunities for public health professionals, civilian society, diplomats, and others to contribute.

Next Steps

Paul S. Keim, Ph.D., NSABB Acting Chair

Dr. Keim announced that the next meeting of the NSABB is scheduled for October 25–27, 2011.

Adjournment

Paul I. Lewis, Ph.D., NSABB Executive Director

Dr. Lewis thanked the members and staff for their efforts in producing the two reports approved at the meeting. He thanked the public attendees for their comments. The exact date of the next meeting will be announced in the *Federal Register*. Dr. Lewis adjourned the meeting at 2:40 p.m.

Attachments:

- A) NSABB Culture of Responsibility Working Group Draft Report**
- B) NSABB Outreach and Education Working Group Draft Report**

Date: _____

Mary E. Groesch, Ph.D.
Executive Director
National Science Advisory Board for
Biosecurity

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes and Attachments are accurate and complete.

These Minutes will be formally considered by the NSABB at a subsequent meeting; any corrections or notations will be incorporated into the Minutes after that meeting.

Date: _____

Paul S. Keim, Ph.D
Acting Chair
National Science Advisory Board for Biosecurity