National Institutes of Health
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Office of Biotechnology Activities

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

February 27-28, 2008
National Institutes of Health
9000 Rockville Pike
Building 31-C, 6th Floor, Room 10
Bethesda, Maryland

MINUTES of MEETING

VOTING MEMBERS

Paul S. Keim, Ph.D. *Acting NSABB Chair*, Translational Genomics Research Institute and Northern Arizona University
Arturo Casadevall, M.D., Ph.D., Albert Einstein College of Medicine
Murray L. Cohen, Ph.D., M.P.H., C.I.H., Frontline Healthcare Workers® Safety Foundation, Ltd.
Susan A. Ehrlich, J.D., Arizona Court of Appeals
Lynn W. Enquist, Ph.D., Princeton University
Barry J. Erlick, Ph.D., BJE Associates, Inc.; Auburn University; and Kansas State University
David R. Franz, DVM, Ph.D., Midwest Research Institute and Kansas State University
Claire M. Fraser-Liggett, Ph.D., University of Maryland School of Medicine
Michael J. Imperiale, Ph.D., University of Michigan Medical School
Stuart B. Levy, M.D., Tufts University School of Medicine, Tufts Medical Center
Mark E. Nance, J.D., GE Healthcare
Michael T. Osterholm, Ph.D., M.P.H, University of Minnesota
David A. Relman, M.D., Stanford University
James A. Roth, DVM, Ph.D., Iowa State University
Andrew A. Sorensen, Ph.D., University of South Carolina
Anne Vidaver, Ph.D., University of Nebraska, Lincoln

EX OFFICIO MEMBERS

Jason E. Boehm, Ph.D., National Institute of Standards and Technology
Brenda A. Cuccherini, Ph.D., M.P.H., Department of Veterans' Affairs
Jeffrey Miotke, U.S. Department of State
Janet K. A. Nicholson, Ph.D., Centers for Disease Control and Prevention
Caird E. Rexroad, Jr., Ph.D., U.S. Department of Agriculture
David G. Thomassen, Ph.D., U.S. Department of Energy
Joanne Tornow, Ph.D., National Science Foundation

FEDERAL AGENCY REPRESENTATIVES

Kay Marano Briggs, Ph.D., U.S. Geological Survey
Kenneth Cole, Ph.D., U.S. Department of Defense
Natalia Comella, Ph.D., U.S. Department of State
Diane DiEulis, Ph.D., Office of Science and Technology Policy
Jerome Donlon, Ph.D., U.S. Department of Health and Human Services
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Maria Y. Giovanni, Ph.D., National Institute of Allergy and Infectious Disease, NIH
David Holmes, Ph.D., Centers for Disease Control and Prevention
Sara Klucking, Ph.D., U.S. Department of Homeland Security
Andrea Lauritzen, Ph.D., U.S. Department of State
Gerald Parker, Ph.D., D.V.M., U.S. Department of Health and Human Services
Robbin S. Weyant, Ph.D., Captain, USPHS, Centers for Disease Control and Prevention

NSABB EXECUTIVE DIRECTOR

Amy P. Patterson, M.D.

GUEST SPEAKERS

Robert Cook-Deegan, Ph.D., Southeast Regional Center for Excellence for Emerging Infections and Biodefense (SERCEB)
Jacqueline Corrigan-Curay, M.D., J.D., Office of Biotechnology Activities (OBA), NIH
Ottorino Cosivi, D.V.M., World Health Organization (WHO)
Mark Frankel, Ph.D., American Association for the Advancement of Science (AAAS)
Allan Shipp, OBA, NIH
Kenneth Staley, M.D., M.P.A., White House Homeland Security Council
Michael Stebbins, Ph.D., Federation of American Scientists (FAS)
Gilbert Whittemore, J.D., American Bar Association (ABA)
Janet S. Peterson, R.B.P, C.B.S.P., American Biological Safety Association (ABSA)
Ray Martyn, Ph.D., American Phytopathological Society (APS)
Ronald Atlas, Ph.D., American Society for Microbiology (ASM)
Stephen Heinig, Association of American Medical Colleges (AAMC)
Patrick White, Association of American Universities (AAU)
Carrie Wolinetz, Ph.D., Federation of American Societies for Experimental Biology (FASEB)
Bruce McPheron, Ph.D., National Association of State Universities and Land Grant Colleges (NASULGC)

February 27, 2008

Call to Order and Review of Conflict of Interest Rules

Dr. Paul Keim, acting chair of the National Science Advisory Board for Biosecurity (NSABB) for Dr. Dennis Kasper, opened the February 2008 meeting of the NSABB at 12:30 p.m.

Dr. Amy Patterson read into the record the rules of conduct for conflicts of interest. The rules are explained in the report *Standards of Ethical Conduct for Employees of the Executive Branch*, which was received by each member when appointed to the NSABB. Members of the NSABB are considered Special Government Employees and were requested to review the steps to ensure that conflicts of interest are addressed. Board members are required to recuse themselves in advance of any discussion in which they believe they have a conflict of interest. Questions should be addressed to the committee management officer of the OBA, Lisa Rustin.

Introductions, Approval of the April 2007 Minutes, and Overview of Agenda

Dr. Keim welcomed the NSABB members, Federal Agency representatives, and members of the public in attendance and watching via Webcast. Board members and *ex officio* members introduced themselves and stated their affiliations.

Judge Susan Ehrlich and Dr. Anne Vidaver reviewed the minutes of the April 2007 NSABB meeting. Dr. Stuart Levy noted that, throughout the document, there was a lack of distinction between dual use research (DUR) and dual use research of concern (DURC). He suggested that the minutes should state at the beginning that DUR is a general subject and that DURC is the current issue of concern. Dr. Patterson agreed to add a note of clarification at the beginning of the minutes as a preface for the reader.

NSABB Motion 1

Moved by Dr. Keim and seconded by Dr. Lynn Enquist, the Board voted unanimously by voice to approve the April 2007 NSABB meeting minutes that had been distributed in advance of the meeting with the editorial changes suggested by Dr. Levy that had not yet been incorporated.

Updates on International Engagement on Dual Use Research

As chair of the NSABB International Engagement Working Group (IWG), Dr. David Franz discussed the October 2007 international roundtable, other international-engagement activities, and another roundtable − the third in the series − planned for Fall 2008. The first formal organized action of the IWG occurred in February 2007 when 17 representatives from other countries were brought together for a roundtable discussion of activities in their countries regarding DURC and to discuss the NSABB draft recommendations.

The October 2007 roundtable focused on the nongovernmental sector – academies, scientific unions, intergovernmental organizations, and foundations. A group of participants involved in life sciences research, primarily from the United States, comprised four panels that discussed relevant activities and plans. The goals of this roundtable were to:

- Enhance awareness, foster communication, enhance coordination, and facilitate cooperation regarding dual use life sciences research issues;
- Learn about current and planned activities of the involved organizations; and
- Provide a foundation for the IWG to identify options for fostering further constructive international engagement.

Questions and issues addressed by the panel members were the scope, goals, and challenges of their current activities as well as the metrics of success. Participants also discussed lessons learned and conveyed advice to others who may be planning similar activities. Finally they described their perception of unmet needs in this area as well as their own future plans. The principal topics from the October 2007 meeting were:

- Underlying concepts and challenges in developing a DUR international engagement strategy;
- Definitional problems confounding the use of terms such as "dual use research," "biosafety," and "biosecurity" in international and national settings;
- Promoting awareness of DUR issues;
- Promoting education and training in DUR issues;
- Promoting communication about DUR among interested parties;
- Approaches to coordination and collaboration;
- The need for international guidance, guidelines, and standards; and,
- Monitoring and evaluation.

All of the presenting organizations reported conducting general awareness-building activities, and some were developing and involved in targeted programs of education. Participants discussed the possibility of creating a Web site for enhancing communications among these groups.

As defined in the NSABB Revised Charter, DUR is biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. As defined by the Oversight Framework Document, DURC is research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.

As chair of the IWG, Dr. Franz stated that he had presented the IWG's background and work at seven meetings in 2007: in Moscow, Islamabad, Singapore, Beijing, Warsaw, Tbilisi, and Bangkok. While some misunderstandings exist about what the NSABB is trying to accomplish, he noted that those misunderstandings are typically cleared up in the ensuing discussions.

The December 5-6, 2007, meeting in Tbilisi, Georgia, was titled "The Dual Use Dilemma" and was cosponsored by the Georgian Association of Medical Specialties and Tbilisi State University; Dr. Franz was the only American on the program. The purpose of this meeting was to introduce the concept of dual use; communicate ongoing work in biosafety and biosecurity and pandemic and epidemic preparedness; consider the university's role in capacity building in research, communication and exchange, and training; and foster international cooperation. The agenda emphasized education and what role the university might fulfill. Consensus was achieved on the following principles:

- Life science research crosses all sectors and is essential to advancing health and well-being;
- Some materials, technologies, and information from the life sciences can be misused intentionally or accidentally;
- A productive life sciences enterprise must be maintained;
- Awareness and education are necessary to prevent the misuse of science while protecting discovery;
- Legislation may be needed, but must be done so as to facilitate the benefits and limit disruption to the industry;
- The culture of responsibility must be strengthened;
- Stakeholders include the Prime Minister, the Ministries, the Academy of Science, nongovernmental organizations (NGOs), and the media; and
- Life sciences are global; therefore, awareness and education efforts must be global.

IWG activities planned for 2008 include continuing to raise awareness and learn what others are doing internationally. Members will continue to make presentations at scientific conferences and workshops as

the NSABB's "emissaries." After the U.S. Government (USG) policy decisions are made, the IWG will begin drafting the NSABB International Strategy. Throughout 2008 and beyond, the IWG will continue to collaborate with the NSABB's Working Group on Outreach and Education.

Cosponsored by the USG and the WHO and hosted by the IWG, a third roundtable will take place in Bethesda, Maryland, in early November 2008. The purpose of this meeting will be to expand the network created at the February 2007 meeting by continuing to raise awareness, learning what others are doing internationally, and discussing the mechanics of international engagement. This roundtable will yield information useful to the draft of the NSABB's International Strategy document. Potential participants include additional countries with oversight "tools" and/or policies pertinent to DURC as well as prior roundtable participants willing to share lessons learned since the February 2007 meeting. The format will be panels of three or four speakers with plenary and breakout sessions.

Question & Answer Session

Regarding feedback from the USG, Dr. Franz acknowledged that it would not be critical for the IWG to await specific policies from the USG because those policies will pertain only to the United States; it will still be possible for the IWG to provide options, ideas, and a "toolbox" as part of its outreach. While the international engagement approach will not change, the IWG will delay preparing a document regarding international engagement until USG policies have been finalized.

The National Academies Report *Biotechnology Research in an Age of Terrorism*, known as the *Fink Report*, has been widely distributed through the InterAcademy Panel (IAP). The IAP has a CD with all reports related to DURC, which has been handed out widely domestically and abroad.

Dr. Levy explained that IWG members have used their resources to identify individuals or meetings to which the DURC issue should be brought. The metric for the IWG is awareness and communication, which is the minimum that can be guaranteed; it is not possible to guarantee that other countries will take action on DURC issues. The IWG is not propagating U.S. policy; it is disseminating information about DURC issues and sharing what the USG has done about DURC.

Regarding whether IWG efforts have led to a self-propagating discussion, Dr. Franz noted that presentations by IWG members have fostered communication and resulted in international engagement. For example, at the Morocco meeting, some Moroccan representatives volunteered to discuss DURC issues with their neighboring countries, countries where IWG members did not have contacts. One measure of engagement may be how many countries have initiated DURC discussions with other countries.

Outreach to the media is needed to permit them to understand the definitions of DUR and DURC. It behooves the NSABB's efforts to have informed science journalists following these issues.

When presenting at international meetings, a standard set of PowerPoint slides would be helpful to keep presenters on message and to avoid potential pitfalls in the delivery of DUR and DURC issues. The IWG or the Working Group on Outreach and Education should be tasked with developing such a tool.

Some countries are more concerned with their own immediate issues, such as HIV and malaria. However, most leaders in the field from nearly every country have shown at least some interest, processing the DUR/DURC information within their frame of reference. Enhanced awareness may be a sufficiently successful outcome.

Biosafety Implications of Synthetic Genomics Technology: U.S. Policy Development

Jacqueline Corrigan-Curay, M.D., J.D., Acting Executive Secretary of the Recombinant DNA Advisory Committee, Office of Biotechnology Activities, explained that DNA synthesis technology could be

used to synthesize partial or whole genomes *de novo*, without needing access to natural sources of organisms or their nucleic acids. This technology is advancing rapidly, and the DNA sequence data of pathogens are openly available, which leads to concerns that this technology and information could be misused to make dangerous pathogens to threaten public health.

The charge to the NSABB on synthetic genomics is to identify the potential biosecurity concerns raised by the synthesis of Select Agents by assessing the adequacy of the current regulatory and oversight framework and by recommending potential strategies to address biosecurity concerns.

Selected recommendations of the NSABB include:

- Increase awareness among investigators and service providers about their responsibility to know what they possess, manufacture, and/or transfer;
- Provide additional guidance and tools for screening orders and interpreting results;
- Foster international dialogue and collaboration;
- Develop and implement universal standards and preferred practices for screening sequences; and
- Ensure that biosafety guidelines address synthetic nucleic acids.

Some practitioners of synthetic genomics are educated in disciplines that do not routinely entail formal training in biosafety, and they are uncertain about when to consult an Institutional Biosafety Committee (IBC). As a result, there is a need for biosafety principles and practices applicable to synthetic genomics.

The USG has considered the NSABB recommendations through a trans-federal policy coordination process that was led by the White House Homeland Security Council and the Office of Science and Technology Policy. The recommendation on the need for biosafety guidance was accepted by the USG with the understanding that implementation would be through modification of existing guidelines as appropriate. USG policy decisions to date include that the federal Department of Health and Human Services (HHS) should update and revise as appropriate the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) and the *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), and that HHS should develop guidance for investigators and laboratory workers that addresses the unique safety issues related to work with certain synthetic nucleic acids. This guidance should offer practical and effective options for managing risks to personnel and public health associated with this research.

Current biosafety guidance is provided by the *BMBL*, which is agent-specific (not technology-driven) and refers to the *NIH Guidelines*. The *NIH Guidelines* notes that biosafety measures are needed when dealing with molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those constructed molecules.

The NIH Recombinant DNA Advisory Committee (RAC) is a federal advisory committee providing advice and recommendations to the NIH Director and the Secretary of HHS regarding recombinant DNA (rDNA) research. Providing a unique public forum for the discussion of science, safety, and ethics of rDNA research, the RAC reviews more than 60 human gene transfer protocols each year and selects approximately 12 protocols per year for public discussion. The RAC provides the NIH with advice and expertise on emerging policy issues related to rDNA research and biosafety, and provides the scientific community and the public an opportunity to participate in its quarterly meetings.

Specific to biosafety, the RAC forwards recommendations to the NIH on selected research that raises important public health issues; most recently, recommendations have been made regarding the introduction of tetracycline resistance into *Chlamydia* species and the introduction of chloramphenicol resistance into *Rickettsia conorii* and *typhi*. Safety symposia sponsored and guidance provided by the RAC in recent years include *Safety Considerations in Recombinant DNA Research with Pathogenic Viruses*, *Biosafety Considerations for Research with Lentiviral Vectors* and designation of research strains of *E. coli* as Risk Group 1 agents.

Most recently, the charge to the RAC regarding synthetic biology has been to consider the applicability of the *NIH Guidelines* to synthetic biology in terms of the degree to which this technology is covered and whether the scope needs to be modified to capture synthetic biology. The RAC was asked specifically to develop draft recommendations regarding principles and procedures for risk assessment and management of research involving synthetic biology. A review of the revised *NIH Guidelines* is currently underway by the RAC's Biosafety Working Group, whose draft work products will be reviewed for approval by the full RAC at its March 2008 meeting. Recommendations will be published in the *Federal Register* in Spring or Summer 2008, providing an opportunity for public comment, and final recommendations will be conveyed to the NIH Director and HHS leadership.

Assessing Biosecurity Concerns Related to Synthetic Biology

Dr. David Relman, chair of the NSABB Working Group on Synthetic Genomics (SGWG), provided an overview of the activities of the SGWG by reviewing its charge, summarizing the October 2007 Roundtable on Synthetic Biology, providing an overview of synthetic biology, and discussing the SGWG's preliminary findings and recommendations. The charge of the SGWG is to identify biosecurity or dual use concerns that may be associated with synthetic biology and that would not be adequately addressed by the DURC oversight framework proposed by the NSABB.

Held in October 2007, the Roundtable on Synthetic Biology was co-hosted by the SGWG and the NIH RAC Biosafety Working Group. Its purpose was to explore the state of the science in synthetic biology, the current capabilities for predicting function, and risk assessment and risk management in a context of uncertainty.

Currently, there is no consensus on the definition of "synthetic biology," and thus there are many definitions, uses, and stated goals. For the purposes of the SGWG, "synthetic biology" refers to the design and construction of novel organisms (e.g., viruses, microbes, plants, animals) with predictable properties and with varying degrees of reliance on a master "blueprint" from nature. It encompasses the design of novel biological "circuits" and components, and construction of organisms (both free-living and dependent) based on properties of components, as well as the redesign and synthesis of existing, natural organisms for specific purposes. Approaches to synthetic biology can be "bottom up" – the design and synthesis of a new organism with predictable properties using basic functional (genetic) components – or "top down" – the design and/or synthesis starting with an extant organism or blueprint.

SGWG deliberations have focused on the biosecurity/DURC risks associated with synthetic biology, whether these risks are novel as compared to those identified for synthetic genomics and recombinant DNA, and whether the biosecurity risks are adequately addressed by the oversight framework for DURC recommended by the NSABB or whether additional measures are necessary. Preliminary observations of the SGWG include:

- A multiplicity of definitions, goals, and approaches exist in synthetic biology;
- Significant limitations remain regarding the current ability to custom-design novel organisms with defined properties, such as pathogens, in a predictable manner, either by *de novo* synthesis or by re-engineering extant organisms;
- The practice of synthetic biology presupposes an ability to predict biological properties from sequence or structure;
- Biological function exists at many levels (e.g., genetic sequence, molecular structure, cellular physiology, organ histology) and continues to elude efforts at formal derivation;
- Further experimental and theoretical work is needed (and can be expected) for improved predictive capabilities;
- Risk assessment is problematic and difficult, especially for organisms that share few similarities with extant organisms, and, therefore, in light of this uncertainty, it is important to conduct synthetic biology research under appropriate biosafety conditions;
- All practitioners may not recognize the biosafety risks presented by synthetic biology;

- It is critical to raise awareness within the disparate scientific communities that engage in synthetic biology research about the possible biosafety risks and need for responsible conduct of research;
- Biosafety outreach and education efforts must recognize that the synthetic biology community is not confined to the life sciences;
- The biosecurity or DURC risks associated with synthetic biology should be considered on the basis of experimental aim and approach;
- As synthetic biology techniques become easier to conduct and less expensive to acquire, the range of practitioners will continue to expand to include hobbyists as well as scientists and engineers; kit-based biology democratizes and disseminates producibility;
- It is unlikely that traditional research/biosafety oversight practices will adequately address the less traditional users, for example, hobbyists;
- The increasing dissemination of synthetic biology technology creates challenges for education and oversight; and
- The goals, potential benefits and risks, and current limitations of synthetic biology are not uniformly understood within the scientific community and the public.

Preliminary recommendations from the SGWG are as follows:

- At present, the proposed system of oversight for DURC should be adequate for addressing the potential for misuse of synthetic biology;
- Synthetic biology should be subject to institutional biosafety review and oversight;
- Oversight of DURC should be extended beyond the boundaries of the life sciences;
- Oversight of DURC should be uniform and comprehensive, and should be extended beyond federally funded research; and
- The USG should include advances in synthetic biology and mechanisms of virulence or pathogenicity in “tech-watch” or “science-watch” endeavors.

Consideration of NSABB Recommendations in the Development of Federal Policy on Dual Use Life Sciences Research

Kenneth Staley, M.D., M.P.A., Director for Biodefense Policy, Homeland Security Council, The White House, discussed the USG policy development process, further steps for the recommendations submitted by the NSABB, and the progress to date on those recommendations. Dr. Staley explained that his responsibilities encompass crisis management as well as short-term and long-range policy development. Within this policy development process, he recognized the need for feedback and pledged to include more interaction after policy recommendations are submitted. He noted that, if more than one federal department or agency is involved in an issue, the President’s staff coordinates consideration of that issue because one of the important powers of the White House is to convene people from throughout the federal government.

For the dual use research issue, high-level officials must be engaged in the policy development process, and non-government expertise and sectors in addition to health must be leveraged to address significant threats. Effective policies should include clear goals and transparency to encourage accountability at the federal level, and policy should not depend on centralized control but should also empower individual agents to act. Some objectives of the policy process by which the dual use issue is being considered are to mitigate risks posed by synthesis of Select Agents; focus on options that balance risk mitigation with any negative impact on the research enterprise and U.S. competitiveness; minimize the economic burdens to industry, the USG, investigators and organizations; consider the NSABB recommendations in the context of other work products; and establish a White House body to oversee implementation. Recent advances in nucleic acid synthesis are opening a new era of genome engineering and design. These advances are poised to dramatically benefit the economy, medicine, and public health while at the same time raising concerns regarding the potential for misuse. The NSABB’s charge is to examine the potential biosecurity concerns raised by the synthesis of Select Agents and recommend strategies for addressing these concerns. In December 2006, the NSABB provided its findings in the report entitled

Addressing Biosecurity Concerns Related to the Synthesis of Select Agents. Four overarching recommendations were in the report:

- Harmonize guidance concerning the Select Agent Rules (SAR) and synthetically derived nucleic acids;
- Implement a framework for screening requests for synthetic nucleic acids;
- Modify current laws and regulatory frameworks; and
- Conduct follow-on studies, analysis, and outreach.

Dr. Staley discussed the current status of tasks 2, 4, and 5 of the NSABB recommendations in the sub-Policy Coordinating Committee (PCC).

Task 2, "Propose a Screening Framework," is being led by HHS. The product for this task is a proposed framework or frameworks for managing the risks of nefarious actors acquiring Select Agent materials via commercial DNA synthesis. The proposed completion date is the fourth quarter of 2008, at which time framework options will be delivered for full PCC consideration. The proposed process is that the HHS-led Interagency Working Group will engage stakeholders in industry and academia to identify and consider options for a screening infrastructure and concept of operations for use by commercial providers, users of synthetic nucleic acids, and the federal government. This interagency working group also will evaluate legal mechanisms for implementation and oversight, and will prepare for full PCC consideration a summary of best options for screening and implementation.

Task 4, "Resolve 18 U.S.C. 175(c) Concerns," is being led by the U.S. Department of Justice (DOJ); partners include HHS, the Department of Defense (DoD), and the Department of Homeland Security (DHS). The product for this task is the issuance of a legal interpretation and the possible development of a proposed amendment to the statute. The proposed completion date for the issuance of the DOJ legal interpretation was January 2008, and the draft amendment should be completed in February 2008. DOJ is working with HHS to resolve questions related to the statutory interpretation, and DOJ has proposed convening an interagency working group to develop language for a proposed amendment.

Task 5, "Update Biosafety Guideline," is being led by HHS. HHS has asked the RAC Biosafety Working Group to draft proposed revisions to the *NIH Guidelines*; the *BMBL* will be revised to refer to the new *NIH Guidelines*. The products for this task are revisions of the *NIH Guidelines* and the *BMBL*. The proposed completion date for revising the *NIH Guidelines* is January 2009; it is anticipated that the *BMBL* revision will be completed by March 2009.

Question & Answer Session

In response to concerns about how to translate public comments and additional NSABB comments into revisions of these draft recommendations, Dr. Staley stated that, within the next 1 to 2 months, a process for doing so would be crafted.

Dr. Patterson reported that the OBA has been considering a workshop to bring the scientific community and the public together to work through the questions posed in Appendix II of the proposed oversight framework. This would be a public opportunity to discuss the practical details about how to implement the oversight framework.

Dr. Staley stated that the oversight framework report received a thorough review within HHS before it was transmitted to the White House and that it has now been transmitted to other Departments. The oversight recommendations will be acted on in the same manner as previous recommendations, although it may be possible to move the consideration of the oversight recommendations a little faster.

Dr. Staley noted that a valid role for the NSABB would be to monitor how the policies are being implemented and how they affect people.

Regarding Select Agents, the NSABB would like an expeditious process for addressing changes that occur after a policy is released. Dr. Staley agreed to try to find a structure to rapidly include emergent concerns into the policy process. The basic premise of this discussion is "do no harm" relative to the populace and to the science. Dr. Staley noted that the policy process is designed to be deliberative and thus to "get it right" the first time, with a balance between process speed and crafting the best policy possible.

WHO Project: Life Science Research and Development (R&D) for Global Health Security

Ottorino Cosivi, D.V.M., Project Leader, Program for Deliberate Epidemics, WHO, reviewed the contributions of the WHO to the elimination of chemical and biological weapons (CBW), beginning in the 1950s. Starting small in 2005, the WHO Program for Deliberate Epidemics has as its objectives to raise awareness and inform about the issue by underlining the importance of life science research, to provide guidance to countries on risk management options for the accidental or potential misuse of the outputs of life science research – from expected or unexpected products (tangible products) to skills and tacit knowledge (intangible factors) – and to develop tools for capacity-building. This Program is a collaborative effort of four WHO departments and programs and their expert networks. The WHO is involved in this issue because of the potential impacts on public health and public confidence in science, and because information varies among member states.

Project outputs include two published reports (2005 and 2006), online consultation (June through September 2007), co-sponsorship with the USG of the International Roundtable (2007), and sponsorship of a regional workshop in Thailand (December 2007). Outreach activities are ongoing, and an international network has been established. Additional planned outputs include guidelines, information and training materials (2008-2009), the second meeting of the Scientific Working Group (2009), and regional workshops as resources permit. The Scientific Working Group focuses on five areas for action:

- Education and training;
- Preparedness for a possible major outbreak of disease;
- Development of risk assessment methodologies;
- Engagement of all stakeholders in the life science community and guidelines for oversight; and
- Capacity building at the country level, including ethics, laboratories, and research.

The regional workshop entitled Research Policy and Management of Risks in Life Science Research for Global Health Security, held in Bangkok, Thailand, on December 10-12, 2007, generated the following recommendations to the WHO for further action:

- Raise awareness among all stakeholders on dual use issues through national and regional workshops, seminars, and international forums;
- Provide technical support, including expert scientific advice, to strengthen laboratory biosafety and laboratory biosecurity, and develop guidelines for risk assessment and DURC management, including social and ethical implications;
- Support laboratory infrastructure and capacity building for research, including training material and tools, specialized training programs and fellowships, and networking;
- Facilitate local and regional networking and collaborations among scientists, laboratories, and research institutions and among different sectors;
- Create mechanisms for sharing information on life science research programs and findings, and promote transparency and openness in research programs and activities; and
- Provide tools and support that can be tailored to help countries develop or strengthen research policies and strategies and related laws, according to their needs and priorities.

The regional workshop also generated recommendations to individual countries for further action:

- Develop, implement, and monitor regulation, legislation, guidelines, and standard operating procedures for laboratory biosafety, for laboratory biosecurity, and for assessing and managing the risks of DURC;
- Develop tools in line with international guidelines and standards that are built on existing regulations for laboratory safety and security, accreditation, etc; adequately funded and monitored; consistent with national research policies; and applied across all agencies involved in life science research;
- Provide adequate financial resources to develop and maintain laboratory infrastructure, fund research activities, and strengthen human resources for research, including training programs in laboratory biosafety, laboratory biosecurity, and management of the risks of life science DUR;
- Raise awareness among all stakeholders at the country level and bring the implications of life science DUR for public health to the attention of international forums, including the World Health Assembly, for appropriate action; and
- Promote information exchange and laboratory networks, and foster dialogue among stakeholders in different sectors and agencies at the country level (e.g., agriculture, industry, environment, and defense).

Dr. Cosivi concluded by stating the need to provide a tool with different risk management options so that each country can develop the appropriate mix of policies. Collaboration at international and national levels is extremely important, and safeguarding public health is of utmost importance.

Question & Answer Session

While there should be greater science literacy in the U.S. population, Dr. Cosivi encountered a good understanding of the issues and challenges to public health when planning the Thailand regional workshop. Public health professionals apparently understand the relevant issues as do the countries in the Asian-Pacific region; one country has already asked for support as it currently addresses these questions.

Once a standard has been established, Dr. Cosivi explained that training materials could be added to educate and inform about the issues and about how to use the guidelines to develop a framework at a national level. Tools for information dissemination and awareness raising could also be added. The structure of the WHO lends itself to a regional approach; the WHO provides information regionally and then the attending country representatives return home to develop national policy, plans, and activities.

Public Comment

Carrie Wolinetz, Ph.D., Federation of American Societies for Experimental Biology (FASEB), encouraged having a stakeholder input opportunity at the April 2008 NSABB meeting while the USG is still formulating its policies. She expressed concerns about the policy formation process moving forward without adequate stakeholder input.

Day One Adjournment

Dr. Keim adjourned this first day of the NSABB meeting at 5:00 p.m.

February 28

Call to Order

As acting chair of the NSABB on behalf of Dr. Kasper, Dr. Keim called to order the second day of the February 2008 meeting of the NSABB at 8:30 a.m. The focus of this day was on outreach and education.

Review of the Charge of the Working Group on Outreach and Education

Dr. Keim noted that the NSABB had made a number of recommendations regarding outreach and education in its oversight report. These included:

- The NSABB should play a continuing advisory role in outreach and education strategies for stakeholder groups, message formulation, development of training curricula mapped to federal policy, and development of tools to convey educational content;
- Educational efforts regarding DUR should have a broad reach; in addition to the domestic academic scientific community, these efforts should include pre-collegiate studies, commercial context, and international audiences;
- DUR should be routinely included in NIH-mandated ethics training;
- Scientific associations and professional societies have an important role to play; and
- The federal government should stimulate development of private-sector training initiatives.

Toward that end, the NSABB established a Working Group on Outreach and Education (WGOE).

At this juncture, Dr. Keim turned the meeting over to Michael Imperiale, Ph.D., chair of the WGOE. Dr. Imperiale introduced the WG members and then reviewed the four-fold charge:

- **Message development** – What are the key points to convey to different stakeholder communities with respect to the nature and importance of the DUR issue?
- **Audiences for outreach and education** – Who are the key audiences for outreach and education efforts? How do the levels of understanding, and thus educational needs, vary for each audience? What kind of input can be sought from various constituencies?
- **Vehicles for information dissemination** – By what means can information regarding DUR be credibly conveyed for the purpose of enhancing awareness of the issue, as well as for developing an appreciation for its import?
- **Solicitation of public comment and assuring public acceptance** – What are the most effective mechanisms for soliciting public input into emerging Federal policies? How can stakeholder acceptance be promoted?

Dr. Imperiale then introduced Allan Shipp, Director of Outreach and Education, Office of Biotechnology Activities, National Institutes of Health (OBA) who addressed OBA's ongoing outreach and education efforts on dual use research.

Outreach and Education Activities on Dual Use Research: Keeping the Community Apprised of Developing Federal Policies

Mr. Shipp summarized the efforts of the OBA regarding outreach and education activities on DUR. Short-term outreach and education goals have focused on raising awareness of DUR issues, apprising the research community on the status of federal policymaking, and promoting input from stakeholders on the NSABB work products and federal policies. Long-term outreach and education goals are to educate about specific federal requirements that emerge from the policymaking process and to sustain awareness and a culture of responsibility.

Consistent with the charge of the WGOE, the key considerations in meeting the short-term and long-term goals are identification of the target audiences and key stakeholders, how their educational needs vary, and how input can best be sought from each; message development for different stakeholder communities; the most effective means for information dissemination about DUR issues for each stakeholder group; and the most effective way to coordinate stakeholder commentary on evolving federal policy.

OBA has moved forward in its outreach regarding DUR issues in three primary areas: keeping the community current on federal policy formulation, ensuring stakeholder input, and engaging the international community. To date, OBA has conducted outreach using electronic tools, organizing presentations and exhibits, and disseminating print materials. The OBA Web site is the portal for information on the NSABB, including meetings and work products; an e-mail inbox is available for public queries, and OBA sends notices and updates through its listserve. (Public queries regarding the NSABB activities can be addressed to nsabb@od.nih.gov. To subscribe to the OBA listserve, a message should be sent to listserv@list.nih.gov with the words "subscribe oba_news" in the body.) More than 21 key constituency groups have received presentations about the nature of DUR issues, the origins of the NSABB, and the activities and work products of the NSABB. Mr. Shipp added that a standard slide set is available from the OBA for the NSABB members to use in their presentations. OBA has set up exhibits at major meetings, either in conjunction with a display on recombinant DNA oversight or alone as an NSABB exhibit; Mr. Shipp showed pictures of the exhibit hardware and examples of the posters and panels used with that hardware. In addition, the OBA has been disseminating FAQs and other educational materials as well as the NSABB work products. The OBA routinely incorporates DUR material into its "IBC Basics" and "Effective IBCs" courses as well as other training sessions for researchers, research administrators, institutional review boards (IRBs), institutional animal care and use committees (IACUCs), and IBCs.

The OBA has been ensuring stakeholder input into the NSABB work products – criteria, code of conduct, communication tools, and recommendations on synthetic genomics – via roundtables, focus groups, and presentations to stakeholder audiences. The international life sciences community also has been engaged on DUR issues through International Roundtables held in February 2007 and October 2007, with one more planned for 2008.

However, because awareness levels are not yet sufficient, the OBA is contemplating the development of widely accessible, multimedia products such as DVDs or Web-based products. To promote robust input into federal policy, the OBA is considering the development of regional "town hall"-type conferences that would convene stakeholders. When new federal requirements emerge, the OBA will also work on developing an array of educational tools and resources. Additional outreach opportunities include the many and diverse audiences that the OBA staff and the NSABB members could potentially reach.

Question & Answer Session

One NSABB member observed that, if an untoward "event" occurs, the media will be in the forefront of educating the public about the event and DURC in general. It was suggested that information and materials be prepared now – materials that could be available to the media within hours – to show what the NSABB has done, how oversight has been accomplished, and who is involved in oversight.

In response to a question about the origin of public queries to date, Mr. Shipp noted that the OBA receives many e-mail queries about the NSABB, mostly from the biosafety community and occasionally from investigators. Most correspondents are concerned about future requirements. Nothing currently on the OBA Web site invites public commentary, but questions and comments can nonetheless be transmitted via e-mail.

One NSABB member suggested that the poster created for exhibits be made into a poster that could be hung on the walls of academic institutions and commercial entities with the addition of appropriate contact information for the OBA and a blank line for local contact information. Such a poster already exists for recombinant DNA.

Update from NSABB Members on Presentations and Other Outreach Activities

Dr. Keim asked the NSABB members to summarize presentations they made at meetings since the last NSABB meeting in October 2007 and to discuss any feedback. The following comments were made.

Dr. Osterholm expressed reticence about outreach before the USG responds to the NSABB report and there is a formal federal oversight in place, although he agreed that it might be possible to conduct outreach on the DURC issue generally.

Mr. Nance has conducted no outreach since October and agreed with Dr. Osterholm's concern about awaiting USG policies and requirements.

Dr. Erlick is waiting to do outreach until more clarification on oversight comes from the USG. He has declined to answer questions about policy details. Many conversations have been confrontational, e.g., "What are you going to do to us?!" He expressed concern about the different messages being promulgated by each NSABB member.

Dr. Vidaver gave a presentation at the Texas A&M agriculture school to investigators, post-doctoral students, and students. She noted that awareness levels were low and that she was unable to answer many of the questions.

Dr. Enquist gave a lengthy presentation at the AAAS meeting in San Francisco; attendance was disappointing. Other NSABB members have made presentations to various classes at Princeton's Woodrow Wilson School; he noted that outreach to this group – an audience of intelligent, concerned people – is difficult without a common message. Most audiences fear that oversight will be put in place that will cause the science enterprise to be tied up in more paperwork.

In addition, Dr. Enquist is a member of the American Society for Microbiology (ASM) publication board that is responsible for 11 journals and thousands of papers published each year. The ASM put in place a method of monitoring papers, and Dr. Enquist is responsible for vetting between two and six papers each week that are marked as Select Agent papers that have been accepted for publication in an ASM journal. He expressed great concern about that responsibility and noted that consistent guidelines among journals are needed.

Dr. Sorensen noted that college presidents are seemingly ill informed on DUR issues, so outreach needs to do focus on the American academy in order to increase understanding of the risks and issues. He opined that it is premature to conduct outreach until the message is clear.

Dr. Casadevall organized a symposium at the ASM Biodefense meeting; the room was filled, and the audience listened politely, but it "didn't quite know what to make of us." A presentation to the Association of Microbiology and Immunology Chairs was greeted with blank expressions and no questions. He also spoke at the seminar at Princeton's Woodrow Wilson School. He agreed with others that it will be difficult to offer a consistent message until the final product is known, particularly when consumers of the message do not perceive a problem. He also noted significant concern among scientists about the additional paperwork that would be required by the USG as a result of DUR concerns, quoting one researcher as saying, "I hope my retirement comes before the rules arrive."

Judge Ehrlich conducted several conversations with The Biodesign Institute at Arizona State University (ASU) and gave a presentation to the ASU College of Law that included many students and professors interested in the regulatory frameworks of science. She also has scheduled a presentation at the Los Alamos National Laboratory, and she secured an invitation for an NSABB member to the Gordon Conference in August 2008, although not at the dual use sessions.

Dr. Cohen spoke at a session last October at the American Biological Safety Association (ABSA). He thanked and congratulated the OBA staff for the availability of the slides, talking points, and other materials. He noted that the products that have already been released have received much attention and that people in the biosafety community are glad to see attention being paid to DUR issues.

Dr. Roth spoke at a seminar at Princeton University's Woodrow Wilson School, was asked to testify in front of the U.S. Senate Agriculture Committee, and was asked by the American Association of Veterinary Medical Colleges to speak on Capitol Hill to staffers. In each case, he chose to talk about the need for research in zoonotic diseases that are emerging from animals into people and that threaten food-producing animals and public health, and the need for funding. He noted that he attempted to avoid talking about anything that would discourage the small number of researchers already conducting this research.

Dr. Fraser-Liggett has not made any formal presentations, but, because of the nature of her research, she often has the opportunity to broach the subject of DURC as part of a presentation or during a discussion. When DUR comes up, depending upon the audience, the subject is met either with some amount of curiosity or complete silence. None of her attempts to initiate discussion about DUR has resulted in lively, thoughtful discussion, which has been disappointing. Feedback from one graduate student who had just participated in a luncheon session in San Diego at which Dr. Fraser-Liggett had discussed DURC said that he was considering an academic research career but that he would pursue other options if he had to deal with another whole set of guidelines, regulations, and restrictions.

Dr. Levy has developed a list of journalists who want to know about antibiotic-related questions but who do not appear to be interested in the subject of DURC. He is trying to develop his own media constituency so that he will be able to teach the public when the time is right. He gave a talk at MIT with members of the biosafety community but has not yet made any public presentations.

Dr. Keim has made eight or nine presentations. Many of the audiences, when primarily composed of biodefense and biosecurity individuals, have engaged deeply in the issues. He noted that these individuals are used to having their research regulated. One of the goals for these audiences is informational – ensuring they know that the NSABB has recommendation (not legislative) authority. He has been attempting to get feedback from the scientific community by using two approaches – his personal story about his involvement in the October 2001 anthrax attacks and the message that, "if you don't engage, you will get regulated." He noted that most scientists do not know what is going on in Washington, D.C. and that policymakers are deciding their future.

Dr. Imperiale has mainly been involved in interactions with graduate students and post-doctoral students. He gave a seminar at the University of Michigan and had lunch with the students; they were very interested in the NSABB, so he took the opportunity to educate them about DUR and related issues. This is the third year in a row he has been talking to graduate students at the University of Michigan, and each year there is no increase in the number of students who have heard of DUR. However, it has been reported to Dr. Imperiale that this topic gets the most discussion in the seminar and that students like to be engaged in this topic. In addition, Dr. Imperiale was on a National Academies committee that was examining the broader issues of science and security; the report came out in Fall 2007, and he was involved in a briefing to the U.S. House of Representatives Science Committee. Although biosecurity issues were only a small part of that report, the House Science Committee was particularly interested in biosecurity issues, showing an awareness and interest on Capitol Hill about this issue.

Followup on Policy Process Discussion

Dr. Patterson discussed the policy development process underway in response to the NSABB's report on synthetic genomics. There are interagency "taskings" that correspond to each of the recommendations from the NSABB involving multiple USG Agencies. She assured the NSABB members that there would be ample public consultation during the policy promulgation process that will unfold during the next several months.

She specifically explained the process by which the federal government is responding to the NSABB's recommendation that the biosafety guidelines be revised. The OBA has been working with the RAC and several expert *ad hoc* members, including people who participated in the synthetic biology symposium held in October 2007. Draft language has been developed that will be discussed at the public meeting of the RAC in March 2008. The RAC will vote on that draft language, which is likely to be tweaked further. It will then be published in the *Federal Register* for public comment, accompanied by a set of questions on some of the more nuanced issues that the RAC's Biosafety Working Group believes need further discussion. The OBA will be hosting a series of public meetings and roundtable discussions with stakeholder communities, including IBCs and investigators, throughout Spring and Summer 2008. Proposed language will be brought back to the RAC in Fall 2008 to be recommended to the NIH Director for incorporation into the *NIH Guidelines*.

Selected Perspectives from the Research Community Regarding Outreach on Dual Use Research

For this segment of the meeting, representatives from diverse stakeholder groups were invited to give brief remarks in response to four specific questions related to the task and challenge of conducting outreach and education on dual use research. These questions were:

- What is the nature and size of the constituency that your organization represents, e.g., number of members, principal professional activities of members?

- What is the level of awareness among your membership with respect to the issue of dual use research of concern, e.g., most members are keenly aware and the topic is on the agenda of annual meetings or few members have any cognizance of the issue? How have you assessed that awareness?

- To the extent your members are aware of the issue of dual use research, what is their perception of it, e.g., that it is of pressing concern and national importance or that it is of uncertain consequence? Similarly, how have you assessed these perceptions?

- What mechanisms of outreach would be particularly effective (or not especially effective) with your membership for soliciting their views on federal policies under development? For education and awareness-building purposes? E.g., Web-based modules, presentations at annual meetings, government-sponsored roundtables, society-initiated professional development activities.

American Bar Association (ABA) – Science & Technology Law Section, Gilbert Whittemore, J.D., Chair

Mr. Whittemore explained that lawyers spend a great deal of time educating their clients about various issues. As such, they can assist in education about DUR, including educating their clients as is relevant regarding potential risks of DUR. Focused input can occur with lawyers who know a great deal about DUR, although currently that number is not large. Although there is a small group of lawyers whose clients have asked them to keep abreast of these issues, the level of awareness of DUR issues among lawyers is approximately the same as the awareness level of the general population.

The ABA has approximately 400,000 members; it is a voluntary association to which not all U.S. lawyers belong. Within the ABA, there are specialty sections that lawyers can join; the Science & Technology Law Section has approximately 12,000 members. Within that section are various committees and divisions that would be interested in the work of the NSABB, e.g., the committees on biotechnology, on public health, on homeland security, and on the rights and responsibilities of scientists.

One of the main tasks of the ABA is to provide continuing education for its members, which means there is already in place a large institutional framework that produces periodicals and books, has an increasing online presence with live programs and teleconferences, and has increasing online communication capabilities in the form of specialized listserves and developing focused input.

American Biological Safety Association (ABSA); Janet S. Peterson, RBP, CBSP, University of Maryland -- College Park

Ms. Peterson explained that the ABSA was founded in 1984 to serve the needs of biosafety professionals. Its mission is to promote the safe use of biological agents through expanding awareness of biological safety. With a current membership of approximately 1,600 and a full-time staff of five, ABSA provides professional development training to the biosafety community, an important function because there exist few formal training programs in biosafety for biosafety professionals. ABSA membership has almost tripled in the past 15 years, and attendance at the annual conference has increased accordingly with a spike in membership since the events of 9/11 and the subsequent letters containing anthrax spores that were sent through the U.S. mail. A presentation describing the NSABB oversight strategy was offered at the 2007 ABSA conference, thus introducing the issue to all attendees.

The ABSA believes that its members possess varying degrees of awareness with respect to DURC. Members whose role at their institution includes IBC-related responsibilities are more aware than members who do not have this role, and ABSA members affiliated with institutions participating in the Regional Centers of Excellence initiative are more likely to have greater awareness of the DURC issue than others. The ABSA members' perception of the importance of DURC is highly variable, but no formal survey of the membership has been conducted on this issue.

The ABSA believes that biosafety officers and IBCs need to be keenly aware of DURC issues. Although this responsibility has not as yet been assigned to IBCs, the ABSA believes that the proposed framework of local oversight, similar to that required by the *NIH Guidelines*, is an appropriate model. Effective outreach methods for biosafety professionals would include presentations at the annual ABSA conference as well as participation in pre-conference courses. Web-based modules would reach those who are unable to travel to conferences.

The ABSA believes that principal investigators constitute the primary audience for DURC education. Training materials and other tools such as points-to-consider documents based on Appendix M in the current *NIH Guidelines* would be essential to each individual investigator as well as to local IBCs. Development by the NSABB or by the OBA of educational resources in biosecurity issues that could be adopted and adapted at the local level would also be greatly appreciated by the ABSA members. Currently, biosafety officers educate investigators about recombinant DNA and Select Agent requirements, so it would be useful to have tools for discussing DURC issues at the same time.

American Phytopathological Society (APS); Ray D. Martyn, Ph.D., president

Dr. Martyn explained that the core purpose of the APS is to strengthen the science and practice of plant pathology. As the second oldest plant pathology society in the world, the APS will celebrate its 100th anniversary this summer at its centennial meeting in Minneapolis. Of the approximately 5,000 members, one-third are from outside the United States. APS members come from many different employment areas, but most are from academic institutions, state and national agencies, and industry.

DUR is a topic of great concern to the APS. Much of the research conducted by plant pathologists is directed at understanding the underlying mechanisms of pathogenesis, virulence, host resistance, and epidemiology, which are critical to disease management and the ability to respond to and recover from a plant disease event. Some of the research in some of these areas might fall into the dual use category, and research into the deployment of beneficial organisms to manage harmful organisms ("biological control") could lend itself to dual use. Plant pathogens have the potential to be used as biological weapons, although such a weapon would be difficult to construct and would likely cause limited direct

impact. However, the APS acknowledges that some public research intended to help control plant diseases might be useful to those wishing to cause harm.

Most plant pathologists are aware of the dual use potential of research, but there exists great concern among APS members about the possibility of censorship of research with regard to oversight. The APS opposes any policy that might impede legitimate research into the basic understanding of plant diseases or the application of information or technology for the prevention and control of plant diseases. The APS also opposes any policy that would severely impede or unduly restrict the legitimate exchange of germ plasm among scientists for purposes of conducting research to prevent or control plant diseases.

The APS has actively participated in and promoted dialogue about DUR and scientific censorship, including participation in the workshop on Scientific Openness and National Security (the precursor of the NSABB) and participation in reviewing the NSABB proposal on DUR. APS members serve on the NSABB.

Regarding publication policies, the APS's members are obligated to discourage any use of plant pathology contrary to the welfare of humankind, including the use of plant pathogens as biological weapons. Reviewers and editors of the APS journals are required to report any suspected misuse of information to the senior editors or the editors in chief, which could result in a rejection to publish. Additionally, the authors must self-select on a manuscript submission form if, in their opinion, anything in the manuscript might constitute DUR.

To expand knowledge and information related to DUR, successful outreach avenues should include Web-based solicitation of comments, jointly sponsored workshops and symposia, publication of white papers, symposia at national meetings, and blogs. Another avenue that might be effective is communication with the new One Health-One Medicine Initiative, which is an effort to unite the human pathology, animal pathology, and plant pathology communities.

American Society for Microbiology (ASM); Ronald Atlas, Ph.D., cochair, Biodefense Committee

Dr. Atlas explained that the ASM is the largest life sciences organization in the world with more than 42,000 members, about one-third of whom are from outside the United States. ASM members are involved in research in a number of areas that aim to find cures for infectious diseases. Many ASM members are well aware of DUR issues and have been at the forefront of DUR discussions, participating in national and international forums on DUR, bioterrorism, and related issues. Although the ASM has not assessed its members' perceptions of DUR issues, the views are likely varied – ranging from "it is a non-issue" to "it is a serious issue that requires government intervention to protect society."

The ASM code of ethics alerts its membership to what broadly could be considered DUR issues, although the term "dual use" is not utilized. Editors of the ASM publications are aware of DUR issues and take those issues into account when reviewing manuscripts. As a result of hosting a 2003 conference, the ASM released a statement that charged the world's publishers with helping to protect humankind from the misuse of science. The ASM sponsors a number of large annual meetings that have provided symposiums and forums for discussion of DUR issues and other issues of biodefense-related research. The Public and Scientific Affairs Board meets annually and has discussed policy regarding this topic.

The ASM members are most likely to pay attention to DUR issues when a proposed federal framework is published in the *Federal Register*, which will trigger serious debate about these issues and formal comment by members and the ASM governing board. Publication in the *Federal Register* will result in the ASM's 42,000 members being made aware of the proposed framework through the organization's electronic alerts and by posts on the ASM Web site. The ASM's monthly journal has highlighted and will continue to highlight DUR issues. While the ASM does allow government bodies and boards like the NSABB to participate in annual meetings, it is difficult to get on the program; therefore, Dr. Atlas suggested that a booth in the exhibition area may be the best way to outreach to the microbiology community.

Association of American Medical Colleges (AAMC); Stephen Heinig, Senior Policy Fellow

Mr. Heinig explained that the AAMC, founded in 1876, currently represents 129 accredited U.S. and 17 Canadian medical schools, 400 affiliated teaching hospitals and health systems, and 94 academic societies. Institutional (but not individual) members participate through the councils and the organizations, and professional development groups. The governance consists of deans of medical schools, the academic societies who voluntarily participate, and CEOs of various teaching hospitals. The AAMC member institutions perform approximately 60 percent of all NIH extramural research.

The AAMC's Group on Research Advancement and Development (GRAND) is a professional development group for research deans and deans of clinical research that provides a national forum for the promotion, support, development, and conduct of biomedical research in medical schools and teaching hospitals. GRAND fosters exchange of information and analysis of issues critical to the research enterprise. Its next national meeting will be on April 17 and 18, 2008, in Bethesda, Maryland.

Mr. Heinig conducted a survey of GRAND members. A total of 14 initial responses out of approximately 100 possible responses indicated that the level of awareness of DUR issues is uniformly estimated as "low," with exceptions for disciplines like virology and for institutions with high containment biosafety laboratories. While the deans report that each institution's investigators are aware of these issues, those investigators do not believe that the DUR discussions currently ongoing will affect them. Respondents stated that the most effective mechanisms for disseminating information about federal policies is through national meetings, institutional visits, and roundtables; for providing education and awareness building, respondents overwhelmingly supported Web-based modules because of the flexibility afforded by this method.

Additional observations from the AAMC survey indicated a strong preference for educational and outreach programs as opposed to regulation or other rulemaking, in part because of the already large amount of time spent by investigators on administration (one federal demonstration project reported an average of 42 percent of investigators' time). Other suggestions and feedback from the survey of research deans stated that education must be topical and focus on good research practices. While society meetings that reach out to faculty were thought most likely to have an impact, others suggested reaching out to university compliance offices with clear and logical rules backed by a defined process.

Association of American Universities (AAU); Patrick White, Vice President for Federal Relations

Mr. White stated that the AAU and the presidents and chancellors it represents are deeply concerned about DUR issues. The AAU is composed of the 60 leading U.S. research universities; the principal constituencies are the presidents and chancellors of these institutions. The AAU's April 2008 membership meeting will feature breakout sessions on DUR issues, one of which is entitled "Science and Security Challenges in the Post-September 11 World." This session will discuss the new rules and regulations pertaining to Select Agents and the inventorying and monitoring of certain chemicals on campuses.

Another constituency of the AAU is senior research officers, who are tasked with administering research on member campuses. An annual meeting of research vice presidents and vice chancellors is held each year, and the AAU surveys them extensively. Much of their conversation, formally and informally, focuses on best practices and how to handle the challenges of administering research. The recently released Gansler/Gast Report, chaired by leaders in the AAU's research vice presidents group, highlighted two relevant recommendations: Recommendation 12 suggests that a deliberative standing entity should be established to address the ongoing and shared concerns of the security and academic research communities, and Recommendation 13 suggests that university leadership at the level of senior vice president of research must educate administrators, faculties, and students about security, export control, Select Agents, and other relevant policies and procedures, and must ensure compliance.

For AAU members, the most effective way to approach compliance with policy and procedures issues is through education; an example would be to follow the method used to educate faculty members about the rules and regulations regarding human subject protections. There exists deep concern that poorly constructed new regulatory efforts could lead to a significant additional effort and cost burden without adequately addressing the safety and security issues.

Federation of American Societies for Experimental Biology (FASEB); Carrie Wolinetz, Ph.D., Director of Communications

Dr. Wolinetz explained that the FASEB is a coalition of 21 scientific societies representing approximately 80,000 biomedical researchers. The FASEB societies range in size from large – such as the American Society for Biochemistry and Molecular Biology or the American Physiological Society – to small – such as the International Society for Computational Biology or the Association for Biomolecular Resource Facilities. The FASEB societies are often thought of as representing the R01-funded basic science investigators, but recently its membership has diversified, and FASEB now represents many clinical researchers and an increasingly large international membership. Although FASEB retains some of the vestiges of its origins as a traditional scientific society, such as publishing a journal and organizing scientific meetings, the main mission of the organization is dedicated currently to research advocacy on behalf of bench scientists.

A FASEB survey of its member societies' leadership showed that only one FASEB society, the American Association for Immunologists (AAI), has a committee related to DUR; the AAI also is the only FASEB society that has a journal article review process for DUR. The other member societies rate DUR issues as being of low priority, not something about which they are hearing from members, and having a low level of awareness.

Regarding public relations problems that the NSABB will need to overcome, Dr. Wolinetz highlighted two concerns: a negative knee-jerk reaction about "yet another compliance issue and another regulatory burden" and political-related concern about government interference in science from a federal executive branch that is not viewed as friendly to science and that is trying to impose unnecessary security regulations. At present, the interplay between federal research funding and regulatory burden is a frequently discussed topic in the scientific community; therefore, any proposal that hints of regulation, oversight, or additional requirements or compliance issues will likely be quite unpopular. DUR issues have not yet been seen among the FASEB community as a research responsibility issue.

Persuading attendees at traditional scientific meetings to attend policy sessions continues to be challenging, and encouraging attendance at a policy session about DUR, which is perceived as an obscure and irrelevant issue by most, will be even more challenging. More popular, and potentially more successful, methods of disseminating information are via newsletter articles, Web modules, USG-sponsored roundtables, and regional meetings. Dr. Wolinetz also suggested working with and following the model of groups like Public Responsibility in Medicine and Research (PRIM&R) to develop "Dual Use 101" sessions for IACUCs, IRBs, IBCs, and PIs.

National Association of State Universities and Land Grant Colleges (NASULGC)**; Bruce A. McPheron, Ph.D., Associate Dean for Research and Graduate Education in the College of Agricultural Sciences, Pennsylvania State University**

Dr. McPheron explained that the NASULGC is composed of 218 member institutions, 76 of which are land grant universities, including 18 historically African-American institutions and 33 institutions serving American Indians. He focused his presentation on the colleges of agriculture within the land grant university system, which are a constituent group of NASULGC. Life sciences are at the core of colleges of agriculture, and between one-third and one-half of the colleges of agriculture at land grant universities administer most of the biological sciences on their campuses, thus providing an administrative structure for potential outreach at these universities.

In terms of awareness of DUR issues, the Agriculture Experiment Station directors – the gatekeepers into the faculty and activities in agriculture – have been discussing DUR-related topics each year at their annual meeting since 2001, although primarily imbedded within discussions of general research priorities. Discussion has been less active as time has passed since September 11, 2001. In addition, the DUR concept is embedded in annual discussions of research priorities communicated to the U.S. Department of Agriculture and to the U.S. Congress, and there have been institution-level discussions as Agriculture Experiment Station directors interact with research vice presidents. While the annual prioritization of research topics involves issues of biosecurity, DUR has not been a topic of continuing discussion in the past five years. The National Institute of Agricultural Security, a 501(c)(3) organization founded in 2002 and to which most of the land grant colleges of agriculture belong, has waned substantially because it did not fit the needs of the member institutions.

Regarding outreach, the first step is for the NSABB to provide a realistic risk assessment of the problem and where it fits on the scale of issues of significant concern. The NASULGC scientists are worried daily about the issues of invasive species and protecting the food and fiber systems. Once it is apparent that policies are needed, clear communications and recommendations should be the next step. Specific steps to achieve clarity would be a well-designed Web presence and a sharing of best practices that include actual situations and solutions as well as scenarios that illustrate situations and solutions.

Agriculture research administrators have annual and regional meetings several times a year, which present an opportunity for outreach to people who would then carry messages and work with the rest of the university research community. Regarding outreach to the public, Dr. McPheron noted that a key opportunity for public education on DUR issues is students – graduate students doing research and undergraduates. Reaching out to these students will inform a new generation of decision-makers, and will also lift science literacy and the intersection of science and policy in the United States.

Question & Answer Session

Dr. Levy summarized two themes from all the speakers as an inadequate understanding of the DURC term and a fear that this possibility will lead to regulation that will impede science.

Dr. Peterson noted concern about whether the NSABB will have regulations that will be similar to the recombinant DNA guidelines, which are not viewed as an impediment to research, or if those guidelines will be more like the Select Agent regulations, which might slow or impede research. There is current uncertainty about the direction of the coming regulations. She also noted the importance of distinguishing between DUR and DURC so that the scientific community understands that not all research will be "of concern."

Dr. Wolinetz noted the diversity of views regarding the definition of DUR and its potential impact, whether this sort of oversight is necessary, and whether it would reduce risk. Answers to these concerns will need to be made clear in order to gain acceptance in the scientific community for taking on another oversight system or set of guidelines.

Dr. Levy suggested that outreach efforts might begin defining "of concern" by showcasing the seven examples from the *Fink Report*, as extreme and clearly obvious DUR issues.

Dr. Osterholm queried whether the presenters' members perceive a benefit from the coming DURC regulations as representing the only way to keep science from experiencing a severe setback or whether members perceive DUR oversight as merely overregulation. Dr. Wolinetz responded that people working with Select Agents share the perspective that DUR is a real issue that needs to be addressed; however, the remainder of the scientific community does not see a problem, does not see its relevance to their research, and does not perceive public pressure to do anything about DUR. Dr. Martyn responded that his constituents are more worried about negative events that could happen easily with current existing knowledge; for example, they are worried about how to respond to and recover from natural events.

Dr. McPheron responded that additional regulatory burden is a significant concern, but a falling lack of confidence in science is also a concern, so any oversight plan should attempt to balance these concerns and try to avoid a catastrophe that would critically damage scientists' credibility.

Mr. White likened this discussion to what has been done to U.S. air travel in that most people do not believe that the security rituals at airports will prevent adverse events. Paraphrasing the responses he has heard from his colleagues, Mr. White said, "The 'bad guys' are winning if we are shutting down the free exchange of research and knowledge. The real penalty we are all wrestling with is the impact of terrorism and the incalculably small risk but high impact events, which we might just have to live with in order to remain a free and open society."

Agreeing that plant pathologists live with the knowledge of the possibility of low-probability/high-consequence events as part of their research, Dr. Martyn clarified that the value of regulation is to help minimize the possibility of escape. However, he noted that there has been no documented case in plant pathology in which an escape of a pathogen has been blamed on a research scientist, because plant pathologists take their safeguarding role seriously.

Public Comment

Members of the public were given the opportunity to comment but offered none.

Effective Educational Tools and Vehicles for Information Dissemination: Perspectives and Experience from the Private Sector

Making a Compelling Case about Dual Use Research to the Scientific Community at Large
Presenters: Mark Frankel, Ph.D., Director, Scientific Freedom Responsibility and Law Program, American Association for the Advancement of Science (AAAS), and Kavita Berger, Ph.D., Center for Science Technology and Security Policy, AAAS

Dr. Frankel stated that various social institutions in the scientific community play important roles in shaping the behavior of individuals connected with them. These organizations serve as a normative reference point for individual researchers, who take their cues from these organizations; therefore, it is important to have an understanding of the values, culture, and standards of these institutions in order to help explain individual behavior. The target audience for the NSABB outreach and education is the scientific community, defined more broadly than just the life science community and including individuals as well as social institutions. The challenge is how to frame the DUR issue in ways that convey its importance, secure acceptance, and promote the desired behavior in the scientific community.

Guidelines for framing the DUR issue successfully include linking it to something with which the audience is already familiar, having the message come from an authoritative and respected source, and casting the message in language that resonates positively for the recipients. Some suggested cues to use in discussions of DUR that are likely to resonate positively with members of the scientific community:

- Include the critical role of science and technology in matters of national security; this has been done since World War II, and scientists have been involved in policy discussions and research related to national security.
- Stress the leadership and ingenuity of the scientific community in national issues, noting that here is something they can contribute.
- Cast the discussion in terms of professional responsibility and accountability, which most scientists will embrace. Self-regulation depends on this.
- Connect the discussion of DUR with other categories with which scientists are familiar, such as responsible conduct in research (research ethics issues), laboratory safety, and IBCs. In this way, DUR will be cast as an extension of what scientists have been doing for years.

Dr. Frankel then discussed the task of educating the scientific community. In his opinion, the NSABB must decide whether it stands on the side of education for compliance or education for a broader understanding of the ethical issues as that stance will frame the structure of the education process. Some people in the scientific community are interested only in compliance and therefore doing the bare minimum; education to achieve that goal consists merely of making sure that everyone knows the facts, the rules, and their obligations under the rules. However, rules and procedures only go so far, and, ideally, scientists should act properly because it is the right thing to do, not because they are being regulated to do so.

The proposed Oversight Framework report uses the phrase "educating broadly" and refers to the associated tenets of responsible research, which fosters a discussion of "principles." Sections of the report address best practices and identifying and overseeing DUR, foster discussions of norms, expectations, and how to resolve difficult and unclear situations. Dr. Frankel expressed his concern that that message may not be made clearly enough within the proposed framework, and suggested that any major educational activity should be launched only after careful consideration of how to get this message across.

Dr. Frankel discussed several ongoing activities at the AAAS. A survey was conducted, in partnership with the National Academies, to understand scientists' attitudes toward education and oversight. Although still being analyzed, the data collected from this study could be useful to the NSABB in framing its DUR messages; the study's results will be made public in April or May 2008. A second study attempts to discover activities at various educational institutions in biosecurity, education, and ethics – responsible biosecurity research. This extensive survey was launched in late January 2008; the hope is that it will generate enough data to help the AAAS make recommendations about what is needed in this area. The AAAS also has produced a series of videos on research ethics that have been available since 1995, and have been used in hundreds of universities throughout the United States and abroad. In addition, the AAAS, along with co-sponsors, developed several practical tutorials on research misconduct presented in 1997 and 2001. Focusing on the misconduct issues of fraud, fabrication, and plagiarism, the purpose of these tutorials was to ensure that the university research community understood their obligations under the research misconduct rules.

Question & Answer Session

Noting that at least 50 percent of the attendees at the practical tutorials were universities that did not want the negative publicity that occurred at, for example, MIT and the University of Pittsburgh, Dr. Frankel stated that opportunities would likely be available for the NSABB to reach organizations that may not see DUR as being as much of a problem as do others. He suggested collaborations between universities and scientific societies because both organizations have normative influence on the individual researcher.

SERCEB Experience in Educating the Investigator Community about Dual Use Research

Presenters: Robert Cook-Deegan, M.D., Principal Investigator, Policy, Ethics, and Law (PEL) Core, Southeast Regional Center for Excellence for Emerging Infections and Biodefense, and Allison Chamberlain, M.S., Senior Program Coordinator

Dr. Cook-Deegan explained that the SERCEB is one of ten regional centers created with the first bolus of National Institute of Allergy and Infectious Diseases (NIAID) funding of biodefense research after the anthrax attacks of October 2001. SERCEB has three private and three public main member universities – Emory University, Vanderbilt University, Duke University, University of North Carolina, University of Alabama at Birmingham, and University of Florida. A steering committee is composed of one member from each of the member universities; approximately 20 other institutions are affiliated with SERCEB.

SERCEB's PEL dual use educational module was developed as a tool to teach scientists (Principal Investigators [PIs], post-doctoral students, laboratory technicians, and graduate students) about biosecurity and the dual-use dilemma, targeting existing investigators and new investigators entering the field. Launched in 2005, it has had more than 650 users. The module walks user through a scenario in which DUR concerns are identified when a Ph.D. candidate ("Ann Lee") attempts to submit her thesis work for publication; the user is then provided with background information on the legal, ethical, and

policy implications that affect "Ann's" work. The goal of the module is to help people create a useful conceptual structure, and the learning objectives are to identify ethical problems that scientists and laboratory workers may encounter, describe principles and strategies to use in dealing with such problems, analyze how biosecurity and bioterrorism relate to the biological sciences, describe new policies affecting bioscience, and address practical and complicated questions affecting scientists.

The most striking finding from a 2007 survey of the module's use by SERCEB members was the variability in assessment of DUR risk in researchers' own work. In one case, two co-PIs had diametrically opposite assessments of whether their work created DUR risks of concern, and, in several instances, different members of the same laboratory had differing feelings about the weight and importance of the DUR debate and its relevance to their laboratory's work. When asked what related issues interviewees would be most interested in learning about, a majority expressed interest in international topics – rules and regulations impacting foreign researchers in the United States or impacting collaborations between U.S. and foreign scientists. Revisions to the module will be made in Spring 2008, and the revised module is expected to be released in Summer 2008.

Ms. Chamberlain discussed the DUR educational panel held on October 31, 2006, and another panel being planned for Fall 2008 at Emory University. The October 2006 panel was planned in collaboration with Duke University's Responsible Conduct of Research program for graduate and post-doctoral students. Of the 59 attendees, 55 completed a survey at the end of class that indicated that the most helpful information learned from the panel was awareness of the DUR issue, that the diversity of panelists and small group discussions led by panelists was effective, and that having well-respected scientists and institutional officials participate helped raise the importance of the DUR topic. A second DUR educational panel is planned to take place at Emory in Fall 2008, with a similar structure to the Duke panel. Preliminary acceptance from three Emory departments has already occurred: the Graduate Division of Biology and Biomedical Sciences, the Emory Ethics Center, and the Emory Science and Society Program.

Other educational activities include four opportunities for international dialogue in South Africa, Poland, Japan, and Hungary; participation in Emory's BSL-3 training program by leading sessions on biosecurity and DUR; creation of a downloadable DUR education packet that is posted on the SERCEB PEL Web site; assisting colleagues with DUR review and education; and working in an advisory capacity to University of California at Berkeley, University of Maryland, and Northwestern University, who are producing a Web portal about DUR to which scientists can submit proposals and get feedback from other scientists about their proposals.

Question & Answer Session

Dr. Cook-Deegan described an encounter with a colleague who was heading the International Genetically Engineered Machine competition (iGEM) team from Duke. One of the two projects involved a microorganism that should have gone through the IBC but had not because it did not involve rDNA. This was an example of a biological experiment that was not – but should have been – captured for review. A similar situation could occur even with clear DURC guidelines, as the technology is evolving quickly. He also noted that some of the more distressing DUR situations would not have been captured by the seven *Fink Report* categories because they were coming from new engineering delivery mechanisms that did not involve much biology.

FAS Educational Efforts Related to Dual Use Research: Web-Based Tools, Case Studies, and More

Presenter: Michael Stebbins, Ph.D., Director of Biology Policy, Federation of American Scientists

Dr. Stebbins explained that the FAS was started approximately 60 years ago by scientists from the Manhattan Project to promote the responsible use of science. These scientists recognized that science had become central to many key public policy questions, and they believed that scientists had a unique responsibility to warn the public and policy leaders of potential dangers from scientific and technical advances and to show how good policy could increase the benefits of new scientific knowledge. DURC is an issue that fits naturally with the core mission of the FAS, which has expanded dramatically in the years since its founding. Dr. Stebbins discussed current FAS activities and its plans for future activities.

The FAS has developed eight learning modules that feature DUR education case studies that are computer-based, include multimedia presentations, and use real case scenarios; Dr. Stebbins spotlighted one of these modules during his presentation. Each module is approximately 20 minutes long and includes a history of the work, why the work is being done, and a description of the experiments; the implication of DUR aspects of the work; and a discussion section in which students are encouraged to talk about the experiments and the DUR concerns involved. A survey of users of these modules found that 92 percent of respondents, one-third of whom were from outside the United States, thought that DUR education should be mandatory and should be taught to graduate students in ethics courses. The FAS hopes to expand the use of and linkages to these modules so that they can become a community resource.

Noting that no method exists to report serious concerns to law enforcement and that awareness is being raised without guidance on what to do when a concern arises, Dr. Stebbins described a survey developed by the FAS in collaboration with the AAAS to examine how scientists view law enforcement. Prior to the survey, the anecdotal evidence was that scientists do not trust law enforcement, a situation viewed as hampering outreach activities for the Federal Bureau of Investigation (FBI). The FAS-designed and FBI-funded survey was administered to the scientific community with the assurance that the data would be released publicly regardless of the results. The purpose of this survey was to create training materials for FBI field agents to reduce the incidences of negative interaction between FBI agents and scientists. While full analysis remains ongoing, initial results of this survey included:

- Eighty-seven percent of respondents would be happy to talk with someone from the public who got in touch with them, but the great majority of respondents would not be happy to talk to law enforcement about their work.
- If law enforcement was talking with them, many respondents feared that their personal e-mails might be read, that they would be asked to monitor colleagues' activities, or that their research would be misinterpreted as a public safety risk.
- An unhealthy level of paranoia exists in the scientific community, as does a misunderstanding of why law enforcement might contact them.
- Sixty-two percent of respondents expressed a willingness to be contacted about more issues having to do with law enforcement.

Believing that a scalable infrastructure is needed to coordinate DUR awareness and other biosecurity issues, the FAS began developing such an infrastructure through its biosecurity education portal but encountered difficulty getting others involved because it was perceived as an FAS initiative. Therefore, the FAS decided to launch a virtual biosecurity center in partnership with other organizations, which at present include the National Academies, the AAAS, and the Center for Strategic and International Studies (CSIS). This community resource will communicate biosecurity efforts as a "one-stop shopping" site for biosecurity information, built by the FAS but managed by the community, that promotes the biosecurity-related activities of other groups. One of the planned uses for the virtual biosecurity center is to be able to grant immediate-needs funding to groups that propose small projects. Funding for this virtual biosecurity center will begin in June 2008, so initial organizational meetings are planned for the near future.

The FAS also operates the District of Columbia Biosecurity Listserv; anyone who wants to sign up for that listserv was told to send an e-mail to Dr. Stebbins at mstebbins@fas.org.

Question & Answer Session

Dr. Stebbins noted that promoting an organization's work and understanding its target audience are equally important. As the NSABB goes forward with developing products, he suggested that the NSABB consider carefully who they are trying to reach, how they plan to reach them, and how they will promote the products. The usual promotion methods of 10 years ago do not work as well today; pamphlets and meetings are no longer an adequate promotional plan.

Dr. Osterholm expressed his support of the FAS virtual biosecurity center. Having the FAS developing a separate and independent biosecurity resource adds to the credibility of the DUR issues discussion, validating that this is not merely a policy from Washington, D.C., but a legitimate scientific concern that needs to be addressed.

Dr. Imperiale encouraged the NSABB members to look at the SERCEB and FAS sites.

Final Conclusions

Noting the impressive presentations from speakers representing a broad array of organizations, Dr. Imperiale commented on the enormity of the educational and awareness-building challenge ahead for the OEWG. One specific challenge will be how the Working Group will formulate recommendations to the USG regarding a campaign of outreach and education when formal federal policy is still under development; it will be difficult to develop a message when it is unknown what the oversight message is supposed to be.

Dr. Imperiale expressed his belief that it is nonetheless acceptable to start making people aware of the issues even if the nature of USG oversight and response to the issues is currently unknown because raising awareness is an important and useful activity. When federal requirements or guidelines emerge, they can be built into awareness-raising activities.

Next Steps. Dr. Imperiale explained that, with the information from this meeting, the OEWG will start to develop recommendations that will be brought back to the full NSABB for its consideration and adoption before transmission to the federal government.

Closing Remarks and Adjournment

Dr. Keim noted that a definite date for the next NSABB meeting, tentatively a public workshop for input on the oversight report, had not been set although originally scheduled for the end of April 2008 in order to thoroughly prepare for a meeting that could be uniquely important.

Dr. Keim requested that the NSABB members receive summarized copies of the public input that has been and is continuing to be received through the OBA Web site.

Dr. Keim thanked the members of the NSABB and the public for their insightful commentaries and adjourned the meeting at 3:20 p.m.

Date: _____

_____
Amy P. Patterson, M.D.
Executive Director, NSABB/Director, OBA

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