National Institutes of Health
Office of the Director
Office of Biotechnology Activities

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

April 19, 2007
National Institutes of Health
9000 Rockville Pike
Building 31-C, 6th Floor, Room 10
Bethesda, Maryland

MEETING MINUTES

VOTING MEMBERS PRESENT

Dennis L. Kasper, M.D., *NSABB Chair*
Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Susan A. Ehrlich, J.D.
Lynn W. Enquist, Ph.D.
Barry J. Erlick, Ph.D.
David R. Franz, D.V.M., Ph.D. **(via teleconference)**
Claire M. Fraser-Liggett, Ph.D.
Michael J. Imperiale, Ph.D.
Paul S. Keim, Ph.D.
Stanley M. Lemon, M.D. **(via teleconference)**
Stuart B. Levy, M.D.
David A. Relman, M.D. **(via teleconference)**
James A. Roth, D.V.M., Ph.D.
Harvey Rubin, M.D., Ph.D.
Thomas E. Shenk, Ph.D.
Anne Vidaver, Ph.D.

EX OFFICIOS and FEDERAL AGENCY REPRESENTATIVES (Present)

Irma E. Arispe, Ph.D., Office of Science and Technology Policy
Kay Marano Briggs, Ph.D., U.S. Geological Survey
Kenneth Cole, Ph.D., Office of the Special Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Susan Elizabeth George, Ph.D., U.S. Department of Homeland Security
Maria Y. Giovanni, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Susan D. Haseltine, Ph.D., U.S. Department of the Interior
Peter Jutro, Ph.D., U.S. Environmental Protection Agency
Sara Klucking, Ph.D., U.S. Department of Homeland Security
Lisa Lee, Ph.D. (for Janet Nicholson, Ph.D.), Center for Disease Control and Prevention
Jeffrey Miotke, U.S. Department of State
Anthony Macaluso, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Mary Mazanec, M.D., J.D., U.S. Department of Health and Human Services
Gerald Parker, Ph.D., D.V.M., U.S. Department of Health and Human Services
Caird E. Rexroad, Jr., Ph.D., U.S. Department of Agriculture

Scott Steele, Ph.D., Office of Science and Technology Policy
David G. Thomassen, Ph.D., U.S. Department of Energy

NSABB EXECUTIVE DIRECTOR

Amy P. Patterson, M.D.

Call to Order/Drs. Kasper and Patterson

Dennis L. Kasper, M.D., NSABB Chair, called to order the seventh meeting of the National Science Advisory Board for Biosecurity (NSABB). He welcomed NSABB members, federal agency representatives, and members of the public in attendance and watching via Webcast.

Amy Patterson, M.D., NSABB Executive Director, described the rules of conduct and conflict of interest considerations that apply to Board members as Special Government Employees. The rules are explained in the report, "Standards of Ethical Conduct for Employees of the Executive Branch," which was received by each member. Board members are required to recuse themselves in advance of any discussion in which they believe they have a conflict of interest.

NSABB Motion 1

The Board voted unanimously to approve the October 2006 NSABB meeting minutes that had been distributed in advance of the meeting, with the editing changes suggested by Judge Ehrlich and Dr. Vidaver that had not yet been incorporated.

Introduction and Agenda Overview

Dr. Kasper noted that this is an important juncture for the NSABB, since it is poised to propose to the U.S. Government an oversight system for dual use research and a set of recommended policies for the review and communication of dual use research. The NSABB Working Group on Oversight Framework Development worked intensively on the response to this charge, and Dr. Kasper provided an overview of the product of the Working Group (WG), described the document's features, and discussed the WG's approach.

As with all NSABB work products, soliciting stakeholder input has been essential to ensuring that the WG's proposal reflects the needs and perspectives of the stakeholder communities and that the concept proposed approach ensures an appropriate balance between reasonable constraints and scientific freedom. To do so, the WG gave its work product on scientists, research administrators, members and staff of Institutional Biosafety Committees (IBCs), and members of the public for comment. On April 4, 2007, the WG also sponsored a roundtable with a diverse group of participants reflecting these various perspectives. Underscoring the importance of public input, the WG scheduled a public comment section of the meeting prior to the Board's full deliberation. Dr. Kasper noted that Dr. Keim would be reporting on this roundtable and the public comment.

In addition, the Working Group on International Collaboration organized a roundtable that brought together individuals from 20 countries and international organizations to discuss the issue of dual use research in the life sciences. This meeting was an important event with respect to information exchange and awareness building. Dr. Kasper noted that Dr. Levy, who cochairs this WG, would be reporting on this roundtable.

Working Group on Oversight Framework Development: Presentation of Draft Framework

As Chair of the Oversight Framework Working Group, Dr. Kasper presented the formal report of that WG, which articulates proposed strategies for minimizing the potential misuse of knowledge, products, or technologies emanating from dual use life sciences research. This proposed oversight framework is the culmination of much of the NSABB's work to date, including efforts to develop criteria for identifying DURC, tools for the responsible communication of DURC, and considerations for a code of conduct for life scientists.

The WG's charge was to propose processes for local and federal review and oversight of dual use research, including identifying optimal features and characteristics of an effective and comprehensive oversight system and delineating the relevant attributes of appropriate review and oversight entities. The WG integrated the NSABB work products into a proposed framework for oversight and developed new tools and guidance as necessary. Half of the NSABB's voting members and nine *ex officio* members served on this WG.

At the WG's first meeting in July 2006, the WG members examined existing models of research oversight already in place and identified those features that might be relevant and successful for oversight of dual use research. Three extant models of research oversight were considered: recombinant DNA, which includes IBCs as a review entity; human subjects research, which includes Institutional Review Boards (IRBs) for reviewing research; and animal research, which uses Institutional Animal Care and Use Committees (IACUCs) for review of research.

The next step was to develop principles to guide the oversight of dual use research. The WG identified key features of an oversight system and then delineated the purpose, roles and responsibilities, and necessary attributes of those key features. An additional tool for use in the oversight process also was developed by this WG, one to guide the risk assessment and risk management of DURC.

The proposed oversight framework has 12 major sections. As this was the first time that the entire oversight framework was being presented to the full NSABB and to the public, Dr. Kasper described these sections in detail. The first five sections – introduction, guiding principles, key features, roles and responsibilities, and steps in local oversight – were new. The criteria and considerations for identifying dual use research of concern *(defined below)* had been presented in detail and approved by the NSABB previously. The proposed evaluation and review of research for dual use potential was new, as was the discussion of proposed strategies for outreach and education.

The Introduction

Dr. Kasper reported that the WG gave a great deal of thought to the introduction of this document in order to set the stage for the proposed oversight strategies within the document, believing that it was essential that dual use research issues be clearly described within the larger context of the vital role that life sciences research plays in the health and well-being of humanity. The introduction presents the concerns that led to the decision that oversight of dual use research — or some subset at special concern — is necessary, what is hoped to be accomplished by the oversight framework, what should *not* happen as a result of oversight measures, and why it is important for the scientific community to participate in the development of an oversight system for dual use research.

Dual use research was defined by the WG as the development of new technologies and the generation of information with the potential for malevolent as well as benevolent purposes. A subset of dual use research that has the highest potential for generating knowledge, products, or technologies that could be misused is called "dual use research of concern" (DURC).

Other key points in the introduction include:

- Life sciences research underpins advances in medicine and public health, a strong agricultural enterprise, a safe and high-quality food supply, and a healthy environment, and contributes significantly to national security and a strong economy.

- Information from legitimate life sciences research can be misapplied to create dangerous pathogens as weapons, to bypass countermeasures, to threaten in other ways the health and safety of humans, animals, plants, and the environment, or to cause harmful consequences to materiel.

- Virtually all life sciences research has dual use potential, but very little comprises DURC.

- During the past several years, concerns have increased about the possibility that new information and products from life sciences research could be subverted for malevolent purposes. The WG documented a number of those calls to actions as examples of the growing acknowledgement in the United States and elsewhere of the need to institute new biosecurity measures to minimize the risk that information from life sciences research could be misapplied.

Agreeing that the possibility of misuse of research information is real and that new biosecurity measures were warranted, Dr. Kasper explained that the U.S. Government announced a number of biosecurity initiatives in 2004, including the establishment of the NSABB, to recommend strategies for the efficient and effective oversight of federally conducted or supported dual use biological research. The NSABB was charged with proposing an oversight framework for identifying, reviewing, conducting, and communicating life sciences research with dual use potential. In doing so, the NSABB was admonished that any recommended oversight measures should not unduly burden or slow the progress of life sciences research, and indeed a major concern of the NSABB is that any oversight or other response be carefully calibrated so as not to do more harm than good to scientific endeavors.

The WG believed strongly that one of the best ways to address concerns about the potential misuse of research information and products is to raise the awareness of dual use research issues and to strengthen the culture of responsibility within the scientific community regarding dual use research. All scientists have a duty to be aware of the potential for misuse of scientific findings and of their obligation to help inform and shape critical policy decisions about biosecurity in the context of the life sciences. New approaches to security measures need to emanate from many sectors of the scientific community – journal editors, authors, researchers, national and international academies of science, and professional societies – as well as the U.S. Congress and other legislative and policymaking bodies, the federal agencies that fund and conduct life sciences research, the federal entities involved in national security, and members of the public. Participating in the development of these security measures is an opportunity to ensure that the process of scientific discovery remains open.

The WG has engaged in some public consultation regarding its oversight charge, but continued and broader dialogue with the scientific and security communities and with the public is essential to develop an oversight system that is useful, relevant, practicable, and accepted. The NSABB recommendations articulated in the oversight framework will be a useful springboard for the U.S. Government in developing and implementing a comprehensive system for responsibly identifying, conducting, reviewing, and communicating DURC. The WG continues to welcome comments on all aspects of its report and has included in the report some specific questions that should be posed during a formal solicitation of public comments to prompt further dialogue.

Guiding Principles

As a first step in proposing an oversight framework, Dr. Kasper noted that the WG identified principles that should underpin any oversight of DUR. These principles articulate the importance of life sciences research in the free and open communication of research information. The default position should be unfettered progress in the communication of science; any decision to do otherwise should be carefully

considered. The principles also acknowledge that life sciences research has the potential to produce knowledge, products, or technologies that can be misused to pose a threat to public health and safety and that it is therefore appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.

Effective oversight will help maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the potential implications of dual use research and is acting responsibly to protect public welfare and security. An oversight system must balance the need for progress with the need for security with a need for research progress, and the degree of oversight accordingly must be consistent with the likelihood and possible consequences of misuse. The foundation for oversight of dual use research is investigator awareness, peer review, and local institutional responsibility. This foundation allows input directly from the investigators, facilitates timely review of research, and demonstrates to the public that scientists are taking responsibility for their research.

The principles also state that the responsible conduct and communication of DURC depends largely on the individual scientist. No criteria or guidance document can anticipate every possible situation that might arise. Motivation, awareness of the potential for dual use, and good judgment are the keys to a responsible evaluation of research for dual use potential, and it is incumbent upon the investigators and the institutions to adhere to the intent and specifics of such guidance. Because life sciences research is dynamic and can produce unanticipated results, the research must be evaluated periodically to discern whether it is DURC.

For the oversight system to be effective, there must be a harmonious approach by different government agencies to the oversight of dual use research, broad awareness of dual use potential is needed in the scientific community and the public, and ongoing dialogues among scientific communities, government agencies, and the public must be ongoing. In addition, the oversight process itself must be evaluated periodically to assess its effectiveness and its impact on the research enterprise and on national security.

Key Features

The WG identified several key features of the proposed oversight system:

- *Federal guidelines developed by the relevant Federal agencies*. The guidelines should take into consideration the recommendations of the NSABB as well as public comments on the NSABB recommendations and on the proposed Federal guidelines. The guidelines ideally should be harmonized among agencies and periodically evaluated and amended to keep pace with developments in life sciences research.

- *Awareness and education*. Education about dual use research issues and policies will ensure that all individuals engaged in life sciences research are aware of the relevant concerns and issues and are aware of their roles and responsibilities in the oversight of such research. Education will enhance compliance, and an enhanced culture of awareness is essential to an effective system of oversight and is a critical step in scientists taking responsibility for the dual use potential of their work.

- *Evaluation and review at the local level*. Evaluation and review of research for dual use potential will demonstrate that scientists and their institutions are attending to the biosecurity implications of dual use research and facilitating the timeliness of the oversight process.

- *Risk assessment and risk management*. The degree of oversight should be commensurate with the degree of risk and the potential impact of any misuse of research information. Risk assessment and risk management should be the foundation for local oversight of DURC. Doing so will help to minimize the potential for misuse while also minimizing the negative impact on the conduct of science and facilitating the responsible conduct of life sciences research.

- *Periodic evaluation*. The WG believes evaluation should take place at both the local and federal levels. Evaluation should focus on the need for oversight, of the effectiveness of the oversight system, and of the administrative burden of the oversight system. Evaluation will promote efficient and effective governance and will facilitate the implementation of any appropriate corrections.

- *Compliance*. As the U.S. Government formalizes the oversight framework into policy and guidelines, mechanisms at the federal and local levels for ensuring compliance will need to be addressed in detail. The WG recommended that federal agencies develop consistent harmonious mechanisms for enforcement, including penalties for noncompliance. The WG recommended that compliance be made a term and condition of funding.

- *DURC beyond the life sciences*. The lines between biology and other scientific disciplines are increasingly blurred as multidisciplinary approaches address complex biological issues. Disciplines not ordinarily considered to fall within the life sciences may yield dual use biological information. Therefore, the WG recommended that the U.S. Government consider the need to apply oversight measures beyond those usually employed in the life sciences disciplines.

Roles and Responsibilities

Dr. Kasper stated that the two critical underpinnings of the oversight system are (1) education about dual use issues and policies and (2) the provision of guidance and tools that facilitate compliance with those policies. The proposed oversight framework delineates roles and responsibilities for researchers, institutions, the NSABB, and the federal government:

- *Researcher roles and responsibilities*. Researchers are the most critical element in the proposed oversight system. They are in the best position to anticipate the types of knowledge, products, or technologies that might be generated, the potential for misuse, and the degree of immediacy of a threat. However, to fulfill this responsibility the Principal Investigator (PI) must be cognizant of the concept of DURC and must be aware that technologies or information produced by life sciences research may and can be misused. Researchers thus have a professional responsibility to be aware of the implications of their work and the various ways in which information from their work could be used, and to take steps to minimize if not eliminate the potential for misuse. This includes being knowledgeable about and complying with all federal and local laws, regulations, and policies for the oversight of DURC, ensuring that their own and their staff members' dual use research training is current, assessing for dual use potential on an ongoing basis their work and that of their research personnel, and communicating DURC in a responsible manner. Researchers should also provide formal assurance to their institutions at least on an annual basis that they are assessing their work for potential DURC.

  The WG recommended that science funding agencies implement a mechanism, such as a check box on new grant applications and competing renewals, whereby the PI notes that the dual use potential of the proposed work has been evaluated and indicates whether such potential exists.

- *Institutions' roles and responsibilities*. Institutions have a number of general responsibilities regarding the oversight of life sciences DUR. These include ensuring that life science research is conducted in conformity with applicable Federal, State, local, and institutional policies; establishing and implementing internal policies and practices that provide for effective and efficient oversight of DURC; and minimizing any negative impact on the conduct of life sciences research. These policies will need to be assessed periodically for effectiveness and impact.

  Another institutional responsibility is establishing mechanisms for advising on dual use research issues and assisting investigators in complying with dual use research policies. This should include the designation of a point of contact within the institution for questions regarding dual use research, a process for investigators to appeal local decisions regarding dual use research, and the way to address internal questions for referral of dual use research issues to the Federal level.

Education on dual use research issues and policies is also a key responsibility; education and training materials developed by the Federal Government are a useful starting point.

Institutions have specific responsibilities regarding the evaluation of research for dual use potential and the review of research that has been identified as DURC. In the majority of cases, an institution may rely on the PI's judgment; in some cases, however, it may be appropriate to assist the PI in deciding whether research meets the criterion for DURC and thus requires further review or oversight. To assist PIs, it may be necessary to make experts available who can assist in making these determinations. A related responsibility is establishing an institutional mechanism for expert committee review, including risk assessment and risk management, so that research can be reviewed and identified as DURC. The local committee should have the necessary expertise to consider the dual use implications of research and to recommend and oversee risk management strategies.

One of the concerns of the WG was the additional burden to institutions that oversight of DUR might entail. Consequently, the WG encouraged using existing infrastructure for review and oversight of DUR. For example, institutions that have an IBC should consider using this body to review potential DURC. Many experiments raising dual use considerations entail recombinant DNA and would be subject to IBC review. *Ad hoc* committee members could bring added dual use expertise to the IBC. Alternative approaches would be acceptable, such as establishing a committee exclusively for DURC or using externally administered committees – for example, an IBC at a neighboring institution, an IBC used by a consortium of institutions, or a commercial IBC that is competent to review DURC.

An especially important institutional responsibility is the development of review processes that do not encumber the conduct of life sciences research that is deemed not to be of concern.

- *NSABB roles and responsibilities*. The WG proposed that the NSABB continue to carry out the functions specified in its charter. This includes but is not limited to advising on the Federal and local oversight of dual use issues, contributing to the development of Federal guidelines for dual use research, advising on the interpretation and application of Federal policies for dual use research, and recommending strategies for outreach and education at national and international levels. In addition, the NSABB should periodically evaluate the oversight system for its effectiveness and its impact on the research enterprise. The NSABB should also serve as a resource to the research community, including the scientific publishing community, on dual use research issues.

- *U.S. Government roles and responsibilities*. The Federal Government should be responsible for developing and implementing an oversight system that is efficient and effective, and that minimizes any negative impact on life sciences research. A key aspect of this responsibility will be ensuring a harmonious governmental approach to the oversight of DUR and the interpretations of policies. A related and equally important responsibility will be to evaluate periodically the oversight system for its effectiveness and impact on life sciences research. Additional roles and responsibilities include education and outreach about dual use issues and policies as well as soliciting public comment on dual use research issues and policies.

Key Considerations for Identifying Dual Use Research of Concern

Review of research identified as potentially being of concern should include an assessment of biosecurity risks associated with the findings, technologies, or biologic entities that might be generated from the research; the identification of the ways in which information technologies or biological agents could be misused; consideration of the potential consequences if the research information, technologies, or biologic agents are misused; and the recommendation of strategies for mitigating or managing the risk of misuse. DURC should be conducted in accordance with the risk management strategies delineated during the institutional review; research results that stem from DURC should be responsibly communicated throughout the research process and at the publication stage.

During the process of developing the criteria for identifying DURC, the NSABB identified a number of considerations and key concepts that were reflected in the final criteria. Most life sciences research has some potential for dual use, so through the criteria the WG tried to delineate a threshold that would identify that subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security.

Evaluation of the dual use potential of research can only be based on a contemporary understanding of the implications of the research results and whether it is reasonably anticipated at that time that such information could be misapplied to pose a threat. Research results may be of concern when they can be directly misapplied to pose a threat, and the scope of a potential threat is a key consideration in evaluating research for dual use potential. This criterion captures threats with broad potential consequences to public health or other aspects of national security – threats to populations rather than to individuals.

The WG emphasized that research that is characterized as DURC should not be viewed pejoratively. Being considered DURC does not necessarily mean that the research should not be conducted or communicated; it does mean that the conduct and communication of that research should be carefully considered from the outset and throughout the research and communications processes. The oversight process is about the responsible conduct and communication – not the restriction – of research.

Evaluation of research for its dual use potential is subjective and can be challenging, requiring scientific expertise and careful, sound judgment about the possibility that others could misapply research results. Additional independent evaluation of the dual use potential of research may offer some additional objectivity, perspective, and knowledge, and may assist PIs in recognizing ways in which information from their research could be misused. Life sciences research is an extraordinarily dynamic field that encompasses many diverse disciplines; therefore, it will be important to periodically review the evaluation strategies and modify them as necessary to ensure continuing relevance. With these concepts in mind, the NSABB proposed **a criterion for identifying DURC: based on current understanding, research that 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, agriculture, plants, animals, the environment, or materiel.**

To assist those who will make a determination as to whether research is dual use of concern, the NSABB has delineated categories and examples of information, products, or technologies that might be especially likely to meet the dual-use threshold. Not all research that fits these categories is necessarily DURC but is research for which the criterion needs to be considered carefully. Moreover, research that does not fall into the categories below might also meet the criterion for being DURC. The categories are information, products, or technologies that could:

- Enhance the harmful consequences of a biologic agent or toxin;
- Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification;
- Confer to a biologic agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection;
- Increase the stability, transmissibility, or ability to disseminate a biologic agent or toxin;
- Alter the host range or tropism of a biologic agent or toxin; or
- Enhance the susceptibility of a host population or generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biologic agent.

After research is evaluated initially for its potential as DURC, the subset deemed to be DURC should undergo more thorough review to determine whether that research constitutes DURC and, if so, how the potential for misuse should be managed. Dr. Kasper noted the tool for guiding this review process that the WG developed: "Points To Consider in Risk Assessment and Management of Research that is Potentially Dual Use of Concern." This guidance is a series of questions to direct thinking about an assessment of the risk of misuse of DURC; it can be found in the appendix of the oversight framework.

Responsible Communication

One of the major charges to the NSABB was to recommend strategies to help ensure that research information with dual use potential is communicated responsibly and in a manner that addresses biosecurity concerns as well as the need for open sharing of research results and technology. Toward this goal, the NSABB developed a set of tools to facilitate consistent decision making about the responsible communication of research information with dual use potential. These tools consist of a set of principles for responsible communication of research with dual use potential, "Points To Consider for Identifying and Assessing the Risk and Benefits of Communicating Research Information with Dual Use Potential," and consideration for development of a communication plan for research with dual use potential. The WG integrated these tools into the oversight framework. Because these tools are designed to help individuals identify and assess the risks and benefits of communicating information with dual use potential and can be employed by a variety of users in many settings, the WG encourages users to tailor and format the tools for their specific purposes.

It is not the intent of the NSABB that every potential communication of research be assessed using the communication tools. Dr. Kasper emphasized that a delay or restriction in the communication of research is anticipated to be a rare necessity and that the default position should be the responsible communication of research.

Code of Conduct

Dr. Kasper explained that a uniformly accepted culture of responsibility among life scientists is pivotal to the success of an oversight system. In recognition of the need for such a culture, the WG incorporated, as a key premise of its oversight framework, a code of conduct for dual use research in the life sciences. This code document is an appendix to the oversight framework. It is an important adjunct to a Federally required oversight system and will primarily be the responsibility of the scientific community. Codes of conduct articulate the shared values and standards of conduct that exist within scientific disciplines as recognized and adopted by the discipline's practitioners. The process of developing, discussing, and adopting codes of conduct has the collateral benefit of raising awareness among scientists by fostering discussion of key issues. For these reasons, codes are typically developed by scientific societies, professional associations, and institutions and are distinct from Federal requirements and regulations.

The Working Group on Codes of Conduct developed a resource document to stimulate the development of codes among scientific societies. The document has three main parts: an introduction that provides a conceptual basis for understanding dual use issues and explains the nature, purpose, and value of codes of conduct; a terse articulation of high-level principles that address the core responsibilities of life scientists with regard to DUR, a Hippocratic Oath-type code that could be easily remembered and incorporated into the thinking of scientists; and a model code of conduct that addresses the specific responsibilities of life scientists throughout the course of the research process, providing standards of behavior from the conceptualization of research through publication.

This code of conduct is meant as a resource for scientific societies and professional associations. While elements of the code may be adopted by these groups, it may also be appropriate to adapt them to the research activities and memberships of a particular organization. The WG expects that the code will be a core element in a program of education within societies and institutions as they consider how to develop their own code and as the basis for ongoing education and training programs.

Outreach and Education

One of the charges to the NSABB is to advise on education, training, and biosecurity issues at Federally funded institutions. The educational content of these training programs will be derived in part from specific Federal policy and requirements that are still under development. In the meantime, the NSABB

has conducted outreach with two key purposes in mind: (1) to hone the development of its recommendations by taking into account the concerns and perspectives of diverse stakeholders and (2) to promote broader awareness of the dual use issue and to sensitize life scientists to its importance. Towards these goals, NSABB members and staff have been engaged in a number of outreach activities – including focus groups, roundtables, and expert panels – to better understand the concerns of various stakeholders and to obtain feedback on work products under development. These activities have the collateral benefit of raising awareness of the issue with key thought leaders and promoting dialogue within the organizations they represent.

The NSABB has made several presentations on dual use issues and NSABB activities at annual meetings of scientists, safety officers, IBC members, research compliance staff, and other stakeholders, including the public. These presentations are an essential means of making the research community sensitive to this issue, keeping the research community apprised of evolving Federal policymaking activities, and providing opportunities for feedback from these groups as the recommendations are developed. The NIH staff have developed an educational exhibit about biosecurity matters in developing Federal policies. The exhibit is shown at major scientific and professional society meetings and where members of the staff are present to answer questions. Exhibits represent an opportunity to educate individuals and to enhance the visibility of the issues with key constituencies.

Under the aegis of the Working Group on International Collaboration, the NSABB hosted an international roundtable with individuals from 20 countries and international organizations. This effort was an important first step in awareness building and information sharing at the international level.

As the NSABB recommendations are transformed into Federal policy, Dr. Kasper noted that additional types of outreach and education would become appropriate – initially to ensure public input into the policymaking process and subsequently to educate all constituencies about emerging Federal requirements. A vigorous program of outreach to the research community and education to those involved in life sciences research after the formal transmittal of the NSABB oversight recommendations to the U.S. Government is essential. With those considerations in mind, the WG made the following observations and recommendations about public outreach during the Federal policymaking process:

- Town hall style regional meetings orchestrated in conjunction with nongovernmental partners such as universities are an important means of generating heightened awareness locally and prompting more locally accessible forums for scientists and others to give input into the federal policymaking process.

- As formal federal policy is developed, public comment should be solicited through formal channels. This includes notices in the *Federal Register,* establishing a publicly accessible docket for collecting public comments on policy that the government is considering and proposing, and formal analysis by federal agencies.

- When the requirements of the oversight of dual use research are formally adopted by the U.S. Government, a communication plan will be needed for the introduction of new federal policies as well as an intensive and ongoing outreach with workshops, presentations, print and electronic materials, exhibits, and other activities to educate about and promote compliance with the new requirements. The material would be used to educate staff and investigators at institutions, as well as the public at large.

- Ongoing education and awareness-building strategies will be needed, including a continuing advisory role by the NSABB regarding such strategies and broad-reaching educational efforts. These educational programs will foster a culture of responsibility, which is important to cultivate early in the development of future scientific talent. While instruction in the responsible conduct of research is an essential ingredient of collegiate and graduate education, instructional materials and resources should be developed for incorporation into all school science programs. Programs should also be developed for international audiences and commercial research environments.

- Education about dual use research should be incorporated into the content of federal grant and fellowship programs, such as NIH-mandated training programs. The NIH presently requires formal training in the responsible conduct of research for all recipients of NIH-funded training grants and fellowships, and the concept of dual use research should be included in this mandate.

- Development of education initiatives by nongovernmental entities should be encouraged. While the Federal government has the ultimate responsibility and is in the best position to educate about Federal policies and requirements, nongovernmental organizations – particularly scientific associations and professional societies – can promote responsible research conduct generally, including best practices. A number of important and impressive efforts are already underway and the U.S. Government should stimulate additional initiatives to include the development of case studies, course curricula, and multimedia educational tools.

Report on the Recent Roundtable Discussion of the Oversight Framework

Dr. Keim explained that one of the most important tasks of the NSABB is to get input from the various stakeholders. To do so, a series of events have been held during the years the NSABB has been impaneled. On April 4, 2007, a roundtable was held for reviewing the oversight framework. The roundtable participants included senior research administrators, research scientists, IBC chairs and committee members, biosafety professionals, and a member of the public at large.

The overall reaction of this group was positive. The introduction was deemed clear and was judged to make a compelling case for DUR oversight. The roundtable panel believed that the recombinant DNA oversight and regulation by the Federal Government is an effective model for DUR oversight. The panel members warned about the likelihood of resistance to change prompted by adding additional oversight at any institution-driven or PI-driven research. There was wide agreement that it was important to raise awareness about DUR issues through education, and the panel supported a code of conduct and education as key to the successful implementation of oversight.

Specific suggestions included that the NSABB develop videos and tele-courses for training and education, and that this training should be targeted broadly to include PIs as well as bench researchers, graduate students, post-docs, and administrators. In addition, IBC personnel and officers need to be educated to raise awareness of DUR. The roundtable panel added that some concepts conveyed in English do not always translate well into other languages; for example, clear distinctions between “biosafety” and “biosecurity” may not exist in other languages.

Strong support came from the roundtable panel to minimize the impact on institutions and researchers. One way to do so, some panel members suggested, would be to use the existing infrastructure and review mechanisms, some of which are in place as a result of recombinant DNA oversight. One suggestion was to capitalize on local infrastructure, including IBCs. However, it was noted that IBCs traditionally have not had expertise in biosecurity; thus, it will be important to include IBCs in the DUR educational process. Uniformity of implementation was also thought to be a potential problem; it was noted that some institutions that regularly deal with biodefense and military research might be better poised to review dual use research, while other institutions might be completely unprepared to review dual use concerns, and might not even have an IBC. Some roundtable panel members suggested that institutions centralize IBC review of DURC or that institutions use commercial IBCs. A regional oversight or review committee was also suggested, for standardizing the process of DURC evaluation since this would lessen the burden on individual institutions while increasing oversight uniformity among institutions.

The roundtable panel offered the concern that oversight of DUR represented an unfunded Federal mandate, observing that even minimal oversight and implementation of infrastructure by an institution could be quite expensive and time-consuming. Institutions would be putting in place a large infrastructure representing a significant burden and workload, and yet are likely to be responsible for only a small number of cases each year. At the same time, panel members recognized that DURC is an important

national and international security issue, and that it is critical to implement oversight that will build public confidence.

Some roundtable participants supported the idea that grant proposals contain a check box saying "this project has been reviewed for DURC." The check box could indicate either no DURC or the potential for DURC at the time of grant submission or renewal; in this way, oversight would have a minimal impact on grant submissions. However, concern was expressed about enforcement and compliance.

The roundtable panel recognized that oversight and compliance could be relatively easily implemented for Federally funded research. However, they noted, much research is not Federally funded, and it is unclear whether and how DUR regulations and oversight would apply in these situations. The panel also recognized that the primary responsibility for identification of DURC will fall to the PIs. In many cases, PIs are ill equipped to make this determination, so it will be crucial that guidance and tools be provided to assist PIs in assessing their own work for DURC potential and so that they can comply effectively with the promulgated regulations.

Public Comment

Gerald Epstein, Ph.D., Center for Strategic and International Studies

Dr. Epstein commended the oversight panel on the package that it had prepared, in particular the recognition that DUR questions will extend beyond the traditional life sciences. In the document's discussion about when DUR would be of concern, Mr. Epstein suggested that the degree of oversight should depend on the degree of risk and not on the extent of inconvenience to the community. He also raised the issue of what to do about DURC once it is "discovered." He suggested that the NSABB discuss more extensively mitigation strategies other than merely halting research of concern – that perhaps an experiment or protocol could be changed to deliver the same scientific value while minimizing risk. Researchers and institutions need specific and useful assistance about how to alter DURC to make it less worrisome.

The scientific, security, law enforcement, and intelligence communities need to engage in a dialogue about the extent to which researchers have the ability and obligation to monitor colleagues' behavior, he said, keeping in mind the traditions of academic and personal freedom. Dr. Epstein suggested the importance of beginning to answer such questions as: What should be done differently? What norms should be questioned? What processes or procedures should be pondered so that individuals can evaluate whether the person doing the research is someone about whom to be concerned? Given that innovative thinking, iconoclastic behavior, brilliance, and creativity are hallmarks of the scientific process, Dr. Epstein observed the line between worrisome behavior and brilliance may not be clear.

Alan Pearson, Ph.D., Center for Arms Control and Nonproliferation

Dr. Pearson noted that the draft report presents a useful initial conceptualization of a potential framework for oversight of dual use research, although he opined that it should be strengthened in the following ways:

1. The guiding principles listed for oversight should state explicitly that the purpose of the proposed oversight system is to minimize potential risks arising from the conduct and communication of DURC. At present, this principle is only implied and distributed throughout the report but it should be stated explicitly because this clarity of purpose is essential to the efficacy of any oversight system.

2. The NSABB should recommend explicitly that the proposed oversight system apply without exception to all relevant Federally conducted or supported life sciences research and to all relevant privately funded life sciences research. This comprehensiveness of scope is essential to

ensure the legitimacy and efficacy of this oversight system.

3. The draft report recommends that individual researchers conduct the initial identification of DURC, but the report then offers highly subjective knowledge- and experience-dependent criteria for making such identification. Subjective criteria will not be clearly understandable, will tend to impede harmonization across the many researchers and institutions that need to engage in this process, will impede consistency and fairness of application, and will not enable the development of standards for the assessment and, if necessary, the enforcement of compliance. The National Research Council's Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, also known as the "Fink Committee," set out objective criteria for the identification of dual use research; the current draft report is a step back from the Fink Committee's work. Assessment of risk will be highly subjective and difficult, but identifying the research needing such assessment should be neither subjective nor difficult. The NSABB should recommend the development of institutional mechanisms for the objective identification and independent review of potential DURC. For example, institutions could develop questionnaires for researchers to fill out, which would enable institutions to identify whether particular projects of research are of concern and thus require further review.

4. Mechanisms for ensuring compliance are essential for the success of the oversight system. The draft report recognizes the importance of these mechanisms but makes no recommendations. The NSABB should include recommendations for such mechanisms as part of its overall set of recommendations to the U.S. Government. Any proposal for an oversight system that does not include mechanisms for assessing and ensuring compliance is incomplete, and it is likely that such an oversight system would be largely ineffective.

5. The NSABB should recommend that compliance be required as a condition of receiving Federal funding. In addition, the NSABB should recommend that the oversight system be based on mandatory Federal regulations, not voluntary federal guidelines. Experience has shown that compliance with voluntary guidelines is less than universal and that implementation and effectiveness of voluntary oversight mechanisms vary considerably. Regulations provide a stronger basis for ensuring effective and universal compliance by researchers and institutions (whether funded publicly or privately) and for the development of universally harmonized approaches to oversight. Such mandatory regulations and mechanisms for ensuring compliance need not be overly proscriptive or onerous, and they can remain primarily local in implementation. For instance, the NSABB could recommend that the guidelines that it is currently developing serve as the foundation for a mandatory system.

6. The risk analysis and management process lies at the heart of the oversight framework, yet this is one of the least developed aspects of the document, and the NSABB needs to give more attention to this issue. For example, the points to consider in Appendix 1 give little guidance on risk management strategies; suggestions are made but there are no recommendations about how various decisions will be made and options chosen, who is responsible, who can have input, and whether, how, and to what degree there will be continuing oversight. It will be difficult to ensure that these processes are consistent, fair, and effective under these conditions. A lack of clarity also exists regarding how decisions to withhold information are to be made and how the potential negative consequences of such decisions – including concerns about intent that may be raised by a lack of transparency about dual use research activity – can be mitigated.

Dr. Pearson noted that additional detail would be included in his written comments, to be submitted after this meeting.

Gregory Koblentz, Ph.D., George Mason University

Dr. Koblentz commended the NSABB on its draft report and on the work conducted to date on this subject. The report highlighted the fact that researchers and PIs are critical to effective oversight of dual use research but that they are not generally well informed about this topic or about how to review

research that may be of dual use concern. As a result, awareness becomes the key issue for how to improve DUR oversight; the report calls for ongoing mandatory education in this area. While the outreach measures outlined in the report are useful, the NSABB members and staff can educate only so many people at any one time.

Adding dual use research issues to the NIH required training program is necessary but not sufficient; education on dual use research should be imbedded in collegiate and graduate education in the life sciences. The federal government should provide incentives for scientists to learn about dual use research issues and to educate students and colleagues about the issues and about how to conduct these reviews and risk assessments. Dr. Koblentz suggested as a model for how this could be achieved: as part of the Human Genome Project, the NIH and other funding agencies required grantees to commit three percent to five percent of their budget for supporting research and education in the ethical, legal, and social implications (ELSI) of the growing availability of genetic information. The ELSI program within the Human Genome Project brought together biologists, social scientists, historians, doctors, legal scholars, and others to address these issues. This interdisciplinary collaboration was necessary to address issues such as privacy and fair use of genetic information, safe and effective integration of genetic information into clinical settings, and ethical issues of genetic research.

Within the field of biodefense, many issues touch on ethics, law, society, and security; such issues could benefit from interdisciplinary research and education. The NSABB should discuss ways of promoting and providing incentives for scientists and researchers to engage in this kind of work as part of the funding process.

Brian Rappert, Ph.D., University of Exeter, England

Dr. Rappert thanked the NSABB for taking on the difficult topic of dual use research. He noted that the NSABB had decided not to announce a code of conduct but rather to suggest considerations for such a code, and wondered who would prepare this code if not the NSABB. While advisory codes have been proposed internationally in recent years, not much has happened as a result. Considerations for the code enumerated by the NSABB reiterate other activities already being suggested by the NSABB. A code of conduct should be recommended by the NSABB; if the United States were to adopt a code of conduct, it would send an important message to international discussions of dual use research.

Dr. Rappert concurred with the NSABB that education is key. Knowledge about dual use issues varies significantly within the scientific community internationally, and it is possible to have two collaborating researchers holding diametrically opposed views about the dual use implications of their work. Merely raising awareness is not sufficient; these education measures should foster a change in dialogue about dual use. Dr. Rappert noted, as an example, that on page 10 there is a suggestion that educational roles be split between the federal agencies and nongovernmental organizations or professional societies. The federal agencies would address education with regard to compliance with requirements and the other groups would focus on wider education and trying to build a culture of responsibility. Dr. Rappert believed that this split might not be a good idea.

Regarding the oversight report generally, Dr. Rappert stated that he was unclear about how Federal agencies will take the process forward from here. If Federal agencies are supposed to come up with the specific guidelines, he wondered how that would be done, whether each Agency would determine its own guidelines, and how those guidelines would be harmonized.

Jo L. Husbands, Ph.D., National Academies

Regarding the local oversight system, Dr. Husbands noted the absence of discussion, as was present in the report of the Fink committee, of unanticipated results in the course of research. A local oversight system provides a place for researchers to report when, during the course of a research project, something unexpected and potentially problematic occurs.

Dr. Husbands requested that the NSABB consider a fairly wide reach for review at the outset; a full review of all research proposals and portfolios at the outset may be an important educational effort, on the assumption that the review process would rapidly diminish after that first full review. Being comprehensive at the beginning will give people more experience with the process while also serving the purposes of review.

Discussion of Oversight Framework

Before the discussion began, Dr. Kasper thanked the public commenters and clarified that, if and after this document is approved by the NSABB, it will be crafted into a draft consensus document that will be made available for public comment. Assurances have been made that the oversight framework will be addressed by various federal agencies in a unified fashion.

Dr. Kasper reminded the public commentators that this framework is a draft and that the topics of compliance and education would receive further attention. He added that the NSABB had deferred detailed recommendations regarding compliance because of the complexity of this issue, and it will be considering this issue in more depth. Regarding education as key to the success of this program, he reiterated that the NSABB will be making specific recommendations about who and what should be included in the educational program, noting that the NSABB generally supports a broad and inclusive educational program that will take place at multiple levels throughout the United States. This draft framework is being released as policy rather than government regulation, he reported, because it will undoubtedly need to be modified, and thus the statements in the document have been written broadly to allow future modification as necessary; to release it as a proposed regulation would be is inappropriate.

The NSABB members then discussed the draft of the oversight framework.

Dr. Cohen noted that the public comments made at this meeting might presage the comments likely to be received once the draft document is released for additional public comment. He suggested releasing, along with the draft document, a list or summary of points that have already been received as well as an indication of how the comments will be incorporated into a subsequent document. Dr. Cohen expressed his thought that a transmittal letter could express these concerns; such a letter would include what the NSABB expects to do, the full anticipated process, and a summary of the comments already received, all of which should also be made available on the Web.

Dr. Fraser-Liggett suggested that additional public comment be solicited by specifically asking for suggestions and models for sections of the framework that need additional detail.

Judge Ehrlich suggested adding the following text in the last paragraph of the introduction about NSABB's expectation that its recommendations will be a springboard: "the need and intent to address compliance and enforcement, awareness of the charter's charge to develop mandatory education and training programs, the understanding that much research is not Federally funded or conducted in Federal institutions, and that details need to be filled out."

Dr. Rubin asked about the timeline for completing the framework, and recommended that the framework document go forward with the explicit understanding that it is not yet complete. In response, Dr. Patterson stated that the framework document should be completed as soon as possible while allowing ample opportunity for deliberation in order to produce the best product possible.

In response to Dr. Imperiale's request, Dr. Cohen expanded on concerns about unfunded mandates. For example, he said that if it is determined that training is needed and the role of IBCs needs to be expanded, it is possible that implementation of these needs would be required but not funded by the U.S. Government. Other examples cited by Dr. Cohen included the use of a checkbox on grant applications – the concern that reviewers would see that box as a "don't fund" box – and the likelihood that the need for oversight will arise in the middle of a funding cycle rather than at the time a grant is submitted.

Dr. Erlick reiterated that to include additional detail in this document would be a mistake at this point, even though the lack of detail might create a barrier with the public. The NSABB wants an open dialogue, with all the issues on the table; the framework and concepts – but not the details – should be in place.

Dr. Levy suggested adding reassurance to institutions that implementation will not cost additional money and to individuals that research will not be delayed. He also suggested that this document include an estimate of approximately how many projects would need to go through the proposed oversight process.

Dr. Lemon asked how the NSABB would be informed of the policy discussions regarding this document. Dr. Patterson responded that the policy development process will be coordinated and that the NSABB members will continue to serve in a consultative role as these policies take shape. She further explained that the NSABB will be transmitting this proposed oversight framework to the U.S. Government as a draft – a set of principles, key features, and roles and responsibilities – with the recommendation for a robust public consultation process as an integral part of the policy development process.

Dr. Steele suggested that the NSABB make clear that it expects to follow up with more detail on the issues of compliance, outreach, and education. Dr. Patterson added that the Board should be clear about what it considers to be the status of the framework.

Dr. Enquist addressed the question of how to convey the fact that the WG worked diligently to define the extent of the DURC problem. He read the relevant paragraph: *"While the NSABB could not quantify the amount of dual use research of concern or the risk of misuse of information from that research, there was a consensus that there is, indeed, the potential for misuse with severe consequences to public health and safety in other areas herein presented. This was a significant factor in the formulation of oversight recommendations."*

Dr. Imperiale stressed that the purpose of this framework is to *minimize* risk, because eliminating risk completely can never be accomplished. Some low level of risk needs to be tolerated in order to cultivate a vibrant life science research enterprise that benefits humanity. Risk can only be minimized; there is no guarantee that someone will not misuse a result of life science research.

Dr. Franz agreed with Dr. Imperiale, explaining that that was the underlying spirit with which compliance should be approached.

Dr. Vidaver noted several issues that she deemed to be minor. She stated that the footnotes are not complete but that she was confident they would be completed before the framework is sent out. Under "Codes of Conduct" on page 44, under "Conducting Research," item 1 addresses the observation of safe practices and ethical behaviors in the laboratory; she suggested adding "classroom, clinic, and field" as other areas in which research is conducted. Dr. Vidaver also suggested adding other sources to the footnote that deals with safe laboratory practices; for example, a book from the American Society for Microbiology. Judge Ehrlich noted that, since the appendix had already been voted on and approved by the Board, the entire Board would have to vote to change the wording; Dr. Patterson agreed.

Dr. Imperiale suggested adding wording that indicates that the NSABB requests that the process of finalizing this document be iterative. Dr. Kasper suggested that such a request be stated in the letter of transmittal.

NSABB Motion 2

A motion to include a letter of transmittal with the document as it is forwarded to the U.S. Government was made by Dr. Cohen and seconded. This motion carried unanimously by voice vote.

The letter will be addressed to the Secretary of the Department of Health and Human Services Mike Leavitt and to the heads of the fourteen federal agencies represented by the ex officio members on the NSABB. Drs. Cohen and Groesch volunteered to make a list of points to include in the transmittal letter.

Revised Oversight Framework Document

Dr. Patterson reviewed the proposed modifications from the previous discussion, including additions to concepts in the introduction, concepts added elsewhere in the document, and concepts to be included in a transmittal letter. Several NSABB members suggested that the report and the transmittal letter should be viewed together (linked) on the Web and elsewhere.

Additional Concepts for the Introduction

- It is important to underscore that the NSABB is presenting this document as a draft oversight framework aimed at minimizing the potential misuse of life sciences research. The NSABB expects an iterative process of consultation with the public and the federal government, and anticipates modifying the document in response to this input.

- The NSABB explicitly acknowledges that no oversight system could anticipate every situation that might arise with regard to dual use research, and the goal is to minimize risk while maintaining a vibrant life sciences research enterprise. The Board spent much time considering the magnitude of DURC and found it difficult to quantify, although tentative analyses suggest that it is proportionately very small, meaning that DURC is an issue of low probability but high consequences.

- Recombinant DNA is an important historical precedent for addressing a complex research activity whose risks are difficult to quantify. The system of oversight for recombinant research has endured over time because it is capable of evolving with technology developments and new scientific understanding and because revising that oversight system has been a publicly transparent process, and engendering public trust is another reason for its success. The system of oversight for recombinant DNA was not embedded in regulation and therefore could adapt to advancing science, continually and consistently establishing a standard of practice that has been embraced by the private and public sectors.

- Regardless of whether life sciences research is funded publicly or privately, the NSABB emphasized that the fundamental principles regarding the responsible conduct and communication of DURC apply in the public and private research arenas.

- At the end of the concluding paragraph of the introduction, the NSABB requested that further attention be paid to issues of compliance and education, consistent with its mission.

Additional Concepts To Be Added Elsewhere in the Document

- The current title, “Proposed Strategies,” should be changed to “Proposed Oversight Framework.” Doing so will emphasize that this document is not detailed guidance but is a framework and a first step forward.

- On page 14, the arrows in the figure that describes the process for review at the local level should be modified to illustrate that only a very small portion of life sciences research is anticipated to be classified as DURC.

- On page 14, the roles and responsibilities of the U.S. Government should be modified to indicate that the Federal Government should ensure that sufficient resources are provided to institutions to fulfill this oversight responsibility.

- To emphasize that the intent of this oversight is not to create impediments to research, "classrooms, clinics, and field" should be added to "laboratory setting" in the Code of Conduct document in the appendix.

- Footnotes should be more complete with respect to page references. A footnote should be added about the 2000 American Society for Microbiology (ASM) biosafety publication.

- A highlighted, key-concept statement should be added to clarify that no oversight system can reduce the potential risk of a misuse of information to zero, and that the magnitude of that risk is difficult to quantify.

Concepts for the Transmittal Letter

- The draft nature of this report should be highlighted. It is a general framework and many details need to be added. This is an opportune moment for public input.

- Some conflict issues have no ideal solution and while the NSABB gave tremendous thought to these issues; further public input is needed in choosing a path forward. These issues are articulated in the questions at the end of the document that are being posed to the public to precipitate additional discussion.

- Concern should be expressed about the potential burden on research institutions. A strong recommendation should be included that compliance with oversight requirements not be an unfunded mandate.

- The NSABB hopes that this will be an iterative process and that further NSABB input and refinement will be possible.

- Issues that need further attention and development, many of which are articulated in the NSABB charter, include compliance, mechanisms for enforcement, and training and education. It should also be noted that training and education will be possible only when the details of the guidance are more fully developed.

- The section on risk management strategies will benefit from input from scientific colleagues and the public.

NSABB Comments on the Revised Oversight Framework

Dr. Imperiale requested that wording be added to the introduction to make explicit that the NSABB understands that intentional misuse cannot be prevented completely.

Dr. Erlick suggested that the NSABB "recommend" (rather than "hope") that this process be iterative and that the NSABB will have additional input.

Judge Ehrlich requested that the concern about an unfunded mandate be removed from the transmittal letter but kept in the introduction.

Additional Public Comment

Alan Pearson, Ph.D., Center for Arms Control and Nonproliferation, clarified an historical comment about the Recombinant DNA Advisory Committee.

Carrie Wolinetz, Ph.D., Federation of American Societies for Experimental Biology, suggested that language regarding the funding of dual use oversight mechanisms include the statement that "such resources dedicated to this purpose should not come at the expense of existing programs."

Megan Davis, Ph.D., Duke University, offered two suggestions. Regarding the flow diagram, the box with "no dual use identified" should be moved to the main line and the "dual use identified" box should be a subsidiary because it is a less frequent event. She also explained that PEL Core should be listed as the Policy, Ethics, and Law Core of the Southeast Regional Center of Excellence for Emerging Infections and Biodefense.

NSABB Motion 3

Dr. Kasper asked for a vote on the issue of whether to vote on acceptance of this document. He explained that a vote of "aye" would be in agreement with voting, with the understanding that some editorial changes would be made. This motion passed unanimously by voice vote.

NSABB Motion 4

Dr. Kasper moved for approval of this oversight framework document, with the modifications discussed at this meeting. The adapted version based on contemporaneous comments will be sent to all NSABB members and a subset of the NSABB will decide whether the comments have been incorporated accurately. Dr. Kasper would then decide whether those changes were substantive and, if so, the NSABB would be reconvened to include public participation and so as to discuss and vote again on those issues. The document will be transmitted to the U.S. Government with the recommendation that robust public consultation be an integral part of the Government's development process. The motion was seconded. The motion passed unanimously, with no abstentions.

Dr. Patterson noted that Drs. Casadevall, Fran, Lemon, Osterholm, and Relman had reviewed the document and voted in favor that it be transmitted with the recommendation for further public input and comment. Their vote was based on the document as it was written, before the changes suggested at this meeting.

Working Group on International Collaboration: Report on International Roundtable

Stuart Levy, M.D., Vice-Chair of the International Working Group, reported on the international roundtable organized by that WG on February 26 and 27, 2007. The mission of the International Working Group is to ensure that the work being conducted in the other NSABB working groups is transmitted internationally. The World Health Organization (WHO) cosponsored this roundtable.

The WHO, the U.S. Department of State, and the Alliance for Prudent Use of Antibiotics provided a list of people who might have an interest in this area, and those people were contacted via cable through the Department of State or by letter or e-mail. While responses made it clear that it was not the role of invited attendees to represent their respective countries, the WG hoped that attendees would take back to their countries and professional organizations the tools and information presented and discussed at this roundtable.

Countries from which participants came were Australia, Argentina, Bulgaria, Georgia, India, Israel, Morocco, Netherlands, the People's Republic of China, Poland, Spain, Switzerland, Uganda, the United Kingdom, and the United States. Participating organizations included WHO, the World Organization for Animal Health, the Food and Agriculture Organization of the United Nations, the International Union of Biochemistry and Molecular Biology, the International Union of Microbiological Societies, the International Council for Life Sciences, and the ASM. Backgrounds of participants were in the basic sciences, medicine and ethics, and they worked for scientific associations, government scientific agencies, scientific journals, and national research councils.

The fundamental purpose of this roundtable was to engage individuals from different countries, to explore ideas and concepts about biosecurity and dual use research, to identify common concerns and issues, and to foster communication and ongoing dialogue. Objectives of this roundtable were to:

- Determine the scope of other countries' activities, interests, and concerns pertaining to dual use life sciences research,
- Inform individuals from other countries and professional societies about the NSABB draft work products and obtain feedback,
- Establish communication with individuals from other countries and the international community on dual use research issues, and
- Collaborate with other countries and the international community to establish a more robust understanding of how to approach dual use life sciences research issues.

Dr. Levy reviewed the agenda for the roundtable, noting that the meeting focused on four areas: the dual use dilemma and its importance, recognizing dual use potential and advancing global health research, balancing public health priorities and national security concerns, and demonstrating what the U.S. Government has done. Each of these four groups had a moderator and four speakers, and every person invited had an opportunity to speak.

A number of consensus points emerged from this meeting including that the U.S. Government and scientists at large should:

- Maintain a productive scientific enterprise and minimize the potential for harm.
- Provide guidance on dual use research to the broader scientific community, defining the problem and the challenges.
- Promote continued awareness of the dual use research issue by building a layered, integrated, international web of prevention, protection, awareness, and understanding.
- Strengthen and sustain a culture of responsibility and accountability.
- Recognize that science is a powerful tool of good for society, and that science and the understanding of biological processes are advancing rapidly.
- Acknowledge that science is a global enterprise and is becoming ever more so, making the challenges of dual use science a global issue to address. Different approaches may be required in different regions and countries.

In addition, it was agreed by the participants that addressing dual use research issues can be accomplished by:

- Defining criteria for identifying DURC;
- Providing educational materials for scientists, students (of all ages), the public, and government decision makers;
- Developing codes of conduct;
- Developing a Hippocratic Oath-like oath for scientists;
- Providing guidance for considering potential publication of scientific research;
- Providing oversight processes, including a framework for risk assessment and risk mitigation and management; and
- Providing guidance for science funding agencies.

Overall, the participants believed that they should keep in touch and get together again. In addition, possible next steps could be to:

- Learn more about the needs of individual countries regarding dual use research issues;
- Consider how best to engage and educate stakeholders including academia, industry, government, policymakers, scientific/medical journal editors and publishers, and the public;
- Develop strategies for engaging potential collaborators;

- Consider how to develop a communications network;
- Continue to integrate International Working Group efforts and activities with the NSABB;
- Consider strategies for ongoing international dialogue; and
- Consider drafting a White Paper for submission to a scientific journal. The contents of the proposed White Paper would begin to define the dual use research issue and challenges, acknowledge previous on ongoing international discussions, describe this International Roundtable, outline its objectives and consensus points, and describe a basic "tool-kit" and the potential use of individual tools.

Dr. Levy noted that he, Dr. David Franz, and the NSABB staff have begun work on this paper.

To illustrate the success of this roundtable meeting, Dr. Levy read the first paragraph of a letter from Koos van der Bruggen, from the Netherlands (to which was attached a draft of the Netherlands' version of a code of conduct on biosecurity):

> "The International Roundtable of 25-27 February was a very inspiring meeting for me. I learned a lot from the experiences in other countries and certainly from your efforts with NSABB. What struck me was that in spite of all differences, in fact everyone is wrestling with the same dilemmas and questions – academic freedom versus bio-risks, pros and cons of code of conduct, etc. The roundtable surely has influenced the draft of the code of conduct on biosecurity for the Netherlands, which I was asked to write."

Discussion of International Roundtable and Follow-Up Activities

Dr. Erlick noted that attendees at the roundtable included individuals from the "arms control world" who are dealing with various treaties. The roundtable provided an effective forum to differentiate the NSABB's mission from their mission, which the participants understood.

Dr. Levy and Dr. Cohen stated that the roundtable meeting confirmed that the NSABB is moving in the correct direction; buy-in from key countries will be achieved, and those countries will influence other countries that have not yet participated. They emphasized that each participant was not obligated to accept the entire presentation, but that the lines of communication should remain open. Professor Angelo Azzi, International Union of Biochemistry and Molecular Biology, has already spoken to UNESCO, and many of the roundtable participants have become "ambassadors" of the NSABB and its mission.

Dr. Enquist applauded the sponsors and planners of the roundtable meeting for involving the scientific societies, which gives scientists a voice that they do not necessarily have through government organizations.

Dr. Fraser-Liggett asked whether future such meetings could be hosted by participants from other countries, so that Bethesda does not become the "center of the universe" for this topic. Dr. Levy responded that international societies will be hosting symposia on this subject, in part because they want to have their own codes of conduct. Other countries, such as Bulgaria, have expressed interest in hosting future meetings.

Public Comment

Donald Avery, Ph.D., University of Western Ontario, expressed concern that there appeared to be no attempt to approach the Canadian government to contact people who were interested in attending the roundtable meeting. In February 2006, the Canadian government hosted a conference on biotechnology and dual use; that conference included 50 people from academia, government agencies, industry, and the scientific press. The result of this conference was a report that includes imaginative ideas and interesting comparisons regarding the deliberations discussed at the current meeting. Dr. Avery also noted that the list of roundtable attendees included only two from the G-8 countries, and it is the G-8

countries that are conducting research that is most similar to research in the United States. Dr. Levy responded that Canada was invited but that no one was named to participate.

Tom Fonts, from Australia, supported the comment about localization. He noted that, in his work with UNESCO on the global database on health law, he has gathered some experts who might be able to work with the NSABB in the future.

Updates on Member Presentations and Other Outreach Activities

Dr. Kasper asked NSABB members to summarize presentations that they had made at meetings since the last NSABB meeting and to discuss the feedback received.

Dr. Imperiale had made a presentation at a meeting at the Southeast Regional Center for Excellence in Biodefense, organized earlier this year, that focused on bioethics. Bioethicists at the meeting stated that the NSABB should propose a bona fide code of ethics rather than the framework for a code. Along with Drs. Casadevall, Fraser-Liggett, and Keim, Dr. Imperiale spoke at the ASM biodefense meeting at a session that was well attended by scientists who are intimately involved in relevant research. Dr. Imperiale also had been asked to brief the research officers of the Association of American Universities Research Officers on the NSABB's activities, and he reported that their concerns were not about academic freedom or restrictions on publications but rather with the issue of DUR oversight being an unfunded mandate.

Dr. Rubin reported that he had made a presentation to University of Pennsylvania alumni about the efforts of the NSABB.

Dr. Keim reported that he and Dr. Cohen had spoken at the American Association for the Advancement of Science meeting in San Francisco. The audience of approximately 50 people, all of whom were engaged in the presentation, asked excellent questions, and offered many comments. Dr. Cohen added that all of the speakers, including at least two members of the scientific press, and nearly everyone in the audience was cognizant of the difficulty of the issues, as well as informed and positive about the work of the NSABB. In particular, Donald Kennedy, Ph.D., the editor of *Science*, spoke about the effort and outcome of how the 1918 papers were handled; he was very positive about the process, integrity, and sincerity with which the NSABB has approached its work.

Next Steps

Dr. Kasper concluded by noting that the main purpose of this meeting had been accomplished – the NSABB had formally handed a key work product to the U.S. Government for its consideration, after having one more opportunity to review it. He also applauded the momentum developed by the International Working Group.

Dr. Kasper thanked the members of the NSABB and the public for their insightful commentaries, and he adjourned the meeting at 2:20 p.m.

The next NSABB meeting will be held on February 27 and 28, 2008.

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: _____ _____

Dennis L. Kasper, M.D.
Chair
National Science Advisory Board for Biosecurity