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

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

December 10, 2008
Legacy Hotel and Meeting Centre
1775 Rockville Pike
Rockville, Maryland

MINUTES of MEETING

VOTING MEMBERS

Dennis L. Kasper, M.D., *NSABB Chair*
Arturo Casadevall, M.D., Ph.D.
Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Susan A. Ehrlich, J.D.
Barry J. Erlick, Ph.D.
David R. Franz, D.V.M., Ph.D.
Claire M. Fraser-Liggett, Ph.D.
Michael J. Imperiale, Ph.D.
Paul S. Keim, Ph.D.
Stanley M. Lemon, M.D.
Stuart B. Levy, M.D.
James A. Roth, D.V.M., Ph.D.
Harvey Rubin, M.D., Ph.D.
Andrew A. Sorensen, Ph.D.
Anne K. Vidaver, Ph.D.

EX OFFICIOS/FEDERAL AGENCY DESIGNEES

Kristine Beardsley, Federal Bureau of Investigation
Valerie Bonham, J.D., National Institutes of Health
Kay Briggs, Ph.D., U.S. Department of the Interior
Kenneth Cole, Ph.D., U.S. Department of Defense
Diane DiEuliis, Ph.D., Executive Office of the President
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Daniel W. Drell, Ph.D., U.S. Department of Energy
Jose A. Fernandez, Ph.D., U.S. Department of Health and Human Services
Maria Y. Giovanni, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Wendy Hall, Ph.D., U.S. Department of Homeland Security
David Holmes, Ph.D., Centers for Disease Control and Prevention
Lawrence Kerr, Office of the Director of National Intelligence
Sara Klucking, Ph.D., U.S. Department of Homeland Security
Theresa Lawrence, Ph.D., U.S. Department of Health and Human Services
Robert Mikulak, Ph.D., U.S. Department of State

Janet K. A. Nicholson, Ph.D., Centers for Disease Control and Prevention
Polly R. Sager, Ph.D., National Institute of Allergy and Infectious Disease, NIH
Ken Staley, M.D., M.P.A., The White House Homeland Security Council
Joanne Tornow, Ph.D., National Science Foundation
Serina Vandegrift, J.D.,L.L.M., Federal Bureau of Investigation
Robbin S. Weyant, Ph.D., Centers for Disease Control and Prevention

NSABB EXECUTIVE DIRECTOR
Amy P. Patterson, M.D., Acting Director, Office of Science Policy, National Institutes of Health

GUEST SPEAKERS

Kenneth Cole, Ph.D., Office of the Special Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs, U.S. Department of Defense
Terry Creque, Ph.D., Office of Intelligence, Department of Energy
Diane DiEuliis, Ph.D., Office of Science and Technology Policy, Executive Office of the President
Eric Gard, Ph.D., Lawrence Livermore National Laboratory
Mary Mazanec, M.D., J.D., Office of Medicine, Science and Public Health, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
Robbin S. Weyant, Ph.D., Division of Select Agents and Toxins, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Call to Order and Review of Conflict of Interest Rules

Dr. Kasper, chair of the National Science Advisory Board for Biosecurity (NSABB), convened the December 10, 2008 meeting of the NSABB at 8:30 a.m.

Dr. Patterson read into the record the rules of conduct and conflict of interest. The rules are explained in the report entitled "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 NIH Office of Biotechnology Activities, Ms. Lisa Rustin.

Introductions, Approval of the February 27-28, 2008 Minutes, and Overview of Agenda

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

Judge Ehrlich and Dr. Levy reviewed the minutes of the February 27-28, 2008 NSABB meeting prior to the minutes being presented to the full board, and their suggestions were incorporated. Dr. Imperiale noted the need for one correction on page 15 in the Discussion section, reference to the University of Massachusetts should instead be to the University of Michigan.

NSABB Motion 1

Upon motion and second, the Board voted unanimously by voice to approve the February 27-28, 2008 NSABB meeting minutes that had been distributed in advance of the meeting, as corrected by Dr. Imperiale.

Dr. Kasper described the agenda for this meeting and then introduced the first speaker, Dr. Amy Patterson.

NSABB Personnel Reliability Working Group: Introduction to the Issue and Charge to the Working Group

Presenter: Dr. Patterson

Dr. Patterson provided background for the NSABB Personnel Reliability Working Group (PRWG). In September 2008, the NSABB was given the charge to recommend to the U.S. Government (USG) strategies for enhancing personnel reliability among individuals with access to biological select agents and toxins. The overarching question posed to the NSABB was: What is the optimal framework for ensuring personnel reliability in a manner that balances the needs for biosecurity as well as rapid progress in the life sciences?

The NSABB was asked to take a fresh look at the goals of such a program, the principles it would embody, how it would be implemented, and the roles and responsibilities of individuals and local and federal institutions. The approach taken by the NSABB PRWG has been to look at the extant frameworks currently in place, to begin to articulate the features of an optimal program, and to delineate the potential risks and benefits of those programs. The PRWG is also considering how to assess whether a program is effective; the tangible costs in time, people, and resources; any negative effects on the research community and the pace of science; and the potential benefits in terms of whether an event has been prevented.

The impetus for this charge to the NSABB at this time was primarily two events – publicity in the summer of 2008 regarding a possible "insider threat" in the wake of an investigation of the Amerithrax case that stimulated public concern and Congressional interest, and an article that appeared in *The Guardian*, a United Kingdom publication, recounting the story about security services intercepting 100 suspects who apparently posed as postgraduate students aiming to acquire weapons material and expertise.

As *The Guardian* article illustrates, personnel reliability is not a topic that is unique to the United States. At the Third International Roundtable on Dual Use Issues in November 2008, participants were asked to engage in an informal roundtable discussion on this issue to probe the extent to which personnel reliability is a concern in each country, what steps countries have taken to put programs in place, and views of this topic internationally. Participants concluded that:

- Extant programs exist around the world similar to those in the United States but they are mostly for government funded defense research.
- Foreign personnel are a key component to research around the world, and hence many of these programs aim to avoid barriers to international participation in science.
- There are lessons to be learned from how private business, such as the financial sector, handles personnel reliability.
- Many participants observed that cultivating and maintaining a culture of openness was a hallmark of the biological sciences, and thus countries should avoid moving toward a culture in which scientists regard each other with suspicion.
- Misuse of expertise is a reality; no system can ensure completely that expertise will not somehow be misused.

- While personnel reliability programs can mitigate but not eliminate the risk of insider threats, they will help with public trust in the scientific enterprise.

The PRWG has been briefed by the intelligence community with regard to approaches, principles, and mechanisms for security clearances. In addition, it has heard from the Battelle Biomedical Research Center, located in West Jefferson, Ohio, which carries out cooperate contracted work for the USG in this area. In light of several briefings that began in October 2008, the PRWG has begun to articulate a vision for an optimal personnel reliability program, to delineate the guiding principles that such programs should embody and reflect, to articulate the specific aims and objectives, and to describe the applicability of those programs. Subsequent to the input at this NSABB meeting, the PRWG will revisit these components of its report and begin mapping out the key features and roles and responsibilities of a personnel reliability program.

Panel on Extant Personnel Reliability Programs

Personnel Reliability Components of the Select Agent Rules
Presenter: Dr. Weyant

Dr. Weyant discussed the security risk assessment (SRA) screening program for Select Agent workers. A security risk assessment is the method used to approve an individual for access to Select Agents. This method has been devised in accordance with the USA Patriot Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The FBI Criminal Justice Information Services Division (CJIS) conducts SRAs for Select Agent programs; these assessments are based on an electronic database check that includes fingerprint information.

The Select Agent Program dates to the mid-1990s, with the passage of the Antiterrorism and Effective Death Penalty Act of 1996. In that Act, the Secretary of HHS was tasked with developing a list of agents of public health concern and developing a system to register any entity involved in shipping these agents. After the events of September 11, 2001, and the ensuing Amerithrax attacks in October 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which expanded the regulatory role of HHS to include possession and use of Select Agents in the United States and also tasked the U.S. Department of Agriculture (USDA) with developing similar regulations to oversee the possession, use, and transfer of agents of concern to agriculture. In addition, the USA Patriot Act addressed access to Select Agents by stating that “no restricted person shall ship, possess, or receive a Select Agent.” Eight prohibited categories from the USA Patriot Act and three additional prohibited categories from the Bioterrorism Response Act of 2001 define a “restricted person.”

The Select Agent Program requires close interaction among three federal departments: through the CDC, HHS regulates agents of concern to public health via 42 CFR 73; through the Animal and Plant Health Inspection Service (APHIS), the USDA regulates agents of concern to the animal industry and agriculture via 7 CFR 331 and 9 CFR 121; and through the CJIS, the U.S. Department of Justice (DOJ) provides risk assessments to the CDC and APHIS Select Agent programs.

The following individuals or entities need to undergo an SRA:

- Nongovernmental organizations (NGOs) that want to possess, use, or transfer Select Agents
- Responsible Officials (ROs) and the Alternate Responsible Officials (AROs) at entities involved in Select Agent work
- Individuals requesting to possess, use, or transfer Select Agents or Toxins at a government agency or NGO

The SRA begins when the Responsible Official requests to update or amend the registration application (Section 4B table of the APHIS/CDC Form 1). Then the CDC or the APHIS assigns the individual a unique DOJ identifying number, the individual submits an FD-961 form and fingerprint cards to the CJIS,

and the CJIS conducts the electronic database check. The CDC or the APHIS notifies the RO of the individual's SRA status ("approved" or "restricted"); if restricted, the CDC or the APHIS notifies the Responsible Official and the individual. An individual may appeal a HHS decision to deny, limit, or revoke access approval under 42 CFR Part 73.20. Currently, SRAs are generally completed within 45 days from the initiation of the process, with the biggest bottleneck being submission by an applicant of fingerprints and the appropriate form to the FBI.

For individuals who will have access to Select Agents and Toxins, the SRA is valid for five years unless terminated sooner by the entity, the CDC, or the APHIS. Responsible Officials, Alternate Responsible Officials, individuals who own or control the entity, and the entity itself must obtain SRA approval each time the certificate of registration is renewed; a certificate of registration is valid for a maximum of three years. Any time the fingerprints of an SRA-approved individual pop up in the FBI system, the CJIS is notified and initiates an investigation, thus providing the FBI with real-time monitoring.

A system has been established to allow scientists to move from one registered institution to another without having to undergo the SRA process each time. That system involves interaction between the Responsible Officials of the host institution and the sending institution, notification of the CDC Select Agent Program, and notification of the CDC or the APHIS when a visit is complete.

From the initiation of the program in 2002 until October 2008, the FBI has processed 28,593 SRA requests, many of which represent the same individual requesting an SRA multiple times. Of those requests, 27,282 have been found to be unrestricted, a reflection of effective prescreening. Approximately 1,000 individuals have cancelled their SRA at some point in the process and 158 have been deemed restricted, of which 51 have appealed their restrictions and 21 of those have been reversed. As of December 10, 2008, approximately 13,000 individuals are working with Select Agents with a current SRA, with 80 percent working in entities regulated by the CDC. Of the approximately 100 individuals who have been found restricted in entities regulated by the CDC, 68 percent have been restricted due to conviction for a crime, with no significant pattern to the remaining 32 percent.

Dr. Weyant referred participants to the additional information available at www.selectagents.gov.

Department of the Army Personnel Reliability Program

Presenter: Dr. Cole

Dr. Cole explained that personnel reliability is one of a layer of systems used by the U.S. Department of Defense (DoD) to safeguard biological Select Agents and Toxins (BSATs). Shortly after the Select Agent Rule became effective, the DoD issued policies and guidelines that were reminiscent of the Defensive Biological Warfare Program, primarily because of the term "Select Agent," which has been used historically for chemical and biological weapons. The DoD reactivated many of those older policies with regard to physical security, safety, personnel reliability, and inventory accountability. Acknowledging that a determined insider cannot be stopped, the DoD recognizes that systems can be put in place to reduce the risk of insider threat from someone with mental or other problems or someone who could be lured into malfeasance by, for example, blackmail. This entire program is called "Biosurety," a U.S. Army term from the mid-20th century.

The DoD's biological personnel reliability program (BPRP) is required for anyone who has unescorted access to BSATs or anyone who escorts or supervises personnel who have not been approved or "vetted" by the BPRP. The vetting process includes a personnel security investigation that is comparable to that for a "Secret" clearance. Individuals who must participate in the BPRP program include those who have unescorted access to BSATs, who escort other individuals not in the BPRP, who control direct access to BSATs (e.g., security guards), who issue means of access to BSATs (e.g., proximity cards and keys), who operate motor vehicles transporting BSATs unless escorted, or who are the Responsible Official or Alternate Responsible Official. For overseas laboratories that employ host nationals, the DoD relies on the U.S. Department of State (DoS) for these investigations.

Currently, approximately 706 people are involved in the DoD's personnel reliability program. The main tenets of the BPRP include that the individual must show a legitimate need to have access to the restricted material, be technically competent, complete a Personnel Security Investigation, and be approved for BSAT access by a certifying official who is usually a direct supervisor. Continuous monitoring by the certifying official/supervisor includes drug testing, urinalysis screening for illegal substances, an annual medical records review by a competent medical authority, a personnel records review, and self and peer reporting of potentially disqualifying information. In addition, a two-person rule is in place for accessing reference stocks – this rule involves two keys possessed by two different people in order to open the refrigerator or cabinet.

Commanding officers or directors appoint the certifying reviewing officials, who certify individuals into and disqualify individuals out of the BPRP as well as review disqualification decisions and continually monitor certification decisions. Dr. Cole reviewed the specific qualifying standards, the disqualifying standards, and the criteria for removal from BPRP duty.

Noting that an SRA is only one step in a personnel reliability program, Dr. Cole discussed additional elements of the DoD personnel reliability program. For contractors, the DoD uses the National Agency Check with Local Agency and Credit Checks; civilian workers are subject to a National Agency Check and Inquiries. For foreign nationals, a limited access authorization background check is conducted; for host nationals, the DOS Regional Security Office conducts a full background investigation.

Since September 2008, the DoD has been reviewing all elements of its BSAT programs, including its personnel reliability program. One recommendation going forward is that the investigation of personnel requesting to work with Category A agents will be increased to a single-scope background investigation, which is a full-scale investigation to assess reliability and background. Installation of duress alarms in laboratories is another uniformly accepted recommendation. Other changes include increasing the amount of closed-circuit television within the laboratories and storage facilities, requiring digital surveillance tapes to be kept for five years and to be reviewed at specific periods of time, and requiring an escort at all times while a sample is being transported.

Committees have been established to examine policy for DoD and Interagency programs performing biodefense research with BSATs, and the Inter-Service Council for Biosecurity and Biosafety General Officer Steering Committee has commissioned a Defense Science Board and a Defense Health Board to conduct independent reviews of DoD BSAT programs. The DoD Working Group will meet in January 2009 after release of various relevant reports to collate recommendations and discuss modification of practices and procedures.

Department of Energy Select Agent Human Reliability Program

Presenter: Dr. Creque

Dr. Creque provided a general overview at the DOE headquarters level. The DOE has three biosafety level (BSL) three laboratories at Los Alamos, Livermore, and Sandia. It maintains a robust and mature personnel reliability program that grew out of the nuclear research and nuclear weapons arena, and the Web site has a complete handbook on the Human Reliability Program (HRP), at http://www.hss.energy.gov/DepPersonnelSec/hrp/flash/handbook/handbook.html. In 2006, the DOE established a Biosurety Executive Team.

The HRP is a security and safety reliability program designed to ensure that individuals who occupy positions affording access to certain materials, nuclear explosive devices, facilities, and programs meet the highest standards of reliability and physical and mental suitability. This objective is accomplished through a system of continuous evaluation that identifies individuals whose judgment and reliability may be impaired by physical or mental/personality disorders, alcohol abuse, use of illegal drugs, abuse of legal drugs or other substances, or any other condition or circumstance that may be of a security or safety concern.

The general DOE HRP requirements are:

- *DOE "Q" security clearance.* This clearance is granted by the DOE indicating the recipient is approved for access to the following levels of classified matter on a need-to-know basis: Top Secret, Secret, and Confidential Restricted Data, National Security Information, and Formerly Restricted Data.

- *Questionnaire for National Security Positions, Part 2.* The annual submission of this information enables DOE Personnel Security to update the personnel security file, which is reviewed annually to ensure that security concerns are identified.

- *Signed releases, acknowledgments, and waivers.* Cleared individuals must review and sign documents to facilitate the collection and dissemination of information and the performance of medical assessments and drug and alcohol testing.

- *Completion of HRP instruction.* HRP instruction must be completed for initial certification and annual recertification. Instruction includes the roles and responsibilities of each HRP-certified individual, including recognizing and responding to behavioral change and aberrant or unusual behavior that may result in a risk to national security, recognizing and reporting security concerns, reporting prescription drug use, requirements for returning to work after sick leave, and the HRP continuous evaluation process.

Presenter: Dr. Gard

Dr. Gard explained that Livermore includes four BSL-2 Select Agent laboratories and three BSL-3 Select Agent laboratories, with 12 people currently approved to work at the BSL-2 Select Agent level and four people authorized to work at the BSL-3 Select Agent level. The origins of Livermore's Select Agent Human Reliability Program (SAHRP) are from the nuclear arena, which is Livermore's main mission, and therefore part of the culture of Livermore.

After summarizing the history of the SAHRP at Livermore and reiterating the basic tenets of the DOE HRP, Dr. Gard contrasted Livermore's SAHRP with the DOE program. The SAHRP does not require a Q clearance because it needed to draw its personnel in part from a pool of foreign talent. The other differences are that no polygraph testing is required, and the written psychological evaluation is replaced with an annual semi-structured interview with a psychologist.

The annual personnel security review is performed locally at Livermore or Los Alamos and not by the DOE as is the case for work with nuclear materials. Therefore, certifying officials for the SAHRP are Livermore and Los Alamos employees.

Lessons learned and concerns include:

- The SAHRP requires many biologists who come to work at Livermore to adapt to a new culture of security.
- Restrictive guidelines result may complicate recruitment of personnel.
- Instituting the new two-person requirements has had a powerful economic impact on Select Agent operations.
- At smaller scale facilities like Livermore, a two-person requirement is more difficult to implement due to smaller numbers of authorized workers.
- The SAHRP is required for those with unescorted access to Select Agents, which helps mitigate the security risk of allowing researchers to work alone.

Discussion

In response to questions about the potential cost of these programs, Dr. Gard explained that, by funding the SAHRP, Livermore becomes less competitive because of an increase in overhead costs. At Livermore there is little thought that concerns related to Select Agents will be downgraded, however, so the culture of security comes at a cost that is not trivial to offset. If all other laboratories were required to implement similar security features, Livermore would be more cost competitive.

As to whether work that goes on in the Livermore laboratories could be conducted in another federal site that would be a shared facility, as is being contemplated for NIH-funded research, Dr. Gard responded that some projects are coordinated with other institutions, although some categories of projects need to be maintained at Livermore depending on the sponsor. There will always be a category of work that needs to remain at Livermore rather than collaborating with universities; for example, Livermore can require a worker to have Top-Secret clearance in order to work on a particular project, thus instituting information security requirements in addition to physical security requirements.

Dr. Cole added that most of the DoD security policy is not written by experts in the biological, chemical, or nuclear fields; policies are written by intelligence specialists. These policymakers must be educated, for example, about the difference between BSL-3 agents and Select Agents, to understand that the biological safety level is an engineering control for safety with the worker in mind and not necessarily to deal with the danger of the agent, and to understand that Category A agents could be used as weapons. He noted that this education is challenging.

Regarding the impact of new regulations on the transportation of BSATs, Dr. Cole explained that the U.S. Navy is the major operator of the overseas laboratories. Transporting Select Agents under the current regulations would add approximately $3 million to costs, part of which cost is the need to use military aircraft to transport samples – an especially prime commodity because of the conflicts currently being waged.

Dr. Cole reported that, in his experience in the nuclear and chemical arenas, self-reporting worked well and required relatively little peer reporting as a result. The DoD requires an annual medical review and trusts the judgment of the medical review officer as to whether a psychological review is necessary. In order to conduct the psychological reviews, Dr. Cole noted the challenge of having an adequate number of psychologists and psychiatrists who can conduct a review and who are also trained as medical review authorities.

In response to a query about whether the potential consequences create a disincentive to self report, Dr. Gard explained that, since Livermore is a large institution of approximately 7,000 people, with areas other than laboratory work that can utilize biological expertise, if someone is not allowed to have access to Select Agents there are other opportunities and it is considered a shift of assignment.

Dr. Weyant reported that, in approximately 100 cases of restrictions, institutions have found other places for these people to work; however, there is one active lawsuit in which an individual claims to have been damaged by restricted access.

Dr. Cole explained that the DoD has many other places for disqualified individuals to work; however, reassignment depends on the reason why the person was disqualified. For example, failure to disclose disqualifying information is grounds for termination, which encourages people to come forward so they will be reassigned and not terminated. However, Dr. Lemon noted that, from a university perspective, individuals are often hired to a specific grant and their employment is dependent upon their ability to work on that grant.

Regarding implementing the DoD program across the entire CDC Select Agent system, Dr. Weyant reiterated that approximately 12,000 individuals are actively working with Select Agents. A number of issues would have to be addressed if the current procedures were changed. For instance, if everyone working on a Select Agent had to undergo the equivalent of Top-Secret clearance, each investigation would take nearly one year, which would be difficult to implement at most universities. Dr. Gard added another significant challenge: the funding agencies would have to change their culture in order to deal with the resulting backlogs in the system.

Dr. Cole explained that contractors are held to the same standards as DoD employees because they are being provided with the same Select Agent material; the DoD instruction is written to cover DoD-owned biological Select Agents and Toxins. With respect to grants, the product is knowledge, not a Select Agent as a material product, and hence grantees are not typically subject to these security requirements and can conduct the research without having to use Select Agents. Most of the academic research that has involved Select Agents has been conducted at DoD laboratories; however, all incoming personnel are subject to security clearances.

Dr. Gard elaborated on the "culture shock" for biologists who come to Livermore and have to comply with the SAHRP, which has had an effect on the recruitment and retention of scientific staff. In his opinion, life scientists seem to expect more openness; the biologists come from the university culture, which has open exchange and few, if any, restrictions. For a long time, even biology at Livermore has operated without many of these restrictions. It is only with Select Agents that Livermore has had to overlay the SAHRP requirement on biological research. The added regulations and the pace of change are what constitute the "culture shock."

Regarding reporting of medications, Dr. Cole said that active military personnel involved in the HRP have that involvement on their medical charts, so when a new prescription is written for that individual, notification is automatic. Dr. Gard added that Livermore employees are proactive in reporting any medications to the medical services for adding to the employee's medical chart, in part because of the random drug and alcohol testing.

In reference to how much time it takes to staff up, Dr. Gard explained that Livermore's SAHRP requirement runs roughly in parallel with getting someone certified for CDC approval. Although all the certification processes are started at roughly the same time, there is approximately a three-month lag time between when an individual is first offered employment to when the employee can begin working in the laboratory, which includes the safety training (which also starts at the same time).

Dr. Cole discussed cost issues. The workers at Battelle and within the DoD already have clearances, since a condition of being hired by the DoD is to be able to pass the background checks to obtain clearance, therefore the cost of obtaining those clearances is not known. The Battelle laboratory in Ohio has billed $1.5 million to implement the additional security standards of the BPRP, however, and it has cost the Navy almost $600,000 to execute the BPRP for the 76 people enrolled. Dr. Weyant stated that the original Select Agent regulations in the mid-1990s were designed to be self-supporting through user fees; the program had to be redesigned to not be self supporting because that concept was not well accepted by the scientific community, in particular by the American Society for Microbiology.

Dr. Sorenson queried how such requirements as the two-person rule or the elaborate security clearances would be funded. Dr. Lemon added that if onerous and time consuming rules are imposed, young scientists will choose an easier career path and not work with Select Agents. As a result, these BSATs will not be studied in an academic environment. Dr. Gard commented that, to counterbalance all the restrictions, enticements should be considered to encourage people to choose research in those fields, which is an additional cost.

Ms. Beardsley stated that none of these security programs could be implemented widely unless the USG paid for them.

Dr. Cole explained the security clearance process for foreign nationals – a security clearance process called a "limited authorization access" involves as many elements of the background checks as possible. With host nationals in overseas laboratories, the DoD relies on the State Department; that clearance is a lower standard than what DoD currently has for its own employees. The databases that are used for both Q clearance and Top-Secret and related clearances are generally available. Cost and time issues are mostly related to interviewing personal contacts and other labor associated with the investigation.

Dr. Keim observed that, currently, the CDC covers the cost of these investigations; universities do not pay for clearance investigations.

Dr. Cole noted that one of the biggest differences between the risk assessment conducted under the Select Agent Rule and the security clearance process conducted through the DOE and the DoD is interrogating the people who have the social knowledge of the individual, with the goal of obtaining opinions as to reliability and dependability. Ms. Beardsley added that another difference is the FBI/CJIS being bound in the SRA process by the "sole purpose clause," which provides that the FBI must investigate whether the subject individual meets any of the restricted categories; the CJIS cannot investigate beyond those restricted categories.

Speaking as the Select Agent manager who is responsible for the activities in Livermore's laboratories, Dr. Gard opined that the local efforts to monitor drug and alcohol use and developing a current psychological profile adds a level of comfort. Even if a Top-Secret security background check is conducted, financial or emotional conditions in people's lives can change quickly, therefore, to have an indication about someone's current state of stability is valuable.

Dr. Cole noted that, traditionally, robust research programs have prevented the element of surprise and allowed technological superiority. However, what is lacking in discussions of Select Agent research compared with the chemical and nuclear communities' research is threat assessment studies – an estimation of the actual risk posed by these agents in the forms and volumes in which they are found in laboratories. The intelligence community following the investigations has been tasked to make those assessments; evaluation of the risk posed will underpin the security requirements.

Dr. Keim asked whether it would be possible to conduct an effective biodefense research program in a sensitive but unclassified way in this country. Dr. Cole responded that laboratories that have similar conditions could validate the research. Much of the research in biodefense is medical countermeasure development, primarily looking at systems biology approaches. Work on a highly pathogenic strain could be validated on a vaccine strain at another laboratory to which the Select Agent Rule would not apply. Even though security and personnel reliability constraints are in place, the science itself is unclassified and civilians without clearance are allowed to review the medical research processes, thus providing some transparency.

Dr. Staley predicted that, if the United States institutes a burdensome security system, scientific research would shift to other countries. To avoid that scenario, it would be important to find a mechanism that achieves international harmonization – reaching for the goal of safe laboratories and safe experiments while maintaining an equal playing field across the international research community. He urged the NSABB to recommend an examination of the extent to which PRPs increase safety and to make sure that the value of these programs is comparable or greater than other measures that might be undertaken. He added that transparency in the appeals process would be important.

Dr. Cole emphasized that the DoD is not able to harmonize its procedures with those of any other organization because it is obligated to take whatever steps are necessary to safeguard its own materials to the confidence of its leadership. He expressed DoD's understanding that doing so may drive the DoD out of certain areas of research, and its hopes that, in the Nation's best interest, HHS, DOE, and others will pick up research in those areas of national concern.

Dr. Rubin cautioned that one untoward event could destroy the public's shaky perception of universities and their scientific research. Dr. Fraser-Liggett expanded those concerns by stating that if a two-tiered

system were implemented in which the DoD and academic institutions each had their own levels of security, an incident that occurred in an academic setting would put all academic research at risk; the public would react negatively to the decision that the "gold-standard" DoD regulations were too difficult to implement. Dr. Erlick noted that whatever system is recommended by the NSABB, it will have to pass the test of being reasonable to the public, to which Judge Ehrlich agreed.

Dr. Kasper noted that BSATs, unlike nuclear weapons, are available throughout the world, including in the most underdeveloped countries, on farms, in the soil, and in animals. Limiting access to these agents is an insurmountable problem when viewed from that perspective.

Personnel Reliability Working Group: Preliminary Findings and Recommendations

Presenter: Dr. Kasper

Dr. Kasper presented the PRWG's progress toward a draft report and discussed the general approach the PRWG has taken. The PRWG had identified eight principles that underpin a vision to guide the oversight of Select Agent research. The group then discussed the aims of an optimal personnel reliability program as well as the potential scope and applicability of such a program. With that platform established, the PRWG had turned its attention to identifying those elements necessary to achieve these aims. Dr. Kasper focused on the PRWG's thinking regarding the vision, guiding principles, aims, and applicability.

The vision drafted by the PRWG states that personnel approved for access to BSATs should behave in a responsible and trustworthy manner that upholds public health and safety, national security, and the integrity of the scientific enterprise. This vision should be fostered by the entire research enterprise and upheld as best as possible by a personnel reliability program. Eight guiding principles support the vision statement:

- *Importance of research on Select Agents.* Research on Select Agents is critical to public health and national security.

- *Role of personnel reliability programs.* These programs are a tool to help make certain that reasonable measures have been taken to ensure the competency of individuals with access to Select Agents and, to the extent possible, their intent and reliability. When rigorously implemented and enforced, personnel reliability measures can enhance the security of Select Agent research, maintain the safety of laboratory personnel, and help earn and maintain public trust.

- *Need for balance.* The oversight of Select *A*gent research must balance the need for security with the need for continued scientific progress that contributes to public health, food safety, economic viability, and national security.

- *Personal responsibility.* Individuals with access to Select Agents have an ethical obligation to recognize and help mitigate the risks posed by the accidental release or intentional malevolent use of these agents.

- *A culture of mindful trust.* The research enterprise will benefit by fostering a strong culture of responsibility, trust, and awareness within the scientific community regarding work with BSATs.

- *Public trust.* Building and maintaining public trust is a responsibility of the entire scientific community. Taking measures to ensure the reliability of individuals working with BSATs will help to allay public concerns about such research. Demonstrating that the scientific community is acting responsibly and proactively to protect public health and security will strengthen public trust regarding Select Agent research.

- *Communication and transparency.* An efficient and effective PRP requires ongoing dialogue among the scientific community, government agencies, and the public. Transparency regarding the personnel reliability measures implemented for work with Select Agents will help build confidence in the ability of the scientific community to responsibly conduct Select Agent research, with the possible added benefit of discouraging those with harmful intent from attempting to divert Select Agents.

- *Need for periodic evaluation.* Despite the inherent difficulty in assessing the effectiveness of a PRP – since it is difficult to know what did not happen due to the implementation of these measures – it is nonetheless important that PRPs be evaluated periodically both for effectiveness and for impact on the research enterprise.

The aims chosen by the PRWG for an optimal personnel reliability program are to mitigate the risk of theft, loss, and intentional or accidental release of Select Agents and Toxins by individuals approved for access to Select Agents and to accomplish this in a manner that does not impede the progress of science. Toward these aims, the PRWG recommended that a PRP should apply to all individuals requiring unescorted access to Select Agents and Toxins and to all individuals who are required to receive a security risk assessment under the Select Agent Program.

Regarding the next steps, Dr. Kasper reported that the PRWG has begun to discuss the specific personnel reliability measures that will help to achieve the vision and aims, although specific recommendations had not yet been crafted, and to discuss the roles and responsibilities of the entities in an optimal program; both of these points will require considerable additional discussion. The PRWG has also identified the need for some additional briefings, including learning how some academic institutions with high maximum containment laboratories are addressing personnel reliability, and some of the tools and methods for psychological assessments and the sensitivity and utility of these tools for predicting behavior. The PRWG has also decided to review the personnel reliability practices in the private sector in working with pathogens as well as risk assessment in other arenas such as the financial and insurance sectors.

Discussion

Judge Ehrlich and Dr. Erlick expressed the need for additional time for the PRWG to meet its reporting obligations.

Dr. Franz requested that NSABB members keep in mind the slippery slope argument – that controlling the insider threat could expand to be applicable to areas other than Select Agents and Toxins, such as synthetic genomics or nanotechnology.

Judge Ehrlich noted that the ultimate protection of science in the United States is the public trust, which requires the PRWG to be thoughtful and transparent in its deliberations about how these changes might affect research.

Dr. Levy suggested that the PRWG recommend guiding strategies for academia and industry that are workable and comprehensive, including a redefinition of “Select Agent.”

Dr. Casadevall expressed his concern that regulations to increase security could end up reducing security because they inhibit research, which is the engine that drives productivity and allows development of countermeasures. It should be possible to debride the Select Agent list significantly to make strains available for legitimate research that will benefit biodefense and other aspects of the biomedical enterprise; for example, anthrax toxins have been developed for anticancer therapy.

Dr. Rubin noted that the real challenge for the PRWG and the NSABB is to educate the public to understand the complexity of research with Select Agents and Toxins. He also suggested that the phrase “eliminate the risk” should not be used, and no one should be held to a standard of eliminating or

preventing risk; "risk" related to research with Select Agents and Toxins can only be reduced – not eliminated.

Noting that universities do not work with weapons, Dr. Lemon stated that any PRP focusing on weapons sends an incorrect message. He also suggested that an effective PRP must be developed locally and centered on the local institutional level; this principle should be incorporated into the guiding principles.

Dr. Keim suggested that an evidence-based investigation could inform the PRWG's recommendations and report to develop a useful program. Such an investigation could focus on assessing a program based upon surrogate markers (e.g., drug use and mental state) and then conducting comparative studies.

Dr. Imperiale explained the importance of educating the public and letting the public know that the NSABB is aware of the issues and that the scientific community, the federal government, and the security community are doing their best to ensure that something bad does not happen. If something bad does happen, he hoped that the public would understand that the purpose of this research is to try to improve life and that, unfortunately, the risk of such events cannot be eliminated completely.

Dr. Cole noted the problem of vocabulary because historically, the term "Select Agent" has been used to identify chemical and biological weapons in offensive weapons programs.

Regarding future meetings of the PRWG, Dr. Kasper explained that several additional working group meetings would be held. After those additional meetings, the PRWG will return to the full NSABB with a more detailed report, having taken into consideration the discussions at today's meeting. He added that any NSABB members who would like to join the PRWG's deliberations were welcomed to do so; they were requested to contact Dr. Patterson. Dr. Lemon suggested that one of the briefings feature a synopsis of the program in the United Kingdom that successfully restricted 100 people from having access to research laboratories.

NSABB Working Group on Outreach and Education: Presentation and Discussion of Outreach and Education Plan

Presenter: Dr. Imperiale, Chair, NSABB Working Group on Outreach and Education (WGOE)

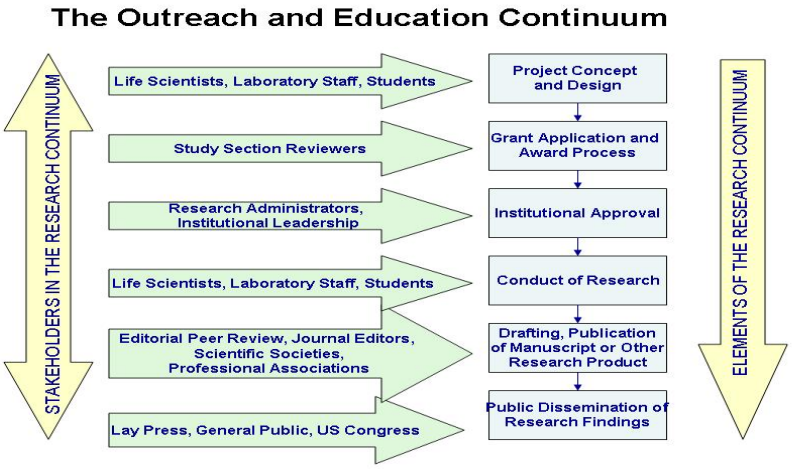
Dr. Imperiale discussed the activities and the strategic plan developed by the WGOE. He hoped that, if the plan is approved by the NSABB, the WGOE could move forward with its agenda. The impetus for the formation of the WGOE was the ongoing concern about the lack of awareness of the dual use issue and the need for concerted education and outreach efforts. Before embarking on the development of an outreach plan, the NSABB first had to formulate concepts and definitions of dual use research of concern (DURC) and identify key stakeholders.

Prior and ongoing outreach efforts by the NSABB members and staff include:

- Educating the scientific community and the public
- Apprising the research community on the status of federal policymaking
- Promoting thoughtful input from stakeholders
- Providing a Web site as the portal for NSABB information, along with an email address for public queries regarding the NSABB and an OBA listserv
- Offering presentations and workshops to key constituency groups about the nature of the dual use issue, the origins of the NSABB, and activities and work products of the NSABB
- Exhibiting at major meetings in conjunction with a recombinant DNA exhibit and as a stand-alone NSABB exhibit
- Ensuring stakeholder input into the NSABB work products through roundtables, focus groups, and presentations to stakeholder audiences

- Engaging the international life sciences community via international roundtables held in February 2007, October 2007, and November 2008

The WGOE developed goals for future efforts, foremost of which is that stakeholders should have opportunity for robust input into federal policymaking regarding dual use research of concern (DURC). Once the USG responds to the NSABB recommendations by implementing a policy, the government will need to undertake education about the specifics of that policy, using various means and tools of communicating the message. Key considerations that will be important in communicating that message include the characteristics of the audience(s) and the best way to distribute the information. Dr. Imperiale presented a diagram of the target audience continuum:



The WGOE has determined that the following key message points should be part of the outreach and education plan:

- Life sciences research is a critically important national endeavor.
- The potential for inflicting harm exists, most likely from someone intent on doing harm, but it is possible to minimize that risk.
- A culture of responsibility should be maintained and increased; the scientific community needs to be responsible for its scientific research. Because of the significant accountability to the public, the scientific community needs to show the public that it is being responsible.
- Ongoing vigilance is needed; often there are unintended results to experiments and new and emerging technologies might present new DURC issues.
- Broad stakeholder engagement is needed from within the scientific community, as it is the responsibility of scientists to educate broadly – not just among those involved in research today but also among those who might engage in research in the future.
- It is critical to maximize awareness of the DURC issue within the entire (larger) community.
- Public trust is essential to continuing support of the research enterprise.
- To foster continued public trust, scientists must implement measures to reduce the risk of misuse to whatever degree possible.

The WGOE presented seven additional recommendations to the NSABB:

- Outreach and education efforts should be coordinated across federal agencies and with those efforts undertaken at academic and private institutions.
- Using existing NIH-mandated training programs would be a good start; training in research responsibility and ethics for graduate students and postdoctoral students on training grants is now required.

- Secondary school students should be educated; reaching students beginning to work in biology will help them understand their responsibility as they engage in science. Their teachers should also be educated.
- U.S. commercial research entities and international audiences should be educated.
- NGOs can help with outreach and education.
- Standardized tools are needed. The education message will have to be tailored depending on the audience, but some baseline, agreed-upon standards are needed so that at least the minimal message is delivered.
- Evaluation is needed to determine whether these education efforts are working. Evaluating effectiveness might be difficult; two suggested possibilities were measuring whether scientific misconduct decreases and whether training programs are being undertaken.

Discussion

Comments included suggestions to:

- contact the National Council for University Research Administrators through their Federal Demonstration Partnership,
- to include a recommendation to fund the WGOE's recommendations so as not to impose an unfunded mandate, and
- to educate the opinion leaders in the security arena of the weapons of mass destruction community.

NSABB Motion 2

Upon motion and second, the Board voted unanimously by voice to accept the report of the NSABB Working Group on Outreach and Education and the plan as presented by Dr. Imperiale.

Update: Federal Response to NSABB Reports on Synthetic Genomics and Oversight Framework for Dual Use Research

Presenter: Dr. DiEuliis

Dr. DiEuliis provided an update on the implementation of security policy actions related to synthetic DNA. She summarized how policy is generated in the Executive Branch through the Policy Coordinating Committees (PCC) of the National Security Council and the Homeland Security Council which are the main forums for interagency coordination and national security policy. She enumerated the eight tasks handed out to the sub-PCCs on the synthetic Select Agents and provided a brief update on the status of each.

1. The Select Agent Regulations (SAR) were developed by the USDA and HHS in partnership with the Department of Commerce. An advanced notice of proposed rulemaking to potentially modify the SAR has cleared sub-PCC review and must go through several other levels before it can be published in the *Federal Register* for public commentary.

2. Developing a screening infrastructure for customers and sequences,which is the responsibility of HHS, has cleared the sub-PCC and PCC reviews. The next step is to fine-tune the details of each component.

3. Conducting international dialogue and outreach is the responsibility of the DoS. The draft outreach strategy has been produced and the sub-PCC has agreed that it is a good plan.

4. Resolving the smallpox language in 18 U.S. Code section 175c has been completed by the DoJ, in an opinion letter that clarifies the agency's understanding of that language. The CDC has posted this letter on its Web site, and it was transmitted to Select Agent officials and institutions that are cleared to conduct Select Agent research within the United States.

5. Updating the biosafety guidelines in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) and the *Biosafety in Microbiological and Biomedical Laboratories* manual (*BMBL*) was the responsibility of HHS. Dr. Patterson led this effort and worked through the NIH Recombinant DNA Advisory Committee (RAC) to suggest changes to the *NIH Guidelines*. A *Federal Register* notice has been drafted and will go out for public comment shortly; after public comment is received, the *BMBL* revisions could follow.

6. Reconciliation of the Commerce Control List (CCL) and the SAR must wait until Task 1 is completed, so this task is yet to be worked on. The CCL is being revised within the next year. The DoC is working on this task, partnering with HHS and the USDA.

7. Convening a panel to revise the SAR with synthetic DNA advances.

8. Developing a predictive oversight framework is the responsibility of HHS, which has contracted with the National Academies to conduct a study to identify the scientific advances needed to enable prediction of biological function from primary nucleic acid sequence.

Regarding DURC, Dr. DiEuliis stated that the NSABB report has been delivered to the Executive Office of the President and briefings from throughout the USG have been received. After the Presidential transition a decision will be made as to the "home" within the USG for deliberations about the dual-use framework. At present, those discussions will occur in the Biotechnology Subcommittee, within the Committee on Science within the National Science and Technology Council.

Presenter: Dr. Mazanec

Dr. Mazanec briefed the NSABB on the public consultation meeting that occurred on July 15, 2008, on the topic of the oversight report. The purpose of the meeting was to gather stakeholder input on the proposed framework for the oversight of DURC. The meeting was well attended and focused on the issues that the NSABB identified in the report as being ripe for public comment as well as some of the questions raised in the report. This one-day meeting was organized into three panels, each of which focused on a specific issue area and a specific set of questions. The invited panelists represented various stakeholder groups; they made a formal presentation and then the panel members received public comment and had a dialogue with each other and the audience. The three areas of focus were the criterion, the code of conduct, and the outreach strategies.

Panel I focused on the criterion for identifying DURC; panel members were asked to respond to three major questions. The most frequently heard comments included that greater specificity would be more advantageous and would probably promote a more consistent implementation. Several people mentioned a list-based approach, and some of the examples of lists included the Select Agent list, the research with agents classified under Risk Group 3 or 4 under the *NIH Guidelines*, the seven experiments noted in the National Research Council report, and the seven examples in the NSABB report. In general, commentators stated that the NSABB was wise in trying to narrow the scope of DURC to the types of research that posed the greatest potential risk.

Panel II focused on identifying and overseeing DURC; specifically, who should make the decision as to whether or not research constituted DURC and the roles of the principal investigator (PI), the institution, and the federal government. Comments were varied on the oversight system and included an oversight system that would provide guidance and might be more voluntary than mandatory. There was discussion about oversight being tied to federal funding of research and there were also comments about a regulatory approach and promulgating regulations. There was also discussion about the role of the

principal investigator (PI) and whether or not the PI should make the initial determination as to whether or not research constituted DURC. While apparently all agreed that the PI may be in the best position to make that determination, it was felt there was added value in having a committee also involved in evaluating research for DURC potential. With respect to federal requirements, everyone believed that requirements across the USG should be harmonized.

Panel III focused on guidance and educational resources. Several impressive private sector educational initiatives were discussed and mentioned as potential models for outreach efforts. It was widely believed that educational efforts must be applied broadly and that these efforts may need to reach below the college level to pre-college students. Outreach to commercial laboratories, international partners, and the public were noted as important. A comment was offered that education about dual use research must stress close communication and mutual learning among stakeholder groups, with the goal of developing, sharing, and refining best practices regarding management and communication strategies. It was also recommended that a more comprehensive communication plan be developed.

Some participants suggested key message areas on which to focus. It was widely agreed that the scientific community must take a central role in participating and defining the problems with and solutions to the conundrum of dual use research. Although awareness is necessary and communication and outreach can raise awareness, it may not be completely sufficient; guidance or other requirements may need to be developed so that all stakeholders know how to respond appropriately to a problem or a situation. It was also strongly believed that scientific societies and professional associations have an important role to play, and that they could function as the conduit for information among member scientists. They could also educate each other and be an important educator of the public.

Participants believed that the NSABB should play a continuing advisory role in outreach and education strategies by reaching out to stakeholder groups, participating in message formulation, recommending training curricula mapped to federal policy, and suggesting tools and educational materials. As for the federal government, dual use research (DUR) should be a required topic for NIH-mandated ethics training and the federal government should stimulate the development of private-sector training initiatives that might include hosting roundtables, doing community outreach, and providing educational materials.

Regarding the next steps, the NSABB report is poised to go into a federal interagency policy development process that will start in January 2009. The priority of this issue should be balanced with its complexity and the need to allow sufficient time to solicit further stakeholder input as the federal policy is developed. The form of future public consultation will be discussed going forward in the policy development process.

Public Comment

Elisa Harris, University of Maryland, made two points. To be effective, any oversight arrangements must apply to all academic, government, and private-sector research. Risk assessment as proposed only focuses on the potential for intentional misuse or misapplication by others; there exists also the risk of misuse or misapplication by the researcher as well as the risk of inadvertence.

Highlights of the Third International Roundtable: "Sustaining Progress in the Life Sciences: Strategies for Managing Dual Use Research of Concern"

Presenter: Dr. Franz, NSABB International Engagement Working Group Co-Chair

Dr. Franz summarized the results of the international roundtable meeting held on the NIH campus on November 5-6, 2008, which was cosponsored by the USG and the World Health Organization (WHO). Two prior roundtable meetings had been held – in February 2007 for country representatives and October 2007 for NGO representatives. With a focus on the lessons learned, the November 2008 roundtable featured presentations from international colleagues about specific practical activities underway in their countries and organizations. A total of 37 countries, 72 organizations, and 130 scientists attended. The objectives of this roundtable were to determine the scope of other countries' activities in DURC, to share

specific approaches, to inform the international community of the NSABB's and the USG's ongoing work, and to establish and maintain communication with other countries and the international science and policy communities to institute a larger and more robust dialogue on issues related to dual use life sciences research. The meeting was divided into three segments – plenary presentations, breakout sessions, and plenary discussions.

Five plenary sessions were held. Alan I. Leshner, Ph.D., representing the American Association for the Advancement of Science (AAAS), described the relationship between science and society including the tensions that exist, the important role of the scientific community in engaging the public, and the AAAS strategy for communicating with the public to enhance their trust in science and ensure that research is responsive to the needs and priorities of the community.

Paul Keim, Ph.D., a member of the NSABB, presented an overview of the NSABB proposed framework for the oversight of dual use life sciences research.

Robert Orr, Ph.D., M.P.A., Assistant Secretary-General for Policy Planning at the United Nations, described the potential role the United Nations, and specifically the Secretary-General, could play in helping to safely harness and disseminate the benefits of the revolution in biotechnology as a contribution to the Millennium Development Goals.

Ambassador Georgi Avramchev, Chair of the 2008 meetings of the Biological Weapons Convention (BWC), described the role and activities of the BWC in preventing biology from being used for malign purposes and explained how the BWC is engaging with the scientific community to develop a culture of responsibility.

Michael P. Johnson, M.D., M.P.H., Deputy Director of the Fogarty International Center (FIC) at the NIH, described the role and activities of the FIC in advancing global health, fostering international collaboration in science, training international scientists, and building capacity for health research.

A session on managing DURC provided practical issues and lessons learned, and consisted of multiple panels focused on the specific steps taken by various nations and organizations to manage DURC. Presenters focused on the areas of special concentration for the roundtable and concentrated on practical experiences and lessons learned regarding why various approaches were selected and how challenges had been met and overcome.

A second plenary session focused on progress at the national level, including updates on activities presented at the first roundtable and new DURC-related activities. During the discussion session other meeting participants made brief comments on DURC-related activities in their countries.

The third plenary session featured the NGO perspective, with descriptions by various NGOs and intergovernmental organizations on their roles in advancing the management of DURC, including encouraging and facilitating activities at the national and international level, promoting a culture of responsibility, raising awareness, educating stakeholder populations and communities, reviewing research proposals, and reviewing scientific communications.

In the four breakout sessions, each group explored activities and strategies for managing DURC in a specific topic area, developed an inventory of various approaches used to manage DURC in that topic area, and considered the practical experience of developing and implementing those management tools. In addition, the groups reviewed these approaches to identify common themes and principles for managing DURC and developed suggestions for future management activities.

Key concepts that arose from the plenary discussions included:

- Science and society are inseparable
- There is an important need to build public trust and confidence in scientific research, and
- There will be regional and local variation in perceived risk and, as a result, there should be regional and local variation and flexibility in the management strategies provided.

In addition, integrating risk management strategies into existing frameworks will increase awareness and understanding within relevant communities, thus preventing potential negative perceptions from the scientific community that management of DURC is an obstacle while still providing an appropriate and prudent mechanism for protection.

Key concepts from the reports of the four breakout sessions included:

- Awareness raising/training and education: Challenges to an increased awareness of dual use research include the existence of a diverse audience, various levels of training and professional development, and many relevant disciplines. Proposed strategies to achieve goals include developing standard components of educational programs and leveraging current educational efforts in areas such as ethics, biosafety, biosecurity, and responsible conduct of research.

- Culture of responsibility/codes of conduct: There is a need to make codes of conduct relevant to the specific audience and context, to customize existing codes, and to encourage the adoption of codes. A major challenge is to convince individual scientists of the importance of attention to DUR issues and their ethical obligations to mitigate misuse of the results of their research. Involvement of the life sciences community in developing and improving codes of conduct can also serve to educate the scientific community and raise awareness.

- Review of research proposals/guidelines for review: Review must occur across the research life cycle, from project design to proposal review to publication. An enriched review process is needed that includes legal, ethical, biosafety, and security expertise as well as scientific expertise. Review mechanisms need to be transparent and should include academia, government, and industry.

- Scientific communications/presentations and publications: Review of research should be ensured at the time of submission for publications as well as review "upstream." A consistent approach is needed for identification of DURC across various scientific publications, and instructions must be provided to authors and manuscript reviewers to identify and manage risks. To facilitate the review of scientific publications, core systems should be established for journals to share experience and best practices, smaller journals need assistance in reviewing manuscripts for DURC, and a registry of experts should be developed for DURC review.

Moving forward, participants concluded that it will be helpful to continue to develop formal and informal mechanisms for sustained dialogue among all stakeholders; to develop and refine educational tools, including codes of conduct, et cetera, and to share best practices and expertise in and procedures for analyzing and managing any dual use potential in the review of research proposals and scientific communications.

Since the November 2008 meeting, a number of activities have been initiated. All of the participants are now connected to the listserv of the Federation of American Scientists (FAS), so they now have access to the training tools developed by the FAS. This listserv will provide the international working group of the NSABB with electronic communication. *The Journal of Biosecurity and Bioterrorism* will publish some of the presentations from international participants at the roundtable and will report on the roundtable. Opportunities are being explored for interface with the Fogarty International Center at the NIH regarding ethical training and other international efforts. A summary of the November 2008 meeting was presented at the BWC Meeting of States Parties on December 1-5, 2008. Diane Scott-Lichter, president of the Council of Science Editors, has offered to provide more information about DUR to the membership of the Council of Science Editors, and will publish a case study and other activities in some of the journals.

Next Steps and Concluding Remarks

Dr. Kasper noted that the PRWG would continue to meet, primarily via teleconference with one or two face-to-face meetings as its work reaches its conclusion.

Dr. Patterson's office will send out a two-year schedule for full NSABB meetings.

Dr. Kasper thanked the members of the NSABB and the public for their insightful commentaries and adjourned the meeting at 3:35 p.m.

The next NSABB meeting will be held on April 29, 2009.

Date: _____

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Amy P. Patterson, M.D.
Executive Director, NSABB
Acting Director, Office of Science Policy
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