# 3rd International Roundtable
# "Sustaining Progress in the Life Sciences: Strategies for Managing Dual Use Research of Concern"

Co-sponsored by the
United States Government and
World Health Organization
Hosted by the
National Science Advisory Board for Biosecurity
November 5-6, 2008
Bethesda, Maryland

## EXECUTIVE SUMMARY

Acknowledging the importance of international efforts to advance the life sciences for the benefit of human health, animal health, and agriculture and the simultaneous need for global efforts to mitigate the possibility that the knowledge generated through life sciences research might be put to nefarious use, the National Science Advisory Board for Biosecurity (NSABB), has hosted a series of International Roundtables on the subject of managing dual use research. The United States Government (USG) and the World Health Organization (WHO) have co-sponsored two of these Roundtables.

Dual use research (DUR) is defined as biological research with legitimate scientific purpose that may be misused to pose a threat to public health and/or national security. The USG/WHO International Roundtables have been aimed at raising awareness of the DUR issue, sharing strategies to manage the risks posed by DUR, and-- the focus of this most recent Roundtable -- sharing lessons learned from DUR awareness raising and management activities that have been implemented. Over 130 participants from 37 countries and over 72 organizations participated in this third Roundtable to discuss the specific activities of their countries and/or organizations regarding DUR issues and closely related topics. There is a growing recognition on the part of scientists, NGOs, governments, and other stakeholders of the importance of addressing the risks associated with DUR, as evidenced by the range and number of activities in place internationally to manage the risks posed by DUR.

This Third Roundtable was held in Bethesda, Maryland on November 5-6, 2008. The NSABB International Engagement Working Group and WHO served as the Planning Committee for the Roundtable. The presenters and participants explored strategies for managing the oversight of dual use life sciences research as well as strategies for fostering international awareness and engagement on dual use research issues, primarily through presentations by countries and organizations that have taken concrete, practical steps to manage dual use research. The specific focus of this Roundtable was on a subset of dual use research termed "dual use research of concern" (DURC). This is considered research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel. The emphasis at this Roundtable was on concrete practical activities currently underway to manage DURC.

The objectives of the Roundtable were the following:

- Determine the scope of countries' activities, interests, and concerns pertaining to dual use life science research, including strategies for managing dual use research of concern;
- Share specific approaches taken by different countries and institutions in managing dual use research of concern and lessons learned from the implementation of these approaches;
- Inform the international community about NSABB work products and the development of USG policy; and
- Establish and maintain communication with other countries and the international science and policy community to establish a larger, more robust dialogue on issues related to dual use life sciences research.

The Roundtable consisted of a series of plenary presentations on the morning of both days, breakout group sessions in the afternoon of both days, and plenary sessions at the end of each day where the breakout groups reported to the entire Roundtable.

Plenary presentations included: a keynote presentation on the relationship between science and society; a presentation that reviewed the NSABB *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing* t*he Potential Misuse of Research Information*, focusing on the various points in the research continuum where interventions can be made to identify and manage DURC; a presentation on the potential role that the United Nations, and specifically the Secretary-General, could play in helping to safely harness and disseminate the benefits of the revolution in biotechnology; a presentation on the role of the Biological Weapons Convention; and a presentation on promoting global health research that focused on building partnerships and training the next generation of researchers.

There were three panels of presenters. The first panel focused on the steps taken by various nations and organizations to address DURC. The presentations described relevant activities, including how they were developed and implemented. Presenters focused on practical experiences and lessons learned, including why various approaches were selected and what challenges have been met and overcome in the execution of these approaches.

The second panel of presenters discussed progress at the national level, where representatives from a number of countries that attended the first USG/WHO International Roundtable, in February 2007, made presentations on the views and activities of their country which were relevant to the issues of DURC. Other meeting participants made brief comments and updates on DURC related activities in their countries.

The third panel of presenters explored the role of non-governmental entities in the management of DURC. The session focused on how various non-government entities (e.g., intergovernmental organizations, science academies, industry, etc.) perceived their role in advancing the management of DURC – through 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.

The main work of the Roundtable took place in the four breakout groups where information and ideas were shared and structured discussions occurred. Each of the four breakout groups addressed a different topic and reported on their findings and recommendations at the last session of the Roundtable.

- *Awareness Raising/Training and Education.* Some challenges to increased awareness of dual-use research include: the diverse audience (academia, industry, and government), the various levels of training and professional development, and many relevant disciplines. There is a need to move to a broader dialogue – across scientific disciplines, at all levels of training and professional development, and beyond the scientific community. Proposed strategies to achieve the goals of heightened awareness and increased education include development of standard components of educational programs and leveraging current educational efforts in various areas, e.g. ethics, biosafety, biosecurity, responsible conduct of research.

- *Culture of Responsibility/Codes of Conduct*. There is a need to make codes relevant to the specific audience and context they are intended for, to customize existing codes and to encourage the adoption of codes. There are challenges to implementing codes of conduct. These include convincing individual scientists of the importance of attention to dual use research 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.* The review of research must occur across the research life cycle from project design to proposal review to publication. Furthermore, there is a need for an enriched review process that is transparent and includes legal, ethical, biosafety and security expertise as well as scientific expertise from academia, government, and industry.

- *Scientific Communications/Presentations and Publications*. There is a need to ensure “upstream” review of research as well as review at the time of submission for publication. It is also important that there be a consistent approach for the identification of DURC across various scientific publications. Editors should work to define an appropriate review process and provide instructions to authors and manuscript reviewers for the identification and management of risks. In order to facilitate the review of scientific publications it would be valuable to establish core systems by which journals can share experience and best practices, advise smaller journals in the review of manuscripts, and develop a registry of experts for this review.

Throughout the Roundtable numerous common themes for the effective management of DURC emerged. While each country, region, scientific discipline, sector, institution, investigator, etc. will need to consider issues associated with DURC relevant to specific interests, needs, and circumstances, there are common elements and considerations across the board. On behalf of the conference co-sponsors Dr. Amy Patterson, Acting Director of the NIH Office of Science Policy, highlighted key concepts that emerged throughout the two days of the Roundtable.

- *Science and society are inseparable.* Scientific progress takes place within society and is intended to serve and meet the needs of society. However, to fully realize the benefits that scientific progress offers for human health and well-being there is a need for public trust and confidence. The public wants assurance that scientists are taking every reasonable measure to assess and mitigate any risks posed by the misuse of information generated in life sciences research. Transparency in any mechanism for the management of DURC will be important to achieving public trust. In addition, there is a need for shared responsibilities—strategies to manage DURC will be most effective if investigators, institutions, the government, industry, editors, publishers, and the public are fully engaged in mitigating risks and supporting the sustained advancement of the life sciences.

- *Existing frameworks.* It will be valuable to consider how existing frameworks can be employed to manage DUR. Introducing concepts of DUR into current education, professional responsibility, and review mechanisms may be an effective and efficient way to achieve the goals of managing DURC. Integrating risk management strategies into existing processes will serve the additional goal of increasing awareness and understanding within relevant communities. It will also prevent potential negative perceptions from the scientific community or others that management of DURC is an obstacle while still providing an appropriate and prudent mechanism for protection.

- *Continuums of risk and misuse.* It is critical to recognize that there are continuums of risk and misuse of knowledge, the latter based on intent ranging from research with unanticipated results which could be misused to intentional misuse. In addition, the perception of risk is based on local situations including the natural occurrence of highly pathogenic disease and public health crises. Therefore it is necessary to have a spectrum of risk management strategies suited to the local context.

- *Need for both flexibility and standardization.* Any risk management strategy will have to be flexible to keep pace with advances in technology and maintain relevance to the local context. However there is a simultaneous need for standards and consistency in management of DURC. Regional approaches may be useful at this stage in establishing international standards and guidelines while allowing appropriately flexible implementation at the local and national level.

There are numerous important opportunities to advance the goals of sustaining progress in the life sciences and managing DURC. An important step will be the development of formal and informal mechanisms for sustained dialogue among all stakeholders. Collaborative, long-term relationships are critical. The establishment of networks will facilitate the development and refinement of educational tools and codes of conduct. Furthermore, it will also facilitate the sharing and acceptance of best practices and expertise in, and procedures for, the analysis of any dual use potential in the review of research proposals, journal manuscripts, and other scientific communications.

## I. INTRODUCTION

The United States Government (USG) and World Health Organization (WHO) co-sponsored an International Roundtable, hosted by the National Science Advisory Board for Biosecurity (NSABB), in Bethesda, Maryland on November 5-6, 2008. The NSABB International Engagement Working Group and WHO served as the Planning Committee for the Roundtable. The presenters and participants explored strategies for managing the oversight of dual use life sciences research as well as strategies for fostering international awareness and engagement on dual use research issues, primarily through presentations by countries and organizations that have taken concrete, practical steps to manage dual use research of concern. The focus was on lessons learned from activities that have been implemented.

### A. The National Science Advisory Board for Biosecurity (NSABB)

In follow up to the 2003 report of the National Research Council, "Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma" ("Fink Report"), the USG agreed that a new government policy initiative was warranted to work toward the development of appropriate safeguards against the risks that knowledge generated by dual use life sciences research may be misused. As part of this initiative, the USG established the NSABB to advise the US Secretary of Health and Human Services, the Director of the National Institutes of Health, and heads of all US Federal agencies with an interest in the conduct and oversight of life sciences research. The NSABB was charged to recommend strategies for efficient and effective oversight of dual use life science research, considering both national security concerns and the needs of the research community. The NSABB was also charged to recommend strategies to foster international engagement on dual use biological research issues.

### B. "Dual use research" (DUR) and "dual use research of concern" (DURC)

Dual use research is defined as biological research with legitimate scientific purpose that may be misused to pose a threat to public health and/or national security.[1] The NSABB has identified a subset of dual use research as "dual use research of concern" – "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel."[2]

### C. Previous International Roundtables

The November 2008 International Roundtable was the third in a series of International Roundtables hosted by the NSABB. The planning committee for each of the three Roundtables was the NSABB Working Group on International Engagement. A current roster of the working group is found at Appendix A.

The first "International Roundtable on Dual Use Life Sciences Research," co-sponsored by USG and WHO and hosted by the NSABB, was held on February 26-27, 2007. This Roundtable involved participation by scientific experts and policy makers from 17 countries and focused on determining the scope of other countries' activities, interests, and concerns pertaining to dual use life sciences research and informing other countries and the international community about NSABB draft work products. It was

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[1] NSABB Charter (Revised March 2008). Available online: http://oba.od.nih.gov/biosecurity/about_nsabb.html
[2] NSABB Report: "Proposed Oversight Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" (June 2007). Available online: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

a valuable opportunity to establish communication with other countries and the international science and policy community on these DUR issues.[3]

The second International Roundtable, "Dual Use Issues in Life Sciences Research: A Roundtable on Strategies for Fostering International Engagement," was sponsored by the USG and hosted by the NSABB on October 10, 2007. This Roundtable involved participation by representatives of organizations already engaged in dual use research issues to explore what they have been doing, their experiences, and their perspectives on what needs to be done to further international engagement. The overall goal of this roundtable was to obtain a comprehensive international "status report," to advance the dialogue already begun, to review efforts already underway, and to identify options for actions.[4]

## D. Objectives of the 3rd International Roundtable

This third Roundtable was different from the previous two International Roundtables with a focus on presentations from countries on the concrete practical activities currently underway to manage dual use research of concern as well as extant activities of various organizations. A focus at the Roundtable was on lessons learned in areas where management activities have been implemented. A full agenda for the meeting can be found at Appendix B.

The objectives of the Roundtable were the following:

- Determining the scope of countries' activities, interests, and concerns pertaining to dual use life science research, including strategies for managing dual use research of concern;
- Sharing specific approaches taken by different countries and institutions in managing dual use research of concern and lessons learned from the implementation of these approaches;
- Informing the international community about NSABB work products and the development of USG policy; and
- Establishing and maintaining communication with other countries and the international science and policy community to establish a larger, more robust dialogue on issues related to dual use life sciences research.

Areas of special interest for the Roundtable included: review and recommendations for managing dual use research of concern (DURC) by national-level advisory bodies, reviewing research proposals for DURC, reviewing scientific communications (including publications) for DURC content, training and education, codes of conduct, and raising awareness.

## E. Participants

Over 130 scientists, government officials, representatives from non-governmental organizations, representatives from intergovernmental organizations, representatives from philanthropic and funding organizations, journal editors, industry and ethicists discussed their specific activities regarding dual use research issues and, as appropriate, related topics. Participants from 37 countries and over 72 organizations attended. A complete list of the Roundtable participants is found at Appendix C.

Individuals were selected for participation based on a variety of criteria. Participants included individuals from countries that participated in the 1st Roundtable, countries that have established activities in the oversight of dual use research of concern, countries with a high level of biotechnology development,

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[3] A summary of this Roundtable can be found online: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html
[4] A summary of this Roundtable can be found online: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

countries that are scientific leaders in their region, countries that receive funding from NIH for life sciences research, countries that receive funding from the US State Department for laboratory biosafety enhancement, and individuals and countries recommended by NSABB members or WHO staff.. Participants included individuals involved in relevant dual use issues in their respective countries, senior government officials, prominent members of the scientific community, and others. Geographic distribution was also taken into account. Participants came from countries in all of the six World Health Organization regions (Africa, Americas, Eastern Mediterranean, Europe, Southeast Asia, and Western Pacific). Many participants represented non-government entities and intergovernmental organizations which were selected based on their interest and activities related to dual use research and their engagement in the area of managing dual use research of concern, as well as organizations considered to be critical stakeholders.

## F. Structure of the meeting

The Roundtable consisted of a series of plenary presentations during the mornings of both days, breakout group sessions in the afternoons of both days, and plenary sessions at the end of each day, where the breakout groups reported to the entire Roundtable.

Plenary presentations included several special presentations on subjects relevant to the management of DURC (summarized in the subsequent section) and three panels of plenary presenters. One panel focused on extant activities for the management of DURC and the practical experiences of implementing these activities, one panel focused on the relevant activities of various countries, and one panel focused on the relevant activities of non-government entities.

The main work of the Roundtable took place in the four breakout groups where information and ideas were shared and structured discussions occurred. Each of four topic areas (awareness raising/training and education, culture of responsibility/codes of conduct, review of research proposals/guidelines for review, and scientific communications/presentations and publications) was addressed by a different breakout group. Over the course of the two breakout sessions, each of the four groups explored activities and strategies for the management of dual use research of concern, developed an inventory of various approaches used to manage DURC in a specific topic area, and then considered the practical experience of developing and implementing these management tools. In addition the breakout groups reviewed these approaches to identify common themes and principles for the management of DURC. Each of the four breakout groups reported on their findings and recommendations at the last session of the Roundtable.

## G. NSABB *Oversight Framework*

The NSABB's charge includes proposing a framework for the oversight of dual use research to serve as a springboard for the US government to develop guidance and guidelines for dual use life sciences research.[5] In 2007 the NSABB finalized its report the *Proposed Oversight Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information (Oversight Framework).*[6] The final report was transmitted to the USG and is currently under review.

The *Oversight Framework* outlines appropriate guiding principles for oversight, the key features of the NSABB's proposed oversight system, stakeholders and their roles and responsibilities relative to

[5] NSABB Charter (Revised March 2008). Available online: http://oba.od.nih.gov/biosecurity/about_nsabb.html
[6] NSABB Report: "Proposed Oversight Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" (June 2007). Available online: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

oversight, major steps in local-level oversight, and criteria and considerations for the identification and evaluation of DURC, and provides tools to assist in reviewing the risks associated with DURC, in the responsible communication of dual use research, and in the development of a code of conduct. A brief summary of the Oversight Report can be found at Appendix D.

At the International Roundtable, Dr. Paul Keim, member of the NSABB, presented a summary of the NSABB's proposed framework, focusing on the need for management of DURC across the research life cycle – from project concept to communication of research results – and the NSABB's recommendations for management strategies at the various areas of special interest for the Roundtable.

Link to Dr. Keim's presentation summary.

## II. PLENARY PRESENTATION SUMMARIES

### A. Keynote: The Societal Context for Dual Use Research

*Presenter:* *Alan I. Leshner, Ph.D.*
*Chief Executive Officer*
*Executive Publisher,* Science
*American Association for the Advancement of Science*

Dr. Leshner provided the keynote address, *The Societal Context for Dual Use Research*, at the opening of the Roundtable. Dr. Leshner focused on the mutual reliance of the science/society relationship, the current tensions that exist between science and society, and the important role of the scientific community in engaging the public. He discussed AAAS's strategy for public engagement, which involves communicating with the public to enhance their trust in science and ensure that research is responsive to the needs and priorities of the community.

Dr. Leshner opened his presentation with a discussion of the context within which science occurs and how society depends on science and science depends on society. In order for people to prosper in modern society, they must have a fundamental understanding of and comfort with science and technology. The strength and growth of nations depends on strong science and technology capacity. Science and technology bring obvious benefits to improve the quality of human life. A strong science and technology enterprise enhances the economic strength and security of nations.

In order for science to prosper, society needs to support and approve the work of the scientific community. However, in recent history, the science-society relationship has grown increasingly fragile. Increasing tensions in this relationship have grown out of factors that are internal to science as well as factors that are external but relevant to science. Scientific misconduct, conflicts of interest, and scandals in human subjects research have caused some tension in the science-society relationship.

Factors external to science have also heightened tensions in this relationship. For example, with the events of September 11, 2001, and the resultant awareness of terrorism, our research priorities have shifted (with a focus on issues such as biodefense and energy security) and the public has realized that science can be put to nefarious use. In addition, there is a degree of confusion about what science is and that engenders a sense of skepticism about science. Skepticism and fear, especially in terms of life sciences and bioterrorism, increase the tensions between science and society.

Tensions arise out of political and economic interests as well. Advances in science, such as increased knowledge about global climate change, have economic implications and, therefore, political implications.

Implementing and addressing advances in knowledge requires the expenditure of resources. In addition, as science advances, we are able to both ask and answer major questions that we have not been able to address before. And some of these questions and answers clash with core human values – for example, values rooted in belief systems and religion.

Dr. Leshner described AAAS's strategy of public engagement to promote harmony between science and society. AAAS's "glocal" strategy of public engagement involves taking global issues and making them locally meaningful. People tend to care about issues that affect their lives directly. This strategy emphasizes communication with the public and includes listening to the public and responding to their concerns and priorities. The strategy both enhances public trust and improves the quality and legitimacy of decisions made by the scientific community. Only by restoring the equilibrium in the science-society relationship will the scientific community be fully able to progress and will society be able to benefit from these advancements.

Link to Dr. Leshner's slides.

## B. Managing Dual Use Research Issues along the Research Continuum

*Presenter: Paul Keim, Ph.D.*
*Member, NSABB*

Dr. Keim discussed managing dual use issues along the research continuum and provided an overview of the *NSABB Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*. He emphasized the fact that the life sciences are moving forward at an accelerating pace, providing the basis for biomedical and public health advances, improvements in agriculture, safety and quality of the food supply, environmental quality, and a strong national security and economy. Nevertheless, good science can be put to bad use.

Dr. Keim provided background on the genesis of the NSABB. The National Research Council of the National Academies issued a report entitled *Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma*, popularly known as the "Fink Report," in October 2003. One of this report's major recommendations resulted in formation of the NSABB. Dr. Keim reviewed the charge to the NSABB, the expertise represented on the Board, the Federal agencies represented on the Board as nonvoting members, and the Board's methods of operation.

In developing the *Oversight Framework*, the NSABB identified several key concepts for a dual use research oversight system. Among these "guiding principles" were the recognition of the important role that the life sciences play in public health, national security, and other areas; the importance of the open conduct and communication of life sciences research; the need to balance the need for security with the need for research progress, and the importance of public trust. The NSABB considered the nature and significance of the DUR problem and concluded that the threat of misuse of research findings exists. The consequences could be severe, but the response to the threat must be measured carefully because the continued rapid progress of the life sciences is crucial to society.

The NSABB determined that DUR is too broad a term to be truly useful. Instead, the NSABB defined the main issue to be dealt with as the more narrow, "Dual Use Research of Concern."

Dr. Keim reviewed other key elements of the NSABB Report, including key features of the proposed oversight system, roles and responsibilities of institutions and individuals, and steps in local oversight of DUR. Most oversight would be accomplished at the local level. (Link to NSABB *Oversight Framework* summary)

The purpose of the NSABB *Oversight Framework* is to provide recommendations to the USG. The report proposes an oversight framework to identify, review, conduct, and communicate life sciences research with DURC potential. It is intended as a framework or springboard for the USG to develop a comprehensive and coordinated DURC oversight policy. The *Oversight Framework* is not intended as comprehensive guidelines but rather as a framework or spring board for the USG to develop a comprehensive and coordinated oversight policy.

The *Oversight Framework* and its component parts – the criterion, the communication tools, the code of conduct – were each developed with stakeholder input gathered through focus groups, roundtables, and other means, including open public NSABB meetings at which each of the products was discussed and debated in depth. Because public consultation is critical to the mission of the NSABB, the USG convened a formal consultation meeting on July 15, 2008, to obtain views from stakeholders and inform further consideration of the NSABB *Oversight Framework* recommendations to assist in the decision as to what final oversight policy for the United States should be adopted.

In conclusion, Dr. Keim emphasized that support for and progress in the life sciences depends on public trust. Effective oversight of DUR will help to maintain public trust. He noted that the course of science would be changed in the next decade based on how DURC is managed.

Link to Dr. Keim's slides.

**C. Managing Dual Use Research of Concern: Practical Issues and Lessons Learned**

> *This session focused on the steps taken by various nations and organizations to manage dual use research of concern (DURC). The presentations described relevant activities, including how they were developed and implemented. Presenters focused on practical experiences and lessons learned, including why various approaches were selected and what challenges were met and overcome in the execution of these approaches.*

***1) National-Level Advisory Bodies***

*Presenter: David Friedman, Ph.D., Institute for National Security Studies (INSS), Consultant to the Israeli Academy of Sciences, and Coordinator, Steering Committee on Issues in Biotechnological Research in an Age of Terrorism, Israel*

Dr. Friedman discussed the activities of the Steering Committee on Issues in Biotechnological Research in an Age of Terrorism (COBART), established 2 years ago in part in response to the publication of the US National Research Council's report *Biotechnology Research in an Age of Terrorism* ("Fink Report"). COBART was established to address biosecurity in the biomedical and life sciences in Israel. Its members are independent experts appointed jointly by the president of the Israel Academy of Sciences and the head of the Israel National Security Council.

COBART's charge was to recommend changes required in Israel's legislative infrastructure; compile a list of biological agents and fields of research that should be subject to oversight; establish a regimen for tracking, supervision, oversight, and legal/regulatory enforcement; and examine the need for a national professional body to guide and maintain biosecurity. COBART was aided in its work not only by review of the NRC report *Biotechnology Research in an Age of Terrorism* but also by work done in other countries, especially including NSABB reports. Of the nine recommendations made by the Steering Committee, the top priority areas were awareness, consciousness raising, and education because the Committee found that DURC was not a well-known topic in the life science or medical communities.

The Steering Committee recommended a two-level model that included national and local level mechanisms and responsibilities for DUR oversight. On the national level, COBART recommended establishing a National Biosecurity Council that would be composed of experts from different areas of biology and medical sciences as well as *ex officio* members from relevant government ministries. The National Biosecurity Council would be located in the Ministry of Health and its members would be approved by the Minister of Health in consultation with the president of the Israel Academy of Sciences and the head of the National Security Council. The National Biosecurity Council would be the policymakers on the national level; they would be responsible for overseeing biomedical research at the universities and medical centers and for overseeing the biotechnology industry. COBART recommended a scientist-based model for oversight at the local level.

The Steering Committee's report and recommendations have been approved by the National Security Council and the Israel Academy of Sciences, with deliberations currently in process in the Ministry of Health regarding implementation. A new law based on the recommendations of the COBART has been approved in the Knesset (Israeli parliament). Preparations are underway for awareness, consciousness raising, and education programs for the life sciences community, with one module supported by a grant from the Sloan Foundation.

Link to Dr. Friedman's slides.

*Presenter: Henri Korn, Ph.D., Editor, Biological Threats, French Academy of Sciences, France*

Dr. Korn discussed a report published in October 2008 completed by the Biosecurity Committee of the French Academy of Sciences and co-authored by Dr. Korn entitled "Biological Threats, Biosecurity, and the Responsibility of Scientists." He provided a general description of this report, its differences from other reports, and what was learned from 2 years of "disconcerting communication" with French scientists.

The recommendations of the French Academy's Report are similar to those of the US National Research Council's report *Biotechnology Research in an Age of Terrorism* ("Fink Report"). A national forum on biosecurity was recommended as a way to raise the awareness of the scientific community, government officials, and the public. Other recommendations included harmonizing international oversight with other European institutions and academies; creating an independent scientific committee for biosecurity, similar to the advisory board of biodefense and oversight, that would act as an interface among and resource for scientists, scientific journals, and possibly the government and intelligence agencies; and adopting codes of conduct for scientists similar to the Hippocratic Oath for physicians.

Other recommendations that differ from reports developed in other countries include:

- The danger represented by malevolent states or groups should be recognized.
- More attention should be paid to international regulation protocols and conventions, particularly to political treaties such as the 1972 Biological and Toxin Weapons Convention (BWC).
- The issue of transparency versus secrecy, critical in the context of freedom of research, is still an issue under discussion. Less secrecy might result in prevention, containment of diseases, respect of the law, and increased public confidence.
- The publication of contentious research could become a source of information for bioterrorists. To deal with this problem, an independent scientific committee for biosecurity that would set the principles to be followed for open versus classified research in publications.

Lessons learned by working on these issues include that scientists and public authorities must work in unison. Scientists can provide the expertise to understand the threats and government authorities can inform the public, promote codes of conduct, and organize experts. Two sociocultural traits help explain some of the difficulties in moving forward on the DURC issue. There is a combination of skepticism and lack of trust by academicians of other people and activities that do not share their professional interest, such as the intelligence, security and military communities. This has deep roots in the social and economic history of France. Conversely, the country's leaders tend to ignore the scientists and the potential hazards. Scientists are considered "irresponsible dreamers." Authorities, however, need to understand that the public must be informed about the potential dangers and the truth cannot be hidden as has been the case in the past.

*Presenter: Koos van der Bruggen, Ph.D., Secretary, Code of Conduct for Biosecurity: Report by the Biosecurity Working Group, Royal Netherlands Academy of Arts and Sciences. The Netherlands*

Dr. van der Bruggen provided the mission statement of the Royal Netherlands Academy of Arts and Sciences (KNAW) and reviewed earlier biosecurity activities in the Netherlands, including a research program for developing means of effective protection against biological weapons, reports of the Dutch Health Council (2001-2002) that provided tools and rules for actions in the case of bioterrorism, and creation of the office of the National Coordinator on Terrorism.

At the request of the Dutch government the KNAW developed a National Code of Conduct for Biosecurity. The Code is directed at preventing a direct or indirect contribution of life sciences research and applications to the development, production, or stockpiling of biological weapons, as described in the BWC, as well as to other misuse of biological agents and toxins. Because the content of a code of conduct must be linked with relevant scientific, social, and political developments and with the daily practice of involved persons and organizations, the Code was developed in an intensive dialogue with stakeholders, including actors from science, government, and industry. The contents of this Code includes raising awareness, research and publication policy, accountability and oversight, internal and external communication, accessibility, and shipment and transport. The target audience for this Code is:

- Researchers and other professionals in the life sciences
- Organizations, institutions, and companies where life science research takes place
- Organizations, institutions, and companies that offer education in the life sciences
- Organizations and institutions that offer licenses for life science research and that fund, facilitate, inspect, or evaluate research
- Scientific and professional unions and organizations of employers and of employees in the life sciences field
- Organizations, institutions, and companies where dual use biological agents toxins are stockpiled or transported
- Authors, editors, and publishers of life science publications and administrators of life science Web sites

Within the Netherlands, the Code has been disseminated in Dutch and English editions. Debates and meetings with stakeholders in research institutes, universities, and companies, and publications in scientific and professional journals have ensured wide dissemination. Audiovisual materials are currently under development. Internationally, dissemination activities have included regional conferences in Africa, presentations at international conferences and workshops, and publication of scientific articles.

Dr. van der Bruggen concluded that the Code of Conduct has contributed to raising awareness on biosecurity in the Netherlands and it has proven to be a useful instrument in combination with other measures and actions. He offered the Code as a possible model for development of codes of conduct in other countries.

Link to Dr. Van der Bruggen's slides.

***2) Reviewing Research Proposals for DURC***

*Presenter: Helen Thorne, Director, Research Councils of the UK, U.S. office*

Ms. Thorne discussed policies and activities that research funders – particularly the UK's Research Councils (the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC)) and the Wellcome Trust – have implemented to help manage DURC.

Earlier in 2008, the British Government published a *National Risk Register*, setting out an assessment of the likelihood and potential impacts of risks that might directly affect the UK. As in other risk assessments, this Register places the risks from nonconventional attacks as relatively low but with potentially very high impacts. The UK systems for managing DURC have evolved over a long time and exist in the context of wider national and international biosafety, biosecurity, and ethical frameworks such as the BWC; six primary UK legislation and statutory regulations deal with DURC (Specified Animal Pathogens Order (1998), Genetically Modified Organisms (contained use) Regulations (2000), Anti-terrorism Crime & Security Act (2001), Control of Substances Hazardous to Health Regulations (2002), Export Control Act (2002), Academic Technology Approval Scheme (2008)). There also exist at least five codes of practice and guidance produced by professional societies.

Research funders (MRC, BBSRC, and Wellcome Trust) have issued a joint statement of common principles for handling DURC:

- Risks from misuse must be balanced against benefits of research.
- Proportionate systems at national and international levels are needed to manage risks.
- Systems should be based on self-governance within the academic community.
- Funders' procedures should enable this approach – funding should be conditional on compliance with legislation and best practices.
- Dissemination of research outcomes is crucial to the scientific enterprise and should be based on self-governance by the academic community.
- Potential misuse should be addressed internationally but should not obstruct collaboration.

The Research Councils, the Wellcome Trust, and other funders make funding decisions based on independent expert peer review and have clear terms and conditions for funding that address ethical issues, produce guidance on good research practice, and have research misconduct policies.

The Medical Research Council (MRC), the Biotechnology and Biological Sciences Research Council (BBSRC), and the Wellcome Trust have similar individual statements for managing DURC. In 2003 the three agencies came together to strengthen their procedures and develop a more consistent policy approach, particularly to look at areas of research not covered by specific legislation. A joint statement issued in 2005 on managing risks from misuse of life sciences research and results offered guidance for applicants, referees, and funding decision makers as well as good practice guidelines.

During the past 3 years, proposals show that applicants are increasingly thinking about issues of misuse and addressing those issues in their applications. To date, only a very small number of proposals have been flagged as potentially causing a concern. None of the agencies report applications that resulted in a serious debate about the merits of the science versus the risks. Wellcome Trust has identified three applications as potentially being DURC over the past three years. BBSRC has identified fewer than a dozen out of over 10,000. In the case of one application that was submitted to BBSRC and flagged as raising dual use concerns the applicant developed a communication plan to mitigate the concerns.

These three funding agencies intend to continue to work together and share experiences, and to include other research councils and other funding bodies in the UK. There is a need for improved awareness raising, especially in areas outside of the regulations. The MRC, BBSRC, and Wellcome Trust support the need for codes of practice, believe there is a need for better coordination of biosafety and biosecurity training, support EU proposals for sharing good practice and awareness-raising efforts, and are committed to building international consensus on DURC.

Link to Ms. Thorne's slides.

*Presenter: Richard Frothingham, M.D., CBSP, IBC Co-Chair and Associate Professor, Duke University Medical Center, United States*

Dr. Frothingham discussed his experiences in reviewing DUR as part of the institutional biosafety committee (IBC) at Duke University. The IBC began reviewing rDNA and select agent research for DUR in 2005, and has continued to review all research that has been brought to it.

Three cases illustrate the IBC review process.

Case 1 (2005) was a proposal to modify ectromelia – a poxvirus lethal in mice – to express a cytokine. The goal was to test a novel therapeutic. The principal investigator (PI) sent this application to the National Institutes of Health (NIH), addressing biosafety and biocontainment but not discussing DUR concerns. The NIH study section reviewers raised the DUR concern and, after discussions, the PI withdrew the application. Formal DUR review was not available at Duke at that time. Such a review might have been helpful to the PI.

Case 2 (2007) involved the use of a retroviral vector to express the light chain of tetanus toxin, which is the active moiety that knocks out neural transmission points inside the neurons. The light chain is not hazardous because it cannot get inside the cells by itself; the retrovirus overcame that inability. The goal of the research was to demonstrate the downstream effects of blocking transmission from some specific neurons. The PI addressed biosafety issues in the application but did not address DUR. After a series of questions from the Duke IBC, the PI changed the application to express a marker gene that would trace the neurons but would not effect their function.

Case 3 (2007) proposed to adapt dengue virus to grow in drosophila. The purpose was to study interactions between the cells and the virus using the genetic toolbox for drosophila. The NIH reviewed the grant favorably. After review and prior to funding, the NIH program raised the DUR question. The PI brought his application to the Duke IBC requesting a review of DUR issues. The IBC considered the knowledge and the material that might possibly be generated and, with four nationally known virologists on the IBC, concluded this research had no meaningful DUR potential. The research proceeded.

Potential outcomes of a Duke IBC DUR review are findings of:

- No significant DUR potential
- Education needed; investigator must complete an online training module.
- More information needed; investigator must provide additional scientific information to assist in the risk assessment process.
- Contingency plan; because a specific outcome of the research could lead to DUR material or knowledge. The contingency plan could include how to recognize the specific outcome, whom to notify, how to secure DUR material, and how to communicate DUR knowledge.
- Modification; investigator is requested to change the research plan to reduce the dual use potential.
- Rejection

The Duke IBC experience indicates that DUR review can occur without a formal regulatory framework or a consensus definition. However, investigators are not ready to identify DUR due to lack of knowledge and a strong disincentive to label their research as DUR due to possible stigma and delays. (Based on the timing of protocol submission relative to the monthly meeting, review by the Duke IBC takes between 14 and 42 days.) IBCs have advantages for review of DUR because they are an existing entity with institutional resources and authority, are experienced in risk assessment, offer "one-stop shopping" for projects using recombinant DNA (rDNA), and have mechanisms for managing DUR. Duke's IBC does not use specific criteria for the identification or evaluation of DUR.

Dr. Frothingham noted some important limitations in using IBCs to evaluate DUR. The Duke IBC has been able to reach consensus on proposals brought before it, despite initial differences of opinions, but it is unknown if other entities would reach the same conclusions. IBCs generally do not capture research that does not involve rDNA, and might not be able to handle the volume that would be involved in reviewing all research at Duke. Expertise is variable among IBCs; Duke has committed substantial resources and money to this IBC but that may not be the case everywhere. While the resource and time costs for the IBC are modest, both benefit and risk are uncertain. No one is known to have been harmed due to misuse of Duke research, but it is unknown whether any "event" has been prevented.

Dr. Frothingham noted that minutes of Duke IBC meetings are public information and are available on their Web site. The published minutes include information on the review of rDNA research for DUR issues. The IBC meetings themselves are open to the public, but the IBC reserves the right to go into executive session to discuss more sensitive topics. That right has not been exercised to date.

Link to Dr. Frothingham's slides.

*Presenter: PhDr. Lukáš Holub, European Commission (EC)*

Dr. Holub presented information about the EC, what the EC asks applicants to do before submitting an application for a grant, what the EC does internally after grant submission, and EC policies regarding DURC. The European Commission can draft proposals for new European laws; propose, manage, and implement policies; and manage and implement financial programs and budget. It is independent from its member state governments and is not engaged in military research, although research activities supported by the EC may have security implications.

All grant application submissions must describe and adequately take into account the ethical aspects, safety, and socioeconomic issues of the project so as to conform to national, European and international regulations. Applicants must fill in an ethical issues table, answering a number of questions regarding research on human embryos/fetuses, research on humans, privacy issues, research on animals, research involving developing countries, DUR, and research having direct military use or the potential for terrorist use.

After a grant application has been submitted, an ethical review begins with an external evaluator and/or the Commission raising ethical issues. Even if the applicants do not flag applications for ethical issues, the EC can submit any proposal to an Ethical Review Panel, which is composed of ethicists from a wide variety of transnational and independent areas; the Panel produces an ethical review report that includes a list of ethical issues.

If an applicant claims there are security implications in the proposed research, the application must go through a security review. In addition, an external evaluator, the EC, or a member state expert from the Program Committee can require a security evaluation. (The program committee members are representatives of the EU's 27 member states who advise the Commission on whether to award proposals.) Any proposal that has been flagged for a security review undergoes scrutiny by an ad hoc "Security Scrutiny Committee" whose members are only from the country(ies) of origin of the proposal. The security review results in one of three outcomes: classification is not required, classification is required, or the proposal is too sensitive to be financed. Minor adjustments have been made to one project that was flagged for dual use concerns, and two classified projects are currently underway.

Mr. Holub also stated that the EC has established a public-private Chemical, Biological, Radiological, and Nuclear (CBRN) Task Force to help identify concrete actions to strengthen safety and security approaches. Key issues for discussion by the Task Force are awareness raising, training and courses, codes of conduct, the role of funding organizations, and security aspects of publication.

Link to Dr. Holub's slides.

***3) Reviewing Scientific Communications (including publications) for DURC Content***

*Presenter: Linda Miller, Ph.D., Executive Editor,* Nature *and the Nature journals*

Dr. Miller discussed biosecurity issues at *Nature* and other scientific journals.

Journals became involved in DURC issues starting with a 2003 meeting at the U.S. National Academy of Sciences, at which editors and security experts discussed the role of journals and editors with regard to DURC. The editor's role has been to uphold the integrity of what is published in the scientific literature and to ensure that enough information is published so the research is reproducible and can be verified. Editors agreed, however, that they would add to their responsibility the assessment of manuscripts of concern for their risk of misuse versus their benefit for public health. A joint journal statement, signed by many journals and publishers, came out of this meeting:

- All papers in peer-reviewed journals must contain enough information to adequately reproduce the results, and editors would not remove methods to make a paper more 'palatable' if it prevents verification and replication.
- Papers that have the potential for abuse would be identified before review and/or publication.
- Consistent internal procedures would be created to handle such papers.
- If a paper were deemed inappropriate for publication as initially written, it would either be modified without compromising its reproducibility or communicated to the scientific community through other avenues.

Dr. Miller noted that the U.S. is bound by National Security Decision Directive 189, which is "To the maximum extent possible the products of fundamental research [should] remain unrestricted. No restrictions may be placed on the conduct or reporting of federally funded fundamental research that has not received national security classification."

The *Nature* journal policy serves many purposes, the first of which is to educate editors about biosecurity. All work of concern is scrutinized by a committee composed of the Editor-in-Chief of *Nature* publications, the Executive Editor of the *Nature* research journals, the Chief Biological Sciences Editor of *Nature*, and the Chief Editor of the relevant journal. If any additional security review is necessary, *Nature* journals maintain a network of advisers on biosecurity. A risk-benefit analysis is requested of referees, using the draft NSABB form, and authors are informed if biosecurity concerns are raised so that modifications can be made. If the decision is to publish, press releases are scrutinized and the editors decide whether or not associated commentary should be published. Dr. Miller presented on the processes used by journals from other scientific publishers that are similar to the *Nature* process for reviewing submissions of concern.

| Step | Nature journals | Science | PNAS | ASM |
|---|---|---|---|---|
| Screen for DURC | Yes | Yes | Yes | Yes |
| Who flags papers? | Editors, authors, referees | Editors, authors, referees, Board of Reviewing Editors | Editors, Board members referees | Peer reviewers through checkbox and journal staff |
| What internal staff are involved? | Standing committee of Editor-in-Chief of Nature titles, Executive Editor of Nature titles, Chief Editor of journal, *Nature* Chief biological sciences editor | Editor-in-Chief, a couple members of Senior Editorial Board | Biosecurity committee of Editor-in-Chief, Executive Editor and Managing Editor (PNAS office made aware) | Editor-in-Chief of journal, Chair of Publications Board (PB) and the PB |
| Scrutiny | Additional biosecurity experts, sometimes general security experts review and fill out the biosecurity risk/benefit checklist | Additional biosecurity experts for review.<br><br>Conference call between subject experts, appropriate Senior Editorial Board members and Editor-in-Chief | After peer review, an appropriate PNAS Board member evaluates biosecurity risk | Consultation of EiC, PB Chair and PB |
| Additional steps | Press release review<br><br>News and commentary consideration<br><br>Biosafety checks | | NAS president and COO made aware of imminent publication.<br><br>Press release reviewed by biosecurity committee before release | |

In the past four years, 74,000 biology submissions have been received by the various *Nature* journals. Only 28 papers of concern have been brought to *Nature*'s DURC review committee; while most of these 28 papers are DUR, they are not DURC and no papers have been rejected due to a high biosecurity risk. At these other journals (*Science*, PNAS, ASM), only one or two papers are reviewed each year as possible DURC and no papers have been rejected for biosecurity reasons since 2003.

Several questions and issues arise about potential publication of a DURC paper: what a journal should do if a risky paper were rejected, whose authority can legitimately order a journal to pause in its publication of a paper, various complexities of jurisdiction of authority. The lack of global standards often leads to ineffective local restrictions. For other global issues, such as informed consent and animal care, journals rely on the sometimes very different local rules of the country in which the research is done. Questions also arise regarding DURC in non-journal publishing, in such venues as university archives, scientist Web sites, methods databases, Internet self-publishing, and preprint archives.

Journals should not be the only safety net, although they represent the final barrier to information spread; over-emphasis on the last step in any process is not wise. Most efforts at detecting DURC belong at the front end, where dangerous research proposals can be identified and classified. The bigger global threat to biosecurity overall is the lack of infrastructure in public health around the world.

Link to Dr. Miller's slides.

*Presenter: Jaclyn Fox, Director of Communications and Publications, Center for Biosecurity of the University of Pittsburgh Medical Center*

The journal Ms. Fox discussed was *Biosecurity and Bioterrorism*, primarily a policy journal to inform policymakers about issues in bioterrorism that is completing its sixth year of publication.

The process used by this journal begins with a prescreening in which each author provides an abstract before submitting a full article. The journal is strongly committed to not restricting publication and has a statement in the information for contributors called "consideration of information that might increase the risks associated with potential bioweapons attacks," which discuses that commitment. Another DURC filter is in the form of a question for reviewers on the review form – "Is it your judgment that the information contained in this paper would substantially lower current existing scientific, technical, or logistical barriers to bioweapons attacks and/or increase the potential future consequences of bioweapons attacks? No/Yes/If yes, how?"

Papers under consideration are discussed at a biweekly meeting of the journal editors. Possible solutions to a finding of DURC in a manuscript are for the author to revise the paper or for the journal to reject it, which does not happen often. New procedures will be promulgated within the next year, to include asking authors to attest to having read this part of the information for contributors, similar to asking authors to attest to having no conflict of interest. In addition, a standing subgroup of the editorial board will be constituted to deal with DURC issues when they arise.

Ms. Fox offered three examples of research that raised dual use concerns for the journal. One paper about aerosol delivery systems for bioweapons was flagged; the editors worked with the authors extensively to modify the article and it was eventually published. A second paper of concern described how powdered substances could be mixed with smallpox virus to confound the usual tests for detection. The author's solution was to encourage readers to write to a third party who would release information – a solution rejected by the journal. Because the authors would not modify the paper in any meaningful way, the paper was rejected by *Biosecurity and Bioterrorism* but was published in another journal. A third paper, modeling airborne anthrax attacks, discussed ideal weather conditions and how to release anthrax in buildings. The concerns were explained to the author and the paper was rejected.

In 6 years, only these three papers have raised DURC questions. This journal always looks at the benefits first, rather than the risks, by asking if publication of the paper would benefit the scientific literature and/or public health. If the answer is "no," then risks should not be taken.

### *4) Training and Education*

*Presenter: Chandre Gould, Ph.D., Institute for Security Studies, South Africa*

Representing an independent policy research institute, Dr. Gould explained that there is a low level of awareness amongst the scientific community in South Africa about DUR issues, and about related national and international laws and norms, Dr. Gould's early work in this area was informed by the investigation and findings of the Truth and Reconciliation Commission with regard to the Apartheid chemical and biological weapons program.

Initial education efforts included seminars for laboratory scientists and post-graduate students at several academic institutions and an accredited lecture in the Department of Clinical Microbiology and Infectious Disease at the University of the Witwatersrand. The lecture was given to second-year molecular medicine students, staff and post-graduate students. The results of these efforts were an indication that there may be better uptake of issues at the undergraduate level than at the postgraduate level. This suggested that education efforts should be aimed at both practicing scientists and undergraduate students. Based on initial efforts, it was decided that a full course for all members of the life science community would be an important component of national non-proliferation efforts. However, the difficulty of obtaining buy-in at the level required for comprehensive national roll-out of such a course has resulted in slow progress.

A November 2007 consultation workshop brought together representatives from industry, government, scientists, academics, specialists in education, and a representative from the Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB). This group agreed that a course was necessary and advised on the format, content, and objectives of the proposed course and helped define the module's target audience. Some of the easier questions – why DUR education is needed, who should be educated, and the topics of that education – were resolved at that meeting. A statement of purpose for the module was developed:

> "To ensure that scientists, engineers, technologists, and medical professionals practice and promote the responsible use of science; are aware of the dual-use nature of their work; are familiar with the national and international laws and regulations governing their work in the context of dual-use research; understand their individual, professional, and institutional responsibilities; and have the theoretical tools to anticipate and resolve ethical problems and risks that result from dual-use research."

It was additionally agreed that ideally, such a course should be rolled-out to all science educators, science students, scientific professionals, and laboratory technicians whose work relates in any way to infectious disease and other biological threats to humans, plants, animals, or the environment. The goal of this course would be *inter alia* to present the science positively so the course is focused solely on risk, danger, and threat. Such a module could be Internet based, should be self-administered, and it should not take too much time to complete, similar to the SERCEB module.

The proposed module has not been fully developed yet because high-level support is still being sought. It is clear that unless there is acceptance of the need for such a course by the scientific community, through professional associations, and for its inclusion in training curricula, the course will not be widely used, and would have limited impact. Consultations with national representative bodies and with scientists in other parts of Africa are on-going. With the help of the Sloan Foundation, it is expected that this education module may be developed in Uganda and Kenya in late 2008 or early 2009.

When thinking through education at an international level, several issues must be recognized:

- Education aimed at reducing a perceived threat is politically charged.
- Developing educational modules of this nature requires dedicated individuals in the countries in which the modules will be developed; dedication is needed to drive this slow process.
- It cannot be taken for granted that all science communities share the same perception of threat or the prioritization of threat.
- When allocating resources to such a process, competing priorities will exist for those resources.

- Education is important but only as one element in a package of remedies to reduce risk.

Link to Dr. Gould's slides.

*Presenter: Michael Stebbins, Ph.D., Director, Biosecurity Project, Federation of American Scientists (FAS), United States*

Dr. Stebbins noted that one of the major challenges to raising awareness of DUR in the life sciences community is the lack of recognition that they have a biosecurity responsibility. On the list of issues that scientists are deeply concerned about, biosecurity falls to the very bottom. Rather, researchers are often preoccupied with the dire research funding issues they have been facing.

FAS launched a series of case studies in DUR education several years ago and has been building on them ever since. The educational series uses computer-based modules or multimedia presentations and real case studies to start discussion among scientists and raise awareness of DUR issues within the community. In the videos, scientists talk about their work and animations are used to explain that work to people who are outside the field. The first eight modules, with the last one to be released soon, are:

- Introduction
- Polio from scratch: Eckard Wimmer
- Inhalation drugs: David Edwards
- Mousepox virulence: Ron Jackson
- Antibiotic Resistance: Stuart Levy
- RNAi: Greg Hannon
- 1918 Influenza: Chris Basler
- Public Concerns: Judge Susan Ehrlich

About 92 percent of respondents to an evaluation of these modules said that DUR education should be taught in graduate student ethics courses. (Approximately one-third of respondents were from outside of the United States.) NIH-funded graduate students are required to take an ethics course. The FAS case studies and other materials produced by other groups are designed to fit inside those courses. About half of respondents wanted more material and half wanted less, which was interpreted as meaning the amount of material was appropriate. Seventy percent of respondents wanted more videos, which are forthcoming. These materials are now being translated into several languages; two case studies have been completed to date, (the polio virus case study was translated into French and the antibiotic resistance case study into Mandarin). Initial plans are to translate all of the FAS case studies into French, Mandarin, Russian, Spanish, and German.

Dr. Stebbins noted that scientists' options are limited once awareness is raised – there is no place to turn if the scientist has concerns about a colleague, there is no place to get advice or to vet concerns about their own work, there is no tracking of concerns, there is no dedicated path for reporting serious concerns to law enforcement, and industry has mostly been left out of the DUR discussion. Therefore, the FAS is building an Ombudsman Reporting Program (ORP) for the United States, a test case that might be expanded internationally. The ORP will be a collection of experts that reviews concerns reported by scientists without revealing the scientist's information. Supportive funding for the ORP will be decided soon.

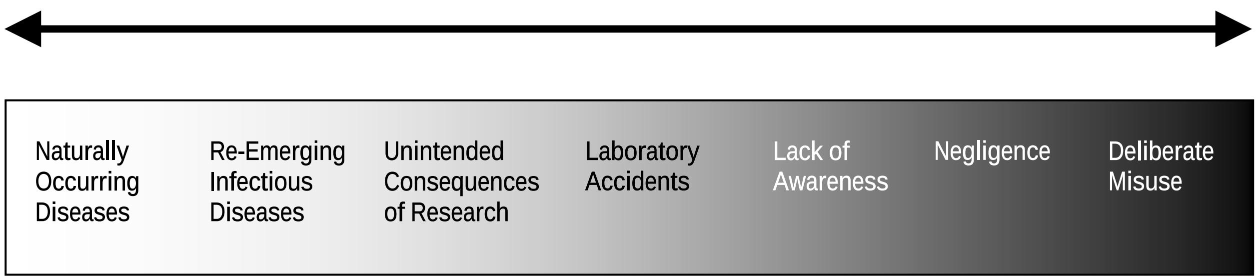
The ORP will be part of a larger program that the FAS will be building, a Virtual Biosecurity Center. The center will have a democratic administration structure initially run by four groups, Center for Strategic and International Studies, the AAAS, and the National Academies Partnering with other groups, creating a central resource for biosecurity information, and obtaining early “buy-in” from other organizations will change the way people communicate biosecurity information. The FAS is hoping to collaborate with international groups to expand the reach of the Virtual Biosecurity Center and. as a result of the meeting, set up an international biosecurity listserv.

Link to Dr. Stebbins’ slides.

***5) Raising Awareness***

*Presenter: Terence Taylor, President, International Council for the Life Sciences (ICLS) and Vice-President Global Health and Security, Nuclear Threat Initiative (NTI), United States*

Mr. Taylor discussed countering biological risks by awareness-raising through direct action. Different countries, different organizations, and different sectors of the life science community have different priorities along the biological risk spectrum:




The major concerns regarding DUR are focused on lack of awareness, negligence, and deliberate misuse. Linking awareness-raising to direct action helps solve “glocal” problems so the DUR issue is not seen as merely a cost in time and money but is understood as conferring important benefits.

Two global objectives have been the cornerstone of the coordinated efforts of the ICLS and GHSI regarding DUR awareness. The first objective is to develop either regional or sub-regional international advisory groups that focus on promoting international biosafety and biosecurity best practices and standards, training standards and curricula, and risk assessment methodologies. The membership of these advisory groups must be multidisciplinary because of the diverse nature of the life sciences and must be geographically representative in content and control. Examples include the International Advisory Group for Russia and Central Asia, the Abu Dhabi Conference in November 2007, and an April 2009 conference in cooperation with regional partners in Jordan, Morocco and UAE.

The second global objective is based on infectious disease surveillance. The focus of this objective is early detection; faster and better diagnostics; building laboratory capacity and human capacity, both of which involve distance learning, training, and curricula to enhance laboratory capabilities; and governance and best practices and procedures. This global objective provides an opportunity to integrate the DURC issue with the latter activities so it can be accepted more readily.

Link to Mr. Taylor’s slides.

*Presenter: Malcolm Dando, Ph.D., Professor of International Security, University of Bradford, UK*

Dr. Dando noted that, although there are many reasons why education is central to concerns about biosecurity, two are particularly salient: education is a prerequisite for many forms of intervention and education can be accomplished within the limitations of existing arms control mechanisms.

Dr. Dando stated that his colleague, Dr. Brian Rappert constructed an interactive seminar in which practicing life scientists in universities are asked questions that are of concern to the security community, e.g., about DUR issues, about communication, and about funding. This seminar was piloted in the UK in 2005 and then, with Sloan Foundation funding, a second series of seminars was conducted in the United States, South Africa, Netherlands, and Finland; a third series was conducted in Japan, Israel, India, Argentina, Uganda, Kenya, Ukraine, and Australia. A total of 26 seminars in the UK and 28 seminars elsewhere produced little evidence that participants regarded bioterrorism or bioweapons as a substantial threat, considered that developments in the life sciences research contributed to biothreats, were aware of the current debates and concerns about DUR, or were familiar with the BWC. These interactive seminars showed the need for education and awareness raising and the importance of engaging researchers in deliberation about what was largely, initially, considered by them to be a non-issue. Other lessons learned included the importance of taking education to the people rather than waiting for people to ask for it, fostering peer-to-peer interaction, understanding the universality of scientists' discourse, and taking advantage of the possibility for fostering interest within practitioner and policy communities.

Dr. Dando described his current efforts at counteracting the pervasive ignorance about DURC. Supported by a British Council Award and in cooperation with colleagues at the National Defense Medical College in Japan, Dr. Dando and colleagues are creating a full educational module resource, which should be available in March 2009. This open-source material is intended to be adapted to different audiences as needed.

At the Meeting of Experts of the States Parties to the BWC in August 2008, Dr. Rappert made a suggestion that the States Parties agree that:

- A fundamental principle in preventing the destructive use of the life sciences is that the benign intent of individuals is not a sufficient response to preventing misuse.
- All those graduating from higher education in fields associated with the life sciences should be familiar with the international prohibition against biological weapons.
- All those undertaking professional research careers should have received effective training or instruction related to preventing the misuse of their research.
- Each government represented should commit itself to initiating a dialogue with their respective national science academies about how the present low level of awareness can swiftly be corrected.

Drs. Dando and Rappert have argued that the goal of educating people is not to apply negative restraints on scientific progress; there will likely be very few examples of such restraints. However, if scientists are educated and aware, much could be accomplished to develop the various dimensions of international prohibition. The goal is to construct effective prevention measures that will ensure, as much as possible, that the revolution in life sciences is not misused by anyone for hostile purposes.

Link to Dr. Dando's slides.

## D. Progress at the National Level

*At the first USG/WHO International Roundtable in February 2007, representatives from a number of countries made presentations on the views and activities of their country which were relevant to the issues of DURC. This session focused on updates on progress made in these activities.*

### *AUSTRALIA*

*Presenter: Seumas Miller, Ph.D., Centre for Applied Philosophy and Public Ethics, Charles Sturt University and The Australian National University, Australia*

Dr. Miller discussed DUR activities in Australia. The major development is passage of the National Health Security Act 2007, which established a national authority within the Department of Health and Aging to administer the Security Sensitive Biological Agents Regulatory Scheme (similar to the Select Agents Rule in the United States). The current regulatory scheme focuses only on safety but this new scheme also concerns security – specifically terrorism. The Regulatory Scheme is to be implemented in early 2009 and is composed of:

- A list of security-sensitive biological agents
- A national register of facilities
- Provisions for security status for those handling security-sensitive biological agents
- Regulations regarding storage, transport, and handling of security-sensitive biological agents
- Inspection and monitoring processes
- Sanctions, including fines and imprisonment, for noncompliance
- A provision for training and an awareness-raising campaign

This new legislation constitutes only a partial response to the DUR issue. The Australian government is considering various new policies and is reflecting on what else they need to do. The government commissioned a report entitled "Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences" that was published in 2007 in the *Journal of Science* and the *Ethics of Science and Engineering*.

Of particular note regarding academic activity in Australia is the establishment in September 2008 of a National Centre for Biosecurity, which is a joint venture of the Australian National University and Sydney University. The focus of the Center is research and education on all matters relating to biosecurity, including but not restricted to DUR issues. In addition, other activities are underway at centers that are connected with the National Centre for Biosecurity.

### *GEORGIA*

*Presenter: George Chakhava, M.D., Ph.D., Georgian Association of Medical Specialists and Tbilisi State Medical University (TSMU), Georgia*

Dr. Chakhava discussed progress in managing DURC in the life sciences in Georgia. Georgia was once part of the Soviet Union and shared all relevant legislation with that country; while more than 10 years have passed since Georgia became independent, not all biosafety legislation has been adapted to the current political situation. Progress on market reforms and democratization has been made in the years since independence, but this progress has been complicated by Russian occupation of two breakaway regions of Georgia. Current regulation is based on several international manuals and guidelines and it complies with the laws of Georgia on healthcare, the Sanitary Code, and export control of armaments, military techniques, and products that have potential dual uses..

The main institutions working on DURC problems in Georgia are the National Center for Disease Control and Medical Statistics of Georgia, the Biokombinat in Tabakhmela (which produces live vaccines for cattle), and the Eliava Institute of Bacteriophage (which manufactures vaccines). Three types of ethics committees exist currently in Georgia – the National Council of Ethics and the Clinical and Research Councils.

TSMU's priorities for DUR issues are the European Research Area, the Bologna Architectural Study for Medical Education, and the EU Code of Conduct for Recruitment. Some international conferences have been held, for example, the conference on December 5-6, 2007, entitled "The Technical Enablers and Challenges of Biological Terrorism." Publications about biosafety, biosecurity, and DURC have already appeared or will be published in the near future. Georgia scientists have participated in the WHO online consultation on life sciences research and development and global health security. Planned activities include international consultations on DUR in the life sciences, analysis of existing codes of conduct, and critical comparative analysis of strengths and weaknesses in this field. An advisory committee on the duality of life science research and international concern is being established at the TSMU.

The process of working together internationally across the spectrum of biological challenges should reduce the impact of already-existing disease threats and reduce the likelihood of intentional misuse of life sciences research. Among several possible solutions are advanced medical education, development of codes of conduct, and awareness raising.

Link to Dr. Chakhava's slides.

***INDIA***

*Presenter: Chavali Kameswara Rao, Ph.D., D.Sc., M.Sc., Foundation for Biotechnology Awareness and Education, India*

Dr. Rao discussed progress in managing DURC in India. The Indian pharmaceutical industry is very prominent; 14 of the top 20 companies in the Asia-Pacific area are Indian, revenue is $1.75 billion and is about 70 percent of the total biotech revenue, the export component is 58 percent, and 47 percent of products are vaccines. Areas of health research are drug development, vaccines, and diagnostics with new interest in stem cell research and nanobiotechnology.

While Recombinant DNA (rDNA) technology is used widely in the agricultural and pharmaceutical sectors, the actual component of modern biotechnology-based pharmaceutical research and development is small. Most pharmaceuticals are produced through conventional technologies, but companies try to use at least some biotechnology to claim the significant government concessions that are given to biotech companies.

Three policy documents have been released to date: a National Health Research Policy (2007), Guidelines for Stem Cell Research and Therapy (2006), and Ethical Guidelines for Biomedical Research (2006). A new policy of biotechnology regulation is separated into three areas – agriculture, fisheries, and forestry; animal and human health; and industrial and environmental health. In addition, there is now a National Disaster Management Authority under the Disaster Management Act, which lists national guidelines for biological disaster management; this document mentions bioterrorism and biowarfare but not DUR technology.

The awareness of DURC in India is low, even in scientific circles. There is no way to identify DURC projects and journals do not have editorial policies about DURC. Channels of outreach that have been attempted include newspapers and magazines – in which it has been difficult to publish serious articles about DURC – and lectures/workshops – which have been successful but for which financing has been a challenge.

Link to Dr. Rao's slides.

***MOROCCO***

*Presenter: Khalid R. Temsamani, Ph.D., Moroccan Ministry of Higher Education and Scientific Research (MHESR), Morocco*

Dr. Temsamani discussed the ongoing activities of biosafety and biosecurity in Morocco. The "2025 Strategy" emerged from a national debate on high priority areas of scientific research, which includes reform of the graduate studies system; a national commission to study the public funding of peer-reviewed research projects; a requirement for universities to abide by the national research priorities aimed at resolving local, regional, or national issues; and mandated accreditation required for research labs to receive funding.

The MHESR has released the first phase of a national survey on scientific research activities and funding sources; only 0.64 percent of the national GDP expenditure is for scientific research. The objective of the national strategic plan is to reach 1 percent by 2010. Most of the scientific research is performed under government or academic control. For general research funding, 73 percent of the funds come from the government, 22 percent from the private sector, 3 percent from international cooperation, 1 percent from public-public partnerships, and 1 percent from public-private partnerships. Approximately 95 percent of university research funding comes from the government, 3 percent from international cooperation, and 1 percent each from public-public and public-private partnerships.

Debate at the university level is not about DURC but about biosafety and infrastructure. Medical schools have national bioethics committees and, in every school of science, science commissions screen research projects and results; however, assessment is not based on DURC. All research on dangerous pathogens is under government control; there are three biosafety level (BSL) 3 labs for human health and one for animal health, and there is no classification yet at the university level.

Morocco's regional framework on biotechnology is the Islamic Education, Scientific, and Cultural Organization (ISESCO) code of conduct for implementing biotechnology in the Islamic countries; this code is not legally binding. Since 2005, a National Committee on Biotechnology was implemented that focused primarily on food issues and environmental concerns (genetically modified organisms [GMOs] and the Cartagena Protocol on Biosafety); the committee has not yet considered biosafety or biosecurity issues.

Within a few weeks, an inter-ministerial committee will meet to draw the roadmap for the national priorities in scientific research for the next year. Two items are on the agenda – creation of a National Commission for Science Ethics and creation of a National Commission for Biosafety and Biosecurity.

The Minister of Health in Morocco is trying to convince other countries such as Algeria, Tunisia, Mauritania, and Libya to get involved in a group purchase of vaccines, which will make the vaccines cheaper for all those countries.

International and regional workshops include a joint U.S.-Morocco workshop on biosecurity and biosafety on November 3-5, 2008. Morocco will be hosting the Biosafety and Biosecurity International Conference 2009 in partnership with the ICLS, the Jordanian Royal Society, and the Emirate Environmental Agency; it will take place in Casablanca on April 2-4, 2009.

Dr. Temsamani has been involved in a study conducted by the National Academies of Sciences on assessing Morocco's capability to control potential biological threats and the Moroccan perspective on potential for unintentional or intentional release of pathogens. This report, which will highlight the progress Morocco has made, will be released in early 2009 and will constitute an important tool for Morocco to improve its system.

Issues still faced by Morocco regarding international cooperation include:

- The need to set up mechanisms at universities that help increase awareness among the academic community about the potential misuse of legitimate life sciences research, including when engaging in international scientific cooperation.
- The need to implement a biosafety and biosecurity curriculum at the 15 National Universities; international cooperation might help overcome this issue.
- Morocco is ready to play active roles at the Middle East & North Africa (MENA) level in areas that relate to biosecurity, including the development of a regional network and/or society.

Dr. Temsamani pledged that Morocco would continue to share and learn from the best practices of other advanced countries. It is desirable to set international standards in the field of DURC that take into consideration freedom of mobility of scientists and of legitimate research materials.

Link to Dr. Temsamani's slides.

***POLAND***

*Presenter: Andrzej Gorski, M.D., Polish Academy of Sciences (PAS), Poland*

Dr. Gorski explained that the Polish Academy of Sciences has 350 elected, corresponding, and full members, 100 scientific committees and 80 research institutions. The PAS has domestic branches in seven Polish cities and stations abroad in Paris, Vienna, Berlin, Rome, Moscow, and Brussels. The PAS also provides independent advice on science issues to the government, the public, and society. Almost all science research funding comes from the Polish government.

Two centers in the world carry on the phage therapy of antibiotic-resistant infections; one is in Georgia and the other is in Poland, at the Institute of Immunology and Experimental Therapy (PAS), Wroclaw. Interesting results are being generated in patients. One weapon against bacterial bioterrorism can be found in the collection of phages that covers more than 80 percent of staphylococcus bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA).

Two DUR-related events have already occurred. An international conference entitled "The Advancement of Science and the Dilemma of Dual Use" organized by PAS was held in Warsaw on November 9-10, 2007, and Dr Gorski delivered a talk at the 11th Forum of the National Ethics Committees of the EC in Croatia on February 28, 2008, on whether DUR is adequately defined and addressed in the current research ethics guidelines.

On October 8, 2008, a first formal meeting convened stakeholders and focused on controversial discussions of what to do. Potential directions include creating a listing of DURC areas, appointing security officers at each scientific center, and introducing a code of conduct related to DURC.

Link to Dr. Gorski's slides.

## *UGANDA*

*Presenter: M. Paul Nampala, Ph.D., M.Sc., Uganda National Academy of Sciences, Uganda*

Dr. Nampala discussed activities related to dual use research of concern (DURC) management in Uganda and which also reflected the activities of rest of sub-Saharan Africa excluding South Africa. Concerns regarding DURC include issues of agriculture productivity and the increased proximity of research to populated areas. Genetically modified crops are now moving from the laboratory to the fields. Laboratories are not well developed, and the biosafety programs at many institutions and universities and in the private sector are dysfunctional. Because of the rapid growth of biotechnology laboratories, more institutions are increasingly handling hazardous material.

Uganda has had periodic outbreaks of emerging infectious diseases that result from highly pathogenic viruses, such as Ebola virus and Marburg virus. For each of the episodes, the biggest challenges have been taxonomic verification and characterization of the strains. Most threat mitigation strategies have focused on outbreak management and external assistance, provided mostly by the World Health Organization (WHO). The Uganda government is fully aware of the danger of relying solely on external assistance. Therefore, measures are underway to facilitate rapid response to future outbreaks of these highly infectious diseases. Such measures include a BSL 3 laboratory at the Uganda Virus Research Institute, a containment facility for GMO testing at the national Research Laboratories. Other research facilities engaged in research with potential application of high biosafety protocols such as HIV and cancer studies have also been established. There is therefore a need to address the issues of risks and dual use research of concern in general that may arise from increase in scope of scientific undertakings for purposes of risk assessments, prevention and mitigation.

With support from the Sloan Foundation, the Uganda National Academy of Science has piloted efforts to promote biosafety and biosecurity within the life sciences. In March 2008, a meeting entitled "Promoting Biosafety and Biosecurity Within the Life Sciences" was held and presentations at that meeting stimulated scientists to take DURC seriously. In July 2008, a follow-up meeting was held to plan, manage, and sustain biocontainment laboratories, co-sponsored by the U.S. National Academies and the African Science Academy Development Initiative. In January 2009 and with support from the U.S. Department of State and the National Academies, Uganda will sponsor an international meeting on standards and good laboratory practices for managing safe, secure, and sustainable laboratories.

For the future, the current system for biosafety and biosecurity oversight needs to be examined, including the national and institutional biosafety committees. The code of conduct and ethics review committees are in place, but it is not clear whether the capacity exists to deal with the complex issues related to biosecurity. It will be important to identify gaps with regard to DURC and to develop options and strategies for addressing those gaps.

Uganda is in the process of crafting a bill and guidelines at institutional levels that will incorporate DURC issues, using provided frameworks that give a clear indication of the needs of a national system. However, the primary concentration is on biosafety aspects, with much less focus on biosecurity. Infrastructure issues are at issue in terms of investment for laboratories as well as investment for capacity building and human capital. Africa needs significant resources devoted to building capacity for enforcement and ensuring compliance with policies already in place.

Link to Dr. Nampala's slides.

***Brief Comments by Countries***

The discussion session afforded an opportunity for other meeting participants to make brief comments and updates on DURC related activities in their countries. Brief comments were made on the situation in the Philippines, Pakistan, Norway, Brazil, China, Libya, the Ukraine and Israel. The Health Minister from Israel informed the participants that the draft legislation described in the plenary presentation on Israel the previous day had just become law. The following NGOs also made comments: ICSU Regional Office in Africa, ICLS, CSIS, and the Center for International Security Studies.

**E. Special Presentation: Harnessing the Benefits of the Biotechnology Revolution while Managing the Potential Risks: The Role of the United Nations**

*Presenter: Robert Orr, Ph.D., M.P.A.*
*Assistant Secretary-General for Policy Planning*
*Executive Office of the Secretary-General*
*United Nations*

Dr. Orr informed conference participants that the United Nations, and specifically the Secretary-General, was planning to launch a new Biotechnology Initiative that would explore what role the UN might be able to play in helping to disseminate the benefits of the revolution in the life sciences, while managing the potential risks.

Dr. Orr acknowledged that the United Nations (UN) Secretary-General has not historically been heavily involved in issues relating to biosecurity and dual-use research although different parts of the UN system have engaged in this agenda.

The Biotechnology Initiative intersects in numerous ways with the issues that the Secretary-General has identified as being key priorities for him during his tenure: promoting the development agenda, managing the food and fuel crisis and addressing a new generation of global challenges: climate change, global health, nonproliferation and disarmament, and counterterrorism.
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The Secretary-General's Initiative also stems from two recent mandates given to him by the United Nations General Assembly. In the Spring of 2006 the General Assembly passed a resolution calling on the UN system to collaborate with developing countries to enhance their biotechnology programs and support risk assessment and management of biosafety. Later that year, the General Assembly called on the Secretary-General to bring together various stakeholders in this area to try to build a common program ensuring that biotechnology advances are for the public good and not for terrorist or criminal purposes.

The Biotechnology Initiative, which will be launched in September 2009, has five proposed objectives:

- To identify and achieve broad consensus, across industry, business, academia, government, and international organizations, on a set of principles to foster international development, including expanding the benefits of biotechnology and the life sciences research while addressing safety and security concerns. This first step, launching the overall initiative, will be accomplished by convening a group of biotechnology leaders to develop the principles.

- To establish a standing group of biotechnology champions from around the world to periodically review scientific advances, assess emerging biotechnology risks, and provide guidance on how to safely harness and disseminate innovations.

- To promote widespread adoption of a risk management approach to promoting biotechnology through as series of international workshops.

- To document lessons learned and enable broad sharing of this information, across regional and national lines, across communities (scientific, political, etc.), and across disciplines (human health, agriculture, etc.).

- To encourage the establishment of regional biotechnology champions who can lead regional discussions and develop networks of experts that can all lead to global consensus.

In light of the multiple crises the world faces—the food crisis, the development crisis, and the climate crisis—and the current financial crisis which deepens each of the other crises, the potential benefits of technology must be explored, disseminated more widely and, in particular, brought to bear to benefit developing countries.

## F. Moving the field forward: Perspectives of Non-governmental Entities

*This session explored the role of non-governmental entities in the management of DURC. The session focused on how various non-government entities (e.g., intergovernmental organizations, science academies, industry, etc.) perceive their role in advancing the management of DURC – through 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.*

### *1) Biological Weapons Convention*

*Presenter: Ambassador Georgi Avramchev, Permanent Mission of the Republic of Macedonia to the United Nations Office at Geneva, Chair of the 2008 Meetings of the Biological Weapons Convention*

Ambassador Avramchev noted that progress in the biotechnology field must be supported and the benefits shared, while minimizing malevolent use. Experience with GMOs, stem cell research, and cloning models all tell a cautionary tale about what happens when science becomes disjointed from policy and the societies in which it is practiced. The scientific community must take the lead to ensure that DURC issues are addressed effectively, but the policymaking community cannot afford to ignore DURC issues. Oversight frameworks for safety and security will provide a firm foundation for collective and collaborative work in the biological sciences, and working together to develop the culture of scientific responsibility and best practices must address explicitly the potential for malevolent use. The BWC is the natural home for such an effort.

Created to ensure that the life sciences are used only for the benefit of humanity, the BWC is the nexus between science and security. It matches prohibitions that ensure that the life sciences are not used for malevolent purposes with protections for scientific freedom, ensuring the right to conduct scientific activities for peaceful purposes. Negotiated more than 35 years ago, the BWC has established a global norm against the development and acquisition of biological weapons. It is an international legal instrument and its terms are legally binding; its process is built around its review conferences held every 5 years, which provide an opportunity to assess how well the BWC meets the needs of international peace and security. As a result of the BWC, no government today would claim that biological weapons could play a legitimate role in national defense.

At present, the BWC is engaged in an intercessional process that provides for annual meetings at the expert and diplomatic levels. The topics of the current intercessional process are relevant to DURC issues. In 2007, the BWC looked at national legal frameworks designed to prevent misuse and punish those who use biology for malevolent aims. The topic for 2008 is biosafety and biosecurity provisions as well as the oversight of science and related outreach activities. In 2009, the BWC will focus on building capacity around the world to deal with biological research, and in 2010 the BWC will focus on what will happen if other efforts fail and a biological weapon is used. All of these issues are critical to sustaining progress in the life sciences.

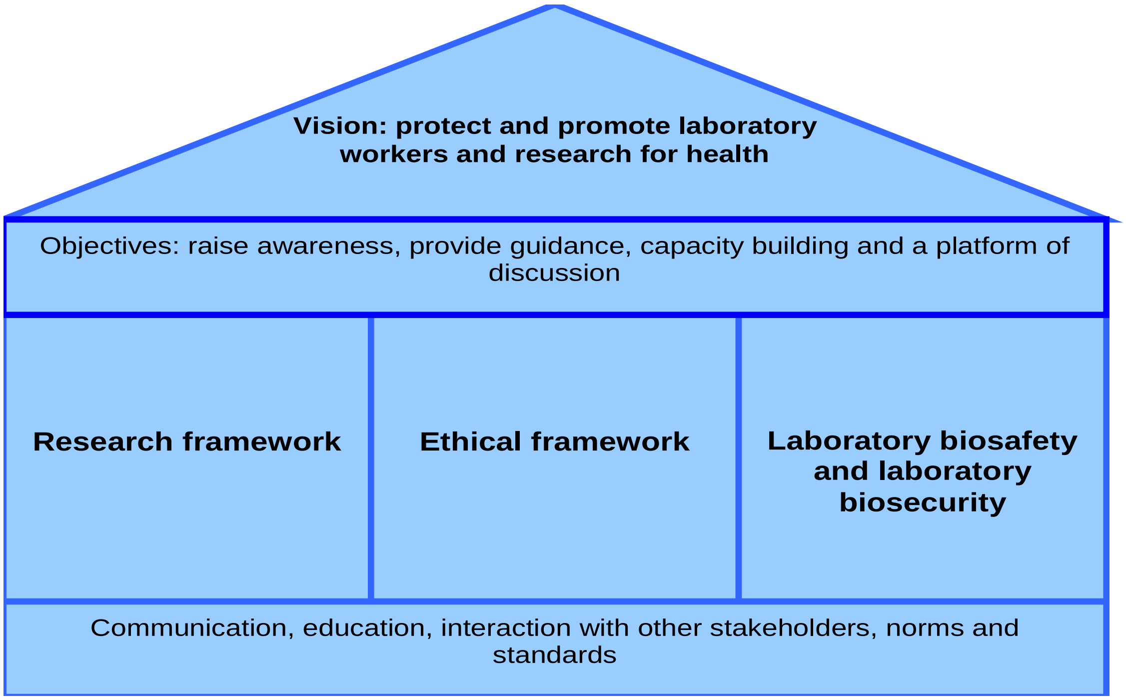
The BWC continues to function between meetings. Member states have nominated national contacts and focal points have been identified in international and regional organizations, professional and scientific bodies, academia, industry, and other stakeholders. This community takes part in numerous interconnected processes, meetings, and discussions throughout the year, some of which are tied directly to the BWC and others of which are more removed. The Implementation Support Unit coordinates communication among stakeholders and ensures that everyone has access to up-to-date information. The Unit's website has become a central gateway for those interested in ensuring that biology is not used for malevolent purposes.

Although the BWC is a key forum on these issues, neither the BWC nor any other process or initiative can, by itself, hope to address the threats to global security posed by the misuse of biology.

***2) Intergovernmental Organizations***

*Presenter: Emmanuelle Tuerlings, Ph.D., Scientist, Department of Epidemic and Pandemic Alert and Response, WHO*

Dr. Tuerlings presented the activities of the WHO with regard to biosecurity and biorisk reduction. The WHO has been raising awareness, building capacity, and providing guidance on DUR issues. WHO activities have been carried out in the areas of research, ethics, and laboratory biosafety and biosecurity; these three areas constitute the main elements of WHO's public health approach to the potential risk posed by life sciences research.




In 2006, a scientific working group met in Geneva and identified five areas for action: education and training, preparedness for a possible disease outbreak, development of risk assessment methodologies, engagement with all stakeholders and guidelines for oversight, and capacity building at the country level.

To raise awareness and provide a discussion platform, the WHO sponsored two scientific working group meetings (2006 and forthcoming in 2009), published three reports (2005, 2006, and 2008), held online consultations (June through September 2007), sponsored a regional workshop (Thailand, December 2007), and established an international network. Outreach activities are ongoing. Guidance and training materials on capacity building are being developed in 2008 and 2009.

Outreach activities of the WHO include, in addition to the regional meeting in Thailand in December 2007 mentioned above, technical support to the laboratory biosafety and biosecurity awareness-raising regional workshops in Central and South America (Brazil 2005, 9 countries, and Guatemala 2006, 10 countries), Iran (2006, 22 countries), Kenya (2007, 21 English-speaking countries), India (2008, 7 countries), Malaysia (2008, 8 countries), and Kenya (2008, 24 French-speaking countries). The WHO has cosponsored and participated in two international meetings with the United States government, hosted by the NSABB and other international conferences and workshops with stakeholders.

Feedback from these outreach activities indicates:

- Uneven knowledge and awareness about DUR
- Importance of life sciences for improving health and economic development
- Importance of national research and laboratory capacities
- Importance of access to materials
- Needs for laboratory infrastructure, resources, and biosafety practices
- Varying needs of different countries, so no single solution exists
- Countries need guidance and support

Link to Dr. Tuerling's slides.

*Presenter: James Pearson, D.V.M., Expert Consultant, World Organization for Animal Health (formed as the Office International des Epizooties [OIE])*

Dr. Pearson explained that the World Organization for Animal Health was formed in 1924 in response to an exotic disease – rinderpest – that entered Belgium. Headquartered in Paris and composed of 172 member countries, the OIE is an intergovernmental organization and is not associated with the UN. The OIE coordinates the activities of 177 reference labs in 32 countries that provide diagnostic and epidemiology support to the OIE Member Countries for 95 diseases. The organization's Web site, www.oie.int, is updated daily with the latest disease information, including reports of outbreaks.

OIE objectives in relation to DUR are to:

- Assist in developing veterinary infrastructure
- Increase disease awareness by member countries
- Increase the technical competence of member countries
- Assist in developing risk analysis capabilities
- Support and provide guidelines for disease surveillance and lab development capabilities
- Facilitate early detection of disease introduction
- Provide disease reporting infrastructure and disease control guidelines
- Provide guidelines for animal movement
- Support science-based biosafety and biosecurity programs
- Develop and provide animal health publications

The OIE addresses DUR by providing an early warning system; international standards for disease reporting, surveillance testing, disease freedom, and diagnostic methods. In addition it provides an infrastructure of OIE reference laboratories and collaborating centers.

Link to Dr. Pearson's slides.

***3) Scientific Academies***

*Presenter: Neil Davison, Ph.D., Senior Policy Adviser, Science Policy Centre, The Royal Society, United Kingdom*

Dr. Davison explained that The Royal Society is the oldest academy of science in the world. He presented activities and lessons learned from The Royal Society as well as the Inter-Academy Panel (IAP). The Royal Society has fostered national and international engagement regarding DUR issues, to include stakeholders such as scientists, policymakers, societies, and funding bodies; a key issue has been awareness raising and developing codes of conduct. Two other major areas of interest are providing scientific and technical input into the Biological Weapons Convention (BWC), and the need for openness and transparency to ensure that the risks are not overstated and that the benefits of scientific research are not jeopardized in discussions of risk. Dr. Davison present on a number of themes that have emerged during the course of The Royal Society's work.

Lessons learned in risk assessment and management are that:

- Sensible policies to minimize risk should be guided by realistic risk assessments.
- Risk should be assessed across the full spectrum of biological threats.

- Shared methodology and terminology should incorporate regional differences.
- Misuse cannot be eliminated completely.
- There is a central role for scientists in risk assessment and management to predict and explain threats, assess risks, devise ways to manage and mitigate risks, and help communicate the risks.

Lessons learned regarding openness and transparency are that:

- Managing the risks while maximizing the benefits is the primary goal.
- Censorship does not prevent misuse.
- Censorship is counterproductive to developing treatments and countermeasures.
- The benefits of delaying or withholding publication are yet to be clearly demonstrated.

Lessons learned regarding education and awareness raising are that:

- Scientists in academia, government, and industry must be educated.
- Training courses in ethics and responsible research are needed.
- Ethical codes and codes of practice can be educational tools.
- Briefing documents, information packages, and Web resources are needed.
- Public engagement is important.

Lessons learned regarding codes of conduct are that:

- Developing a culture of responsible international stewardship is the overall goal.
- International strategies are needed to harmonize safety, security, and codes of conduct.
- Codes should be tailored to specific fields and specific audiences.
- Target audiences should be involved from the outset and in drafting the codes.
- Building on pre-existing guidelines and procedures is efficient and effective.
- Self-governance through peer pressure is likely to be most effective.
- Questions remain regarding the specifics of oversight, penalties, reporting, and whistle blowing.

To move the field forward, the Royal Society believes that it is necessary to engage the life sciences community at all levels of professional training, providing opportunities for education and awareness raising through further development of educational resources and training modules. In addition, the Royal Society supports the continued involvement of international scientific organizations as part of efforts to strengthen the BWC. Planned activities at the Royal Society's Science Policy Centre for 2009 include a meeting on biological risk assessment methodologies with the International Council of the Life Sciences (ICLS), participation in the IAP Biosecurity Working Group (BWG) program of work, and a joint symposium on synthetic biology.

Activities of the IAP BWG include co-organizing two international forums on biosecurity, an emphasis on increasing the engagement of national academies around the world and other international scientific organizations to raise aware of biosecurity and DUR issues, and contributing toward and aiding the development of codes of conduct. The primary lesson to emerge has been that the *IAP Statement on Biosecurity* has had a significant effect in raising awareness among other academies; 71 academies around the world have signed it and this document has energized those academies to move forward their own initiatives and activities.

Planned activities of IAP BWG members include a December 2008 biosecurity meeting in China and a 2009 international workshop on education that will survey strategies and resources, consider ideas for filling the gaps, and discuss approaches for including education on DUR issues in the training of life scientists.

Link to Dr. Davison's slides.

***4) Scientific Unions***

*Presenter: Angelo Azzi, M.D., Ph.D., President, International Union of Biochemistry and Molecular Biology (IUBMB)*

Dr. Azzi discussed the activities of the IUBMB, which is composed of more than 70 societies all over the world. The mission is to support the growth and advancement of biochemistry and molecular biology – including biotechnology – as the foundation of biomolecular sciences. While promoting science, the IUBMB also works to prevent the undermining of public confidence in the life sciences or life scientists as well as to prevent the life sciences from being used for malevolent purposes, particularly in the field of biology and medicine.

The IUBMB code of ethics, accepted in 1995, includes an obligation of the organization's members, students, teachers, and associates not to engage knowingly in research that is intended for the production of agents for biological warfare or bioterrorism and not to promote such agents. There is no monitoring for adherence to this code of ethics.

Activities of the IUBMB related to biosafety and biosecurity include conferences, symposia, and lectures; fellowships; publications; and setting standards for the Ph.D. degree in the molecular biosciences. Each year, at least 2,500 people are exposed to IUBMB discussions.

Link to Dr. Azzi's slides.

*Presenter: Daniel Sordelli, Ph.D., President, International Union of Microbiological Societies (IUMS)*

Dr. Sordelli explained that the IUMS was founded in 1927 and its members are 97 microbiological societies in 65 countries. The IUMS is a member of the International Council for Science (ICSU). The major goal of the IUMS is to promote research and open exchange of scientific information for the advancement of the health and welfare of humankind and the environment. Stakeholders are individual societies and the scientists who belong to those societies. Mechanisms used by the IUMS to carry out its activities include scientific congresses, sponsoring of and participation in specific meetings, activities by executive board members, dissemination of information and recommendations through its Web site (www.iums.org), and the use of divisions, committees, commissions and confederations.

The IUMS public policy committee created a code of ethics, which was adopted in August 2008, that deals with the misuse of scientific knowledge, research, and resources. Member societies must have their own code of ethics, must adopt the IUMS code, or must at least not be opposed to the intent of the IUMS code. Of the 97 individual societies, only 5 have their own codes. After a short preamble, the code reads: "IUMS is opposed to the misuse of microbiological knowledge, research, and resources. In particular, IUMS also strives to promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons and therefore to protect the public's health and to promote world peace." One lesson learned is that whereas it is difficult to impose a specific code, it is very possible to make member societies aware of the need to have a code of ethics and to pass on that requirement to their constituencies.

Regarding activities related to DURC, the IUMS convenes triennial congresses, the latest of which was held in Istanbul in August 2008 and included a symposium on biosafety and biosecurity. Executive board members are involved in meetings addressing DURC issues, including the CAS/IAP International Workshop on Biosecurity in Beijing in December 2008.

Goals and future efforts of the IUMS include to:

- Raise awareness of DURC-related issues by facilitating roundtables, workshops, and symposia at major scientific microbiology meetings.
- Promote education of stakeholders on DURC-related issues by facilitating interaction between specialists and potential audiences.
- Engage in international projects fostered by organizations pursuing similar DURC-related goals.
- Enhance communications with stakeholders to more efficiently convey recommendations on DURC-related issues.

Link to Dr. Sordelli's slides.

***5) Industry***

*Presenter: John Mulligan, Ph.D., International Consortium for Polynucleotide Synthesis (ICPS)*

Dr. Mulligan presented information about the ICPS, an industry consortium that has attempted to address some DURC issues. His company is Blue Heron Biotechnology, which is a gene synthesis company that builds genes for scientists in industrial, university, and government laboratories. Dr. Mulligan spoke on behalf of the ICPS and the Industry Association for Synthetic Biology (IASB); together these two associations represent most of the gene synthesis capacity in the world.

Commercial gene synthesis is an appropriate example of a DU technology that is international. It has the potential to significantly improve the productivity of biomedical research and to allow researchers access to pathogenic DNA in ways that do not involve the risk associated with actually possessing the pathogens. Dr. Mulligan provided one specific example of research on reconstruction of the SARS virus.

The ICPS supports regulation, believing that effective regulation could promote the growth and utility of gene synthesis technology but noting that ineffective regulation could hamper research and increase the danger from pathogens. Given that belief, the ICPS has worked with representatives of the U.S. Federal Bureau of Investigation (FBI) to develop a model governance framework. The goals for the governance framework were to promote and eventually compel responsible behavior, to enable technology improvement and promote the sharing of operational wisdom, to build on the current IBC review process, and to foster and support international transparency and cooperation.

From the industry point of view, it is crucial to deploy effective biosafety and biosecurity measures while retaining the ability to deliver high-quality products at a low cost in a way that is effective for customers. From the law enforcement viewpoint, it will be important to be able to deter, interdict, respond to, and investigate criminal acts. To do so, records must be retained in a way that will support tracking what has happened if a malevolent act occurs.

The ICPS and the IASB are supporting a tiered screening framework along with an ongoing process of engagement with various national governments. This tiered screening process spreads the responsibility among everyone involved in gene synthesis technology. Individuals who place orders are responsible for identifying themselves and their institutions. Institutions bear responsibility for reviewing the people who place an order, often through use of an IBC or equivalent. Companies are responsible for screening orders to determine whether the order is for a sequence that should not be provided. It is hoped that the government will provide a clearly defined reporting process; toward that end, a pilot reporting process is in place with the FBI in which the FBI is working with three U.S. gene synthesis companies to develop a reporting framework. In addition, GeneArt (a German company that is the largest gene synthesis supplier in Europe) has an active interaction with the German government on the export of synthetic genes.

Regarding companies that refuse to participate in these consortia and their standards, the ICPS and the IASB will use peer and social pressure to encourage other companies to join. The largest groups missing now are the synthesis groups in China.

Link to Dr. Mulligan's slides.

**G. Special Presentation: Promoting Global Health Research: Building Partnerships and Training the Next Generation**

*Presenter: Michael P. Johnson, M.D.*
*Deputy Director*
*Fogarty International Center*
*National Institutes of Health*

Dr. Johnson described the great interest in global health over the past decade, and the recent rapid expansion of global health interest and programs among students and research/training institutions. This creates significant opportunities for increased global partnership in the overlapping areas of research, training, and service delivery. This interest began in the last decade, during which there have been unprecedented increases in attention and funding for global HIV/AIDS, which has included enormous increases in U.S. Government financial support for global HIV/AIDS prevention, care and treatment. The research budget in global health has not seen the same dramatic increase, but the substantial awareness and support for global health and global health research collaborations on the part of the U.S. will likely increase in both HIV/AIDS and more broadly.

U.S. research and training institutions are working to respond to the growing student interest and opportunities by creating university-based global health centers. In the U.S. alone, there are approximately 120 U.S. university-based programs in global health, and a substantial subset have considerable infrastructure, as evidenced by; (1) institutional commitment and funding, (2) cross university collaboration in global health, (3) significant ongoing foreign collaborations, and (4) offer a triad of research, training, and service delivery. A group of these university-based global health programs are moving toward a more formal status of an academic society that includes accreditation, curriculum development, training and degree standards, and academic journal development.

As the opportunities in global health expand past HIV/AIDS, they are also poised to expand past infectious diseases. The increased life expectancy worldwide will increase the need to focus on chronic, non-communicable disease, as well as infectious diseases, in programs and research. Examples of non-communicable diseases with a rapidly growing global burden include cancer, cardiovascular disease, mental health, and trauma/injury.

The increased inter-connectedness of the people and countries of the world is also fueling new collaborations in global health. Internet communication technology, global travel, and a new focus on health diplomacy will lead to even more opportunities in global health.

The Fogarty International Center at NIH has a mission of stimulating global health research across the NIH, and providing support for global health training and capacity-building. Strong working relationships with the other Institutes and Centers of NIH lead to both co-funding and intellectual collaboration. Fogarty has a new strategic plan which includes; (1) training US and foreign global health researchers, (2) responding to the new global epidemics of chronic, non-communicable diseases, while continuing work in global infectious disease, (3) fostering “implementation science”—the science of how scientific discoveries in specific social, economic, and cultural settings can be expanded and delivered across regions and countries to benefit the maximal number of people, (4) supporting increased institutional capacity for health sciences, which can be in the form of centers of excellence or hubs, and utilization of IT to do this, and (5) fostering institutional partnerships to achieve this ambitious agenda.

The work of the Fogarty International Center is relevant to deliberations on DURC and its management. Some Fogarty programs that seem especially relevant to the topic of the Roundtable include the following programs:

- A research ethics program with direct grants to investigators in over 12 countries, plus agreements and collaborations with another two dozen countries, to develop long-term training opportunities, often degree-related, in research ethics. This program includes the analysis and development of national standards and guidelines, to participate internationally, and fosters these ethics scientists and practitioners to be a part of the global community in research ethics.
- Fogarty supports a program in global infectious diseases. This program funds a number of investigators throughout the world to look at various aspects of mostly tropical or global diseases such as tuberculosis, malaria, dengue fever. Some of these raise important biosafety issues because of the technology and laboratory support needed to carry out these studies. This appears to present another opportunity for collaboration. In some cases, there are collaborations between the US Department of Defense and foreign military organizations. Fogarty also supports a program in ecology of infectious diseases that has relevance to biosecurity, and would be a potential possible focus for collaboration on DURC. A number of viral diseases are examined in the context of changes in ecology, drought, and deforestation.
- Fogarty has a framework program that provides support to mostly US universities to bring together multiple schools within a university in developing global health curricula. Thus, for example, a school of public health will be encouraged to collaborate on global health with a school of nursing, a school of law, a school of liberal arts, a school of engineering, etc. These collaborations encourage the discovery of new ways to train, conduct research, and deliver services in a global context, and to work on cross-cutting issues of mutual interest, such as management training, ethics training, and information-communication technology training.

Dr. Johnson identified several characteristics of the Fogarty programs that appear to lead to successful global health collaborations and capacity building. These include the following:

- Long-term capacity training, often degree-related, which leads to increased capacity and to the development of long-term relationships between U.S. and foreign investigators.
- Local control and flexibility are important. Fogarty’s foreign partners have a great deal of control over the programs, including the choosing of who gets trained. This leads to appropriate local research capacity through a high rate of return to the host country following training in the U.S., which counters the “brain-drain” syndrome.

The collaborative nature of the Fogarty programs brings foreign scientists into the global community, a key point in the deliberations of this meeting. Fogarty sees itself as a catalyst with its small grants to develop greater human capacity and institutional capacity building, and ultimately, collaborative long-term relationships.

Link to Dr. Johnson's slides.

## III. BREAKOUT SESSIONS

### A. Awareness Raising/Training and Education

#### *1) Current Status*

There is wide variability in the international scientific community's level of awareness about dual-use research. This variability exists across national boundaries, across relevant disciplines, and across sectors. Concerns regarding biosafety can outweigh concerns of biosecurity, especially in developing countries. Extant efforts to raise awareness have been successful, even though limited in some cases. It is challenging to accurately assess the level and scope of awareness. Overall, however, the level of awareness is not sufficiently high or widespread. Various curricula address dual-use issues, some of which have been developed to specifically target dual use research and others, primarily, to address biosafety or biosecurity. There are also extant programs to "train-the-trainers." Educational efforts of note include the following:

- The American Association for the Advancement of Science (AAAS) is holding a workshop at the end of November 2008 to review educational tools, etc. related to DUR.
- The WHO is developing guidelines that should be available for broad use in 2009.

#### *2) Challenges*

The group identified some challenges to increasing awareness of DUR and education regarding DUR, including the diverse audience, the various levels of training and professional development, and the many relevant disciplines that are impacted by DUR concerns.

There are numerous existing frameworks for the education of scientists and other stakeholders. Extant courses on bioethics, biosafety, biosecurity, and responsible conduct of research (RCR) are available, and, in certain contexts, required. While these types of courses each provide a valuable opportunity for the introduction of DUR education into existing curricula or programs, this approach is not free of challenges. For example, if DUR issues are introduced into bioethics curricula there is a need to determine the most appropriate way to effectively teach about DUR in that context. Similarly, responsible conduct of research training could provide an appropriate venue for education about DUR. Before that approach can be entirely effective, however, the scientific community must embrace the fact that attention to DUR issues is an integral element of responsible research conduct (just as is the case with human subject protections and animal welfare). In addition, extant educational models may not reach sufficiently broad audiences. For example, many training activities are geared only towards undergraduate and graduate students. Also, the identification and education of IBC members may need to increase as awareness of DUR increases and as local institutions begin implementing DUR review. These situations create numerous challenges in terms of education as well as resource support for educational efforts.

The international nature of the DUR problem and the increasingly global life sciences community pose other challenges for training and education efforts. Awareness raising, training, and education efforts may best be led by local scientists. These individuals will be in the best position to know the local life sciences context and tailor any efforts to the priorities, interests, and needs of the local community—making the curriculum appropriate and relevant. However, in order for any of these or other efforts to manage DUR to be truly successful, there will need to be approval from higher levels and from non-scientific stakeholders (i.e. political sectors). There is also the need for some level of consistency in the education and training provided to life scientists worldwide. As above, however, differences in scientific and educational systems and infrastructure may necessitate that educational efforts are tailored to local context—to address issues related to the appropriateness and relevance of the training to the intended audience(s). These concerns need to be addressed as materials developed in, for example, the United States are disseminated to developing countries. In addition, effective or promising educational modules should be developed in multiple languages.

Training programs and educational materials need to be sustainable. It is important that the educational materials remain available and stay relevant as science advances and as priorities shift. In addition, relevant stakeholders should be held to some level of accountability for the success of training and education efforts.

Finally, many of these challenges point to the need for a common understanding of DUR and the associated risks. The scientific community understands the concept of "do no harm," but it is challenging to fully understand how to accomplish this, especially in terms of DUR. Some basic level of common understanding of the DUR concept and associated risks could go a long way in advancing the awareness and effective management of DUR.

***3) Moving Forward***

The group identified a variety of opportunities to advance the goals of increased awareness of DUR and to enhance education and training on DUR issues. Overall the group identified the leveraging of current educational efforts in various areas (i.e., ethics, biosafety, biosecurity, responsible conduct of research) and the development of standard components of educational programs as important efforts to advance DUR education and training.

There are a variety of populations who should be educated about DUR. To that end, the group identified two specific goals:

- Provide undergraduate training and education on DUR; and
- Strengthen researchers' preparedness to handle DUR issues; they often do not fully understand the issues or know the relevant policies and regulations.

The group identified networking as an important next step in enhancing awareness internationally, across relevant disciplines, and across sectors, especially now when there is only minimal awareness of DUR issues in some places. Identifying contact persons in different countries, organizations, institutions, etc. is useful in raising awareness. Partnering with professional societies and NGOs also provides valuable opportunities, especially in terms of working at both regional and national levels. Networking efforts can also be leveraged to share ideas and best practices, so that duplication of effort can be avoided. The group also explored the concept of developing a group or network of "champions." Identification of a champion—ideally an organization to advance the goal of raising awareness—would be particularly useful. Champions could be identified in various countries and regions, from all sectors (government, academia, and industry), and from relevant disciplines.

The group agreed that the development and review of standard components of a module by a credible, international body would be valuable in promoting the implementation of educational activities. Electronic or web-based modules that could be self-administered and completed in a short period of time would provide tools to raise awareness. These would not be perceived as overly burdensome and may be a useful first step.

The group discussed the value of certification of training. Certificates could be awarded at successful completion of an education module or some other training. Certification of DUR training could be required for job applications, etc. Accreditation was also noted as potentially useful in validating training and education efforts.

The availability of training and education opportunities should be advertised in relevant publications as well as during relevant meetings of scientific societies, scientific unions, etc.

The group also identified opportunities in response to some of the identified challenges. For example, by using technology such as video-conferencing to provide training across geographic areas will also provide opportunities to network and discuss DUR issues from a variety of perspectives.

Efforts to raise awareness will be most effective if they incorporate basic elements that support a level of standardization and are tailored to local (i.e., country) needs. Opportunities to share materials and network regionally and internationally will accelerate the process of raising awareness in both developed countries and countries with emerging and developing economies.

Link to Awareness Raising/Training and Education slides presented at the closing plenary session.

## B. Codes of Conduct/Culture of Responsibility

### *1) Current Status*

The breakout group identified that codes of conduct have already been developed by various groups, and inventories of codes have been assembled by other organizations and can be found at two websites. (http://projects.exeter.ac.uk/codesofconduct/Chronology/index.htm, http://www.biosecuritycodes.org/codes.htm)

There exist a range of codes of conduct—from general statements of ethical principles to codes of conduct that are explicit and/or directive. This continuum of codes of conduct includes the following categories:

- *Statements of ethical principles*: These codes may reach a varied audience, not only scientists.
- *Aspirational codes*: These codes may serve as a starting point for developing later frameworks (i.e. codes of ethics).
- *Educational or advisory codes of conduct*
- *Enforceable codes*: These codes involve a form of requirement, for example a legal requirement, and may also involve punishment for violation. Enforcement could occur when acceptance of a code is a condition for membership in a professional group, is required for licensing within a profession, or is required for employment at an institution (i.e. codes of practice).

A given code may contain elements of each category in this continuum, and a given code may develop over time.

Breakout group participants discussed the code-related activities of the groups, organizations, and/or nations they represented:

#### i) Extant Codes

- *Dutch Academy Code of Conduct*. This code is an example of an educational and advisory code that specifically covers issues of biosecurity and serves a specific audience with specific content. The code's key characteristic is raising awareness. Its prescriptions are not compulsory.

- *International Union of Biochemistry and Molecular Biology (IUBMB)*. The IUBMB has produced general principles for a code of ethics that are then adapted locally. The code of ethics includes a warning against misuse of science and against bioterrorism. It is not clear how enforceable the code could become. Membership consists of societies from different countries, so if an individual violated the code, the IUBMB would not have many options for enforcement.
- *International Union of Microbiological Societies (IUMS)*. The IUMS has produced an aspirational code of ethics—a short, very general statement. The draft was submitted to member societies. Some local societies already had codes of ethics in place, so it was sometimes difficult for them to accept another one. It was also difficult to devise a code to fit everyone's interest. The IUMS enforces the code by requiring its acceptance as a prerequisite for union for membership.
- *InterAcademy Panel (IAP) Statement on Biosecurity*. The statement offers guiding principles from which organizations, associations, and others can develop specific codes for their specific audiences.
- *Mexico National Center for Epidemiological Surveillance and Disease Control Code, Ministry of Health*. This is an aspirational and educational code, 2 pages long, and mandatory. The code covers one institution and has been accepted by 500 individual signatories who work at the institution. The code is part of quality assurance. Since the institution has a large faculty with diverse foci, it was difficult to find a code that incorporated the concerns of all specific groups within the institution, and negotiation was required.
- Other codes include:
  - American Society of Microbiology
  - *Code of Ethics for the Life Sciences* (Somerville & Atlas)
  - NSABB Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences (Appendix 3. *Proposed Oversight Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*)
  - International Union of Pure and Applied Chemistry (IUPAC)

**ii) Related Activities of Interest**

- *Biological Weapons Convention*. Recent discussions at the BWC have covered oversight, education, awareness raising, and codes of conduct, including adoption and/or development. A synthesis paper from the August 2008 Meeting of Experts has been developed (*Synthesis of Consideration, Lesson, Perspective, Recommendations, Conclusions and Proposals Drawn from the Presentations, Statements, Working Papers and Interventions on the Topics Under Discussion at the Meeting of Experts*), with sections 12 and 13 being most relevant to the breakout group's discussions. A web resource was also developed in follow-up to the BWC Meeting of Experts. The Meeting of States Parties in December 2008 is seen as an opportunity to reach international agreement on how to move forward on codes of conduct.
- *Science community in Japan*. The process of discussing codes has served as a mechanism for raising awareness. The process has highlighted the importance of local development of codes of conduct. The Japanese microbiology society is using the IUMS code as the basis for its own effort in developing a code of conduct.

- *University of Manila, Philippines*. The process started with a biosecurity and biosafety committee, with the aim of education and capacity building. The aim is to build in a code of conduct into the educational curriculum.

***2) Challenges***

While most breakout group participants agreed that the focus should be on encouraging the development of codes rather than their harmonization, there was some dissension, with concern that the call for multiple codes may undermine long-term goals—professionals need clarity and security, and having overlapping codes with unclear jurisdictions could be problematic. There may need to be consistency in principles and perhaps in enforcement. One of the responses to this objection was that evolution was expected—we are not yet prepared to have a universal code, but one could eventually emerge as agreement is achieved. The group members agreed that any framework created now should encourage codes to converge. Participants also agreed that major principles should emerge and be held in common, and, certainly, principles should not oppose each other. However, there is a place for tailored and more detailed codes for specific disciplines or other specific groups.

The group identified several challenges to the broad and effective development and implementation of codes of conduct. For one, it will be challenging to convince individual scientists of the importance of paying attention to DUR issues and that they have an ethical obligation to prevent or mitigate the misuse of the results of their research. In addition, there are challenges to putting existing codes and frameworks into practice and enforcing them, as appropriate.

In addition to looking at an individual-level culture of responsibility (individual scientists recognizing that their work may pose risks and they have a responsibility to consider and mitigate those risks), there are challenges to implementing a broader culture of responsibility. This would include scientists having an awareness not only of the risks of their work but also the work of their colleagues and the broader scientific community. Both of these levels of "culture of responsibility" raise questions regarding appropriate actions in the face of potential problems and identified risks: to whom and how can scientists report , what should they report, and is there a need to protect "whistle-blowers"?

***3) Moving Forward***

Overall the breakout group identified three principles for moving forward with developing and implementing codes of conduct. 1) There is a need to make codes relevant to specific audiences and the specific contexts in which they will be applied. 2) It will be useful to customize existing codes. 3) Adoption of codes needs to be encouraged.

The group expressed encouragement for the implementation of codes at the national level, by scientific bodies, at academic institutions, and by industry. In addition, the group agreed that inclusion of codes of conduct in mandatory ethics training may be the most effective way to put codes into practice. This would support codes taking root as part of the culture of the scientific community and other relevant fields. The Hippocratic Oath was cited as a successful code that has permeated the culture to the extent that, even beyond the medical profession, everyone understands the basic concept of "do no harm."

The following were identified as characteristics of successful or promising activities:

- Consistency with internationally accepted norms, laws, frameworks, and principles. (Participants cited the Biological Weapons Convention, UNSCR 1540, and Australia Group agreements.)
- Level of detail appropriate to the particular issues, i.e. biosecurity or dual use. Content of codes can be more specific for specific communities or disciplines.

- Successful engagement of scientists through professional societies, associations, etc.
- Taking advantage of best practices and information sharing in the evolution of codes. To this end, the group discussed the value of a clearinghouse for codes activities, where information and tools could be made available on the web.

Harmonization was identified as a good, long-term goal, but the current need is to broaden the involvement of the life sciences community in thorough, iterative discussions to evolve and improve codes of conduct. Finally, the group concluded that involvement of the life sciences community in developing and improving codes of conduct can also serve to educate the scientific community and raise awareness.

Link to Codes of Conduct/Culture of Responsibility slides presented at the closing plenary session.

## C. Review of Research Proposals/Guidelines for Review

### *1) Current Status*

During the breakout sessions participants shared brief descriptions of the systems in place in their respective countries or organizations for managing dual use research of concern during the research proposal review stage. Participants also shared biosafety, biosecurity, ethics, and other review frameworks related to dual-use research proposals.

The descriptions of the systems in place in various countries and organizations also took place within the context of the plenary presentations, describing the specific procedures in place for handling the review of dual use research in life sciences research proposals in the European Commission, at Duke University's IBC and in the UK Research Councils and the Wellcome Trust.

In addition to discussion of procedures being followed, including those presented in the plenary, the breakout sessions included a general discussion among all the participants and identification of some general observations that arose from the preceding days' discussions.

Please refer to the end of this section for a link to the slides presented at the closing plenary, which include a summary of each of the descriptions shared by breakout group participants. A few of these descriptions are highlighted here.

- *Southeast Regional Center of Excellence for Emerging Infections and Biodefense, United States (Allison Chamberlain, M.S.):*
  Founded in 2004, the Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB) is one of 10 biodefense research centers of excellence funded by the National Institutes of Health (NIH). SERCEB leadership created the Policy, Ethics, and Law (PEL) Core to specifically examine the policy, ethical, and legal issues associated with biodefense research. The PEL Core's advisory committee comprises individuals from seven institutions who are largely responsible for decisions about which projects the Core focuses on. The expertise of these individuals ranges from genetics to virology to law to bioethics.

  As the governing body for SERCEB, the Scientific Steering Committee reviews all research proposals coming into SERCEB for funding consideration. During this review, the Steering Committee conducts a cursory review for DURC before passing the proposals likely to receive funding on to the PEL Core. The PEL Core's advisory committee then conducts its own dual-use review of each proposal, taking into account the NSABB criteria (pp. 16-22) and the Fink report criteria (pp. 5-6), as well as a few bioengineering technologies that did not fit cleanly into those categories. Depending on the number of proposals in a given funding cycle, the PEL advisory committee's turnaround time to send comments back to the Steering Committee ranges from 4 – 14 days. The purpose of the review is to identify any DURC concerns, such as increasing a pathogen's host range or virulence. If the PEL advisory committee identifies potential points of concern in a proposal, the PEL advisory committee conveys a list of comments and questions to the Steering Committee, which in turn sends them to the project's Principal Investigator (PI) along with a copy of SERCEB's Dual Use Policy and a request to take SERCEB's online dual use educational module. The Steering Committee directs each project PI to address the PEL advisory committee's comments and questions before funding is disbursed. The Steering Committee communicates with each PI to ensure that he or she is clear about these potential concerns. Researchers are also asked to inform the Steering Committee of any developments that arise in the course of their research that have dual-use potential. Thus far, the PEL Core advisory committee has reviewed 44 proposals and has identified 14 as having dual-use concerns.

In June 2007, the PEL Core published a paper on its review process.[7] Supplementary materials to that article describe three examples of proposals that were identified as having potential dual-use concerns. One proposal involved a project on a microneedle vaccine delivery system. The PEL Core advisory committee questioned whether the delivery system could potentially be used to covertly deliver toxins or pathogens. Since this project did not involve recombinant DNA (rDNA) research, it may not have been reviewed by an Institutional Biosafety Committee (IBC). The project's dual use concerns came to light because the project was part of a SERCEB grant proposal. SERCEB identified the potential concerns and conveyed some questions to the PI. The PI responded that dual use was not a concern in the proposal because microneedle delivery requires intimate skin contact and significant interaction with a potential victim would not go undetected. The PEL Core advisory committee decided that the PI should at least consider this concern, however, and asked the researcher to address potential misapplication of the delivery technique and to elaborate on the steps to prevent it.

In another recent example, two researchers voluntarily brought to SERCEB their concern about a project for which they were seeking publication. The SERCEB PEL Core shared with the researchers communication strategies from NSABB's communications plan. This type of request might become more common as education and awareness increase.

Incorporating dual-use training and oversight mechanisms into existing programs, regulations, and requirements may be the most practical approach to devising a process for dual-use review. The PEL Core utilizes the SERCEB funding review mechanism as an opportunity to also review proposals for dual use concerns. The PEL Core uses the responsible conduct of research training requirements that many institutions have in place for their young investigators as avenues to host dual use educational panels or promote their online dual use training module. Moreover, SERCEB's Science & Safety Biosafety Training Program at Emory University started incorporating dual use training into its BSL-3 and BSL-4 hands-on biosafety courses to inform practicing biosafety professionals about the importance of dual use oversight. This strategy of building DURC training and oversight requirements into existing procedures and regulations, rather than creating new and separate dual use oversight systems, is worth including in the inventory toolbox.

[7] Davidson EM, Frothingham R, Cook-Deegan R. Science and security: practical experiences in dual-use review. Science 2007;316(5830):1432–1433.

- *Centers for Disease Control and Prevention, United States (Janet K.A. Nicholson, Ph.D.):* The Centers for Disease Control and Prevention (CDC) is a sister agency to NIH within the U.S. Department of Health and Human Services (HHS). CDC has in place a number of processes for DURC review. Many of the proposals that CDC receives for research with dual use potential come through the Coordinating Center for Infectious Diseases (CCID), which reviews all research papers submitted for publication.

  Currently, the CCID does not evaluate projects for DURC before they are completed; rather, these concerns are identified when an article is submitted for publication and undergoes formal internal agency vetting, the agency clearance process. The Associate Directors for Science are the points of contact in that review. High-profile projects are conveyed to the highest levels of the organization.

  Papers characterizing the genome of the 1918 influenza virus, published in 2005 in *Nature*[8] and *Science*,[9] triggered pre-publication review by CCID. These papers also led to the creation of an eight-member Institutional Biosecurity Board (IBB), which includes some IBC representatives and some Associate Directors for Science. The board created a questionnaire with a risk-benefit analysis to be administered to investigators involved with DURC. However, nearly all standing monthly meetings of the IBB have been cancelled because of the paucity of proposals of concern.

  In reviewing proposals for DURC, the IBB discusses whether the research should be published and, if it is decided in the affirmative, what considerations should be taken into account with regard to changes that should be made prior to publication. CDC has developed a policy, created an on-line training tool for DURC, and has provided briefings of the Associate Directors for Science.

- *University of Texas Medical Branch (Stanley M. Lemon, M.D.):* At the University of Texas Medical Branch (UTMB), an IBC reviews all work pertaining to the use of rDNA as well as any infectious agent. A “Notice of Use” form is conveyed to the IBC with a brief description of the research in question and its conformance, if any, to any NSABB experiments of concern. To date, no substantive concerns have been raised from a dual-use perspective. Recertification of the project takes place every 5 years unless there is a major change in experimental design.

The group discussed a variety of extant review procedures. While review for dual use potential is not currently integrated explicitly into all of these review mechanisms they provide opportunities for the introduction of DUR review into current practice. It was suggested, for example, that the biosafety review for rDNA research would be a practical point for the introduction of DUR review. The group discussed three primary points where review of research currently occurs: 1) scientific peer review of proposals, 2) review at the time of funding, and 3) pre-publication review.

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[8] Taubenburger JK, Reid AH, Lourens RM, Wang R, Jin G, Fanning TG. Characterization of the 1918 influenza polymerase genes. Nature 2005;437(7060):889–893.
[9] Tumpey TM, Basler CF, Aguilar PV, et al. Characterization of the reconstructed 1918 Spanish influenza pandemic virus. Science 2005;310(5745):77–80.

***2) Challenges***

Awareness of DUR issues is variable. In some countries there is a good deal of awareness, whereas in others there is very little. However, overall, there appears to be increasing awareness, evidenced by the number of countries that are taking action to manage DUR.

A central challenge in the review of research proposals for dual use potential is that the review cannot merely be a scientific review. A review of research proposals for dual use potential needs to be "enriched." There are security, ethical, and legal components in addition to strict scientific considerations. The review must consider and weigh the risks posed by the research, which requires robust scientific expertise. However, security expertise also needs to be represented in DUR reviews. As the review also pertains to a balance between scientific and investigative freedom and the need for security, there is an ethical component to the review and any review body must be appropriately equipped to address this issue. Finally, it is important that DUR review is transparent and should include participation by the public. To address the need for "enriched" DUR review, it may be necessary to broaden the membership of IBCs, if they will be performing DUR review.

The group struggled with the relative merits and disadvantages of a narrow versus a broad approach to DUR review. Some participants suggested that review for DURC should focus on the most consequential DURC. Such a system would require the development of well defined, clear and objective criteria for the identification of DURC. This approach would allow for consistency in implementation, mitigate the most serious risks, and very clearly capture only research proposals that raised DUR concerns. Other participants felt that a simpler system would be more pragmatic. Rigidity in definitions and criteria may result in research that actually is DURC not being captured, since it might not neatly fit the criteria. In addition, especially as science advances and becomes increasingly interdisciplinary, it is hard to classify even areas of research that uniquely raise DUR concerns. A broader system would encourage all scientists to think about the dual use potential of their research.

This tension highlights the challenge of defining DUR as well as what differentiates research with dual use potential (which could arguably include all life sciences research) from dual use research of concern (DURC), which would presumably require some action to mitigate the risks posed. Definitions for DURC could range from a "checklist" approach, i.e. focus on a specific list of research areas or agents of concerns, to a more open-ended approach based on the general concept of DURC. Various bodies (including the NSABB and the NRC Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology/"Fink Committee") have developed criteria and/or identified categories of research to aid in the identification and analysis of DUR. However, no countries have developed or adopted objective criteria for identification of DURC. Absence of a definition or criteria for identifying DURC could lead to ineffective oversight that captures either too much or too little research. In addition, it is important to address the possibility that definitions and criteria may differ between and among countries and institutions and to recognize the problems such inconsistency would cause.

As additional definitions and criteria are developed, a way must be found to ensure that significant areas have not been omitted. This is a particularly challenging as it is difficult to anticipate what areas of research will present dual use risks in the future and how advances in science will impact current definitions and understanding of risks. Procedures will need to be developed that will ensure that definitions are sustainable and modified when necessary.

The group identified a number of questions that will need to be addressed in developing and implementing additional DUR review systems:

- Do the definitions of DUR and DURC fit real research protocols—both in terms of sensitivity and specificity?
- Is the review reproducible? Will different reviewers reach similar conclusions, in terms of categorization of research? Will they suggest comparable management strategies?
- Does the inclusion of a discussion of dual use in a grant application enhance or reduce the application's score?
- Does review for dual use potential increase public confidence? Does this review in any way worry the public?

***3) Moving Forward***

The group identified several overarching concepts that are important to move the field of DUR review forward. Review of research must occur across the research life cycle from project design to proposal review to publication. There is a need for an enriched DURC review process that includes legal, ethical, biosafety, and security expertise, in addition to scientific expertise. The review mechanisms need to be transparent and research in all sectors (academia, government, and industry and others in the private sector) needs to be included.

The group identified review across the research life cycle as important for a variety of reasons. It is important to mitigate risks before work begins, to the extent possible. However, at the outset, the full extent of risks that could arise may not be known. There may be unanticipated developments that pose new risks. An ongoing and iterative process that would include a variety of relevant parties in the review process, including investigators, institutions, funding bodies, and editors and publishers, will be necessary.

The point of reviewing research proposals for dual use research of concern is not to place unnecessary constraints on or prohibit research, but rather to create a situation in which research can proceed safely, securely, and with the confidence of the public.

Link to Review of Research Proposals/Guidelines for Review slides presented at the closing plenary session.

## D. Scientific Communications/Presentations and Publications

### *1) Current Status*

During the breakout sessions participants shared brief descriptions of policies, procedures, and other mechanisms in place at their journal or organization for reviewing medical and scientific manuscripts for dual use research of concern. The descriptions of extant practices also took place within the context of the plenary presentations describing the specific procedures in place for handling the review of dual use research.

#### i) Extant Journal Policies, Statements, and Activities

| Journal Title | Link to Policy, Statement, Activity, etc. | Other References and/or Notes |
|---|---|---|
| *Nature* | Policy | Refer to Dr. Linda Miller's presentation summary |
| *Biosecurity and Bioterrorism* | Policy | Refer to Jaclyn Fox's presentation summary |
| *Proceedings of the National Academies of Science* | Policy | Refer to Dr. Linda Miller's presentation summary |
| *American Society of Microbiology* | Policy | Refer to Dr. Linda Miller's presentation summary |
| *Science* | Policy | Refer to Dr. Linda Miller's presentation summary |
| *The Council of Science Editors (CSE)** | White Paper | |
| *The International Committee of Medical Journal Editors (ICMJE)*** | At present, the group is debating whether to mention DURC, and, if so, what should be said on the subject. | |

*CSE is a membership organization consisting of more than 1,000 editorial professionals, representing approximately 650 journals from around the world, in the sciences. A focus of CSE is promoting integrity in scientific publications.
** ICMJE, representing five of the highest circulation, highest impact medical journals, including the *Journal of the American Medical Association* (*JAMA*) and the *New England Journal of Medicine* (*NEJM*), *The Annals of Internal Medicine*, as well as other national and international journals, has been meeting for some time to, for example, advise authors on good form for structuring articles. The group's "uniform requirements" are influential.

- In addition NIH/OBA staff had prepared a background summary document that identified DURC-related policies and procedures of a variety of medical, scientific, and other journals for distribution to the breakout participants.

#### ii) Extant Mechanisms for the Management of DURC

Discussion of current journal policies and activities related to management of DURC revealed a variety of mechanisms that are in use by various journals.

- *Instructions for Authors: Science, Annals of Internal Medicine, Biosecurity and Bioterrorism*, and others noted that their journals all have instructions for authors. In some cases, these instructions require reviewers to respond to specific questions that do or might relate to DURC.

- *Instructions for Reviewers:* Reviewers for *Biosecurity and Bioterrorism* are given the following question to answer on their review forms: Is it your judgment that the information contained in this paper would substantially lower current existing scientific, technical, or logistical barriers to bio weapons attacks an/or increase the potential future consequences of bioweapons attacks? [Choices for response are: no, yes, if yes how.] This is called a "prudence review."
- *Guidance for Editors:* NSABB has developed a set of communication tools for responsible communication of research with dual use potential, including principles and "Points to Consider for Identifying and Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential," which *Nature* (and possibly other scientific journals) uses as a form with its referees. *Nature* has noted no resistance to use of this form.
- *Press Releases, News, Policy Forums, Commentaries, Editorials, Etc.:* *Science*, *Nature* and other major journals provide press releases as well as commentary, in part, as public acknowledgement of safety precautions and biosecurity concerns.
- Other vehicles currently in use that relate to DURC mentioned during the breakout session include the following: Master Courses, society newsletters, websites and others.

**iii) Experience with Dual Use Research Manuscripts**

The group discussed the magnitude of the dual use research problem as it relates to scientific publications, the number of manuscripts submitted that raise dual use concerns, and the number of manuscripts that have been rejected. (Refer to Dr. Miller and Ms. Fox's plenary presentation summaries for information on the experiences at *Nature* and *Biosecurity and Bioterrorism*.) At *Science* the evaluation of papers of dual use concern takes a significant amount of time. Since such papers are rarely submitted to *Science*, however, the overall burden is not significant. Concerns have been raised at the peer review level only four times. To date, *Science* has not rejected any papers that raised concern.

***2) Challenges***

Journals desire minimal disruption to openness/transparency. At the same time, editors acknowledge that they act as gatekeepers for issues related to protection of public health, that journals are the last step in the review process and, as such, are the final barrier to this form of information dissemination. However, journal editors should not be considered the ultimate safety net. Over-emphasis on the last step in any process is not prudent. The determination that a research paper represents dual use research of concern should be made upstream of submission to journals, at the institution or organization supporting the research, and action taken. The editors would like determination of DURC to happen upstream, before it is submitted for peer review and possible publication, and prefer that nothing that raises serious dual use concerns should come to a journal that has not been flagged beforehand. They realize, however, that this will not always happen. Lack of satisfactory upstream review may be due to a lack of procedures for research review, problems with local expertise in institutions, or disagreements and the absence of simple criteria.

Emphasis was also given to relevant NSABB *Oversight Framework* and how the NSABB represents a balance between the use of science for good and for nefarious purposes. While processes need to be in place upstream throughout the research continuum, as identified by the NSABB, at this time journal editors may be doing the most, globally, to provide the necessary review. Capacity for DURC review is building at different points in the continuum. It was noted that there is great variation in upstream review among countries. Increasingly, some key journals, such as those of the ASM, receive many manuscripts from other countries, and many journals receive a substantial number of international submissions because online submission has removed previous barriers.

**i) Need for Standard Practices and Consistent Approaches**

While mechanisms exist to provide for standard practices and consistent approaches to identifying and dealing with potential cases of DURC, there are a number of challenges that need to be confronted.

The journal editors discussed the importance of an international consensus on how to identify DURC. Some believed the "Fink report" definitions would be a good starting point/tool while others liked the NSABB concept of a criterion for identifying "dual use research of concern" because it is narrowing and focusing. They believe the NSABB has done its best to identify criteria we know, if fulfilled, will cause harm.

A number of journals, however, already have processes in place for dealing with manuscripts that raise DUR concerns and believe the only question is what it is called.

Thus, not having an internationally agreed definition is an important issue but is clearly not a major barrier to moving forward with the review for DURC by journals. It is an issue, however, that needs to be addressed further. Regardless, editors and the public need to understand, that while not every manuscript of concern will be caught, the risk of publishing such information will be reduced overall. It was stated that at this time, with some uncertainty about definitions, special emphasis should be placed on careful vetting of the most high risk manuscripts.

The question of whether journals have a responsibility greater than their individual rejection of a given paper of concern was discussed as a serious challenge. If a paper is rejected, what is the journal's responsibility, if any? What is a journal's responsibility toward poor quality science papers with DURC potential, other than to reject them on the basis of the science? What if the science is of high quality? Would the journal reveal the identity of referees to the author to encourage dialogue? (Many journals have a policy against this unless the referee agreed.) Inform the author's institution, in addition to the corresponding author? The funding agency? The NSABB? These are questions that the editors have been asking themselves. It was stated that editors have neither the authority nor the resources to police researchers' behavior, particularly authors of rejected manuscripts.

**ii) Engagement of Media/Medical and Science Writers**

Public perception is an important element in the DURC discussion. If the public is scared about DURC they can put pressure on the research enterprise to halt research. It is important that the public knows that there is a rigorous process to look into these issues. Press releases and communications officers can help to assure that journalists have information that they can use to convey to the public on how due diligence was applied to mitigate risks associated with a specific DURC publication, thus reducing the potential for over reaction. Educating the media is also critical. Those journalists who cover life sciences publications in influential medical and scientific journals are a key group and should be informed, in general, about DURC issues.

How to engage the lay media ahead of the publication about a particularly sensitive manuscript is a major concern. Science writers could receive advance information regarding the articles about to be published in order to help ensure the correct message gets to the public. This must occur prior to publication, at the very latest during the period of embargo prior to publication, while the article is available only to the press.

A special problem occurs when a researcher turns to publication in the lay media when he or she is unable to publish in a peer reviewed scientific journal. A related problem occurs when an author tries to capitalize on serious concerns raised about DURC prior to publication. This happened in the case of the botulinum toxin in milk article. The U.S. government, very late in the process, requested that the editor not publish the paper as it was viewed as a "blueprint for terrorists," but the government's request led to the publicizing the article in the lay press and did not stop publication in the journal. An additional issue is that the Web ensures many outlets for communication and ultimately editors and researchers will not be able to "control the message" of any given study.

**iii) Identifying Manuscripts of Greatest Concern**

Questions arose that, since the previously referenced botulinum toxin in milk article and the 1918 pandemic influenza papers were published, what types of papers raise sufficient concern that they should not be published?

Journals need to be able to obtain expert review of technical and security aspects of a DURC manuscript and, if a decision to publish is reached, to provide background that helps in writing explanatory commentary. Government scientists and security experts are an important resource. This led to comments that it was critical that any DURC review be expedited and that if DURC concerns were raised very late in the process—especially if an article is already available to the press online, but embargoed, it could lead to friction and misunderstandings—as with the botulinum toxin in milk manuscript cited above.

**iv) Education and Training**

The question as to whether or not training for peer reviewers was necessary was discussed. *Science* does not offer special training and believes that the general information for reviewers contains sufficiently specific guidance and reviewers have not asked additional questions about security issues. The World Association of Medical Editors (WAME) noted the association's recent survey of its editors, which indicated that only two percent had had any formal editorial training. A vast majority of these editors have never considered DURC issues and potentially might be in a position to publish manuscripts rejected elsewhere. WAME provides free on-line education of editors because many of its members are from developing nations, and even those who are not may be "resource poor." Editors look to peer reviewers to provide expert review regarding content, scientific misconduct, and many others issues in addition to, potentially, DURC. Ultimately, the editors must decide what should be published, but should clearly not be considered the sole arbiters of what constitutes DURC.

**v) Review of Conference Presentations/Poster Sessions/Abstracts/The Internet**

The group acknowledged the importance of identifying DURC in conference presentations, abstracts, poster sessions, the Internet, etc., but recognized the inherent difficulties of implementing review mechanisms for these settings. If DURC is not identified and managed in these settings, the value of journal editors screening for and managing DURC as a barrier to releasing research of concern maybe diminished because the information will already be in the public domain.

### *3) Moving Forward*

#### **<u>i) Need for Standard Practices and Consistent Approaches</u>**

Editors from a broad range of journals should plan a process to move forward. Issues that should be considered include:

- Editors, authors, and reviewers need to learn about what DURC is and have resources available that discuss DURC.
- Editors should consider dealing with DURC in their Instructions for Authors and Instructions for Reviewers.
- Editors should consider asking authors to confirm or deny DURC in their manuscripts submissions, perhaps along with their conflict of interest declarations. Alternatively, there could be statements of due diligence in acknowledgments rather than having the editor rely only on asking authors to confirm or deny DURC in their manuscripts.
- Editors should agree on ways to make author instructions more uniform, including, where possible and appropriate, directions and a consistent definition of DURC across journals.
- If Institutional Biosafety Committee (IBC) or a similar committee review was involved in a given paper, journal editors should be informed about this and receive the details.
- As part of the editorial review process, reviewers could be provided with a checklist to streamline the process.
- It will be important to reassure authors that rejection based on DURC issues will not alter the process that journals already follow when authors protest rejection.

#### **<u>ii) Codes of Conduct and Awareness Raising</u>**

Codes of conduct must address the responsibilities of authors, editors, and publishers of scientific publications and possibly non-scientific communicators as well. Codes of conduct and awareness raising can educate communicators, and communicators can also help disseminate codes of conduct and build awareness, including among the public. The Dutch Code is a model for broad inclusion and specifically addresses the role of journal editors.

#### **<u>iii) Core Advisory System</u>**

An international advisory body that journal editors could turn to in specific situations would have a number of benefits. Some journals do not have ready access to relevant experts. The advisory body would be especially useful to resource-poor editors. This would also reduce individual journal review burden.

Broad expertise would be needed, including science, intelligence, and security expertise. It was agreed that there should be international representation, members should participate as volunteers, and funding is essential.

Advisory body members would have to be educated beyond "standard reviewers." They could be called upon to facilitate the review of complex or especially sensitive manuscripts and could advise smaller journals in the review of manuscripts for DURC. Also, journal editors could turn to this body if experts conducting DURC review for their journal disagreed.

Concerns were discussed regarding: to whom the advisory group would report, how members would be selected and appointed, and how to handle disagreements that might occur between the science reviewers and those advising on security and ethical issues. It was understood that ultimately editors need to make the final decision.

In addition to the concept of establishing an advisory body, the group discussed the option of providing a web-based resource that could include a registry of relevant experts, best practices, etc. Because journals may need help in trying to decide whether a manuscript poses a DURC problem that requires action, it would be useful to have a list of reviewers that could be shared among journals. If a list or group were developed, it was agreed the members' identities should be known. In addition, it was suggested that a database or "register" of cases submitted and outcomes could serve to provide "lessons learned" to the community, inform best practices, and provide a perspective on how big this problem is. Although it was emphasized that manuscript confidentiality would need to be preserved, case information could be used to educate and inform all stakeholders and develop more effective procedures. This presents challenges regarding the appropriate home for such a website and who should have the responsibility to keep the site updated.

Overall, there is a need to ensure "upstream" review of research as well as review at the time of submission for publication. It is also important that there be a consistent approach for the identification of DURC across various scientific publications. Editors should work to define an appropriate review process and provide instructions to authors and manuscript reviewers for the identification and management of risks. In order to facilitate the review of scientific publications it would be valuable to establish core systems allowing for journals to share experience and best practices, advise smaller journals in the review of manuscripts, and develop a registry of experts for this review. The establishment of networks will allow for the development and refinement of educational tools, codes of conduct, sharing of best practice, and expertise in and procedures for the analysis of any dual use potential in review of research proposals and scientific communications.

Link to Scientific Communications/Presentations and Publications slides presented at the closing plenary session.

## IV. ADDITIONAL FINDINGS AND THEMES IDENTIFIED IN PLENARY AND BREAKOUT DISCUSSIONS

There is a broad array of DURC management activities already underway by various countries and organizations. These activities cover many of the areas which were of special interest at this Roundtable, including awareness raising, training and education, codes, reviewing research proposals, scientific communications and publications, and the work of national-level advisory bodies.

While many challenges exist for all stakeholders, addressing dual use research also poses unique challenges in various sectors and for specific stakeholders. For example, the challenges for management of DURC in industry are unique, in that funding may come from within, there may be less independent scrutiny of research plans, and a different value may be placed on early announcement of discoveries. DURC management strategies may need to differ—even though the same DURC concerns might be raised—depending on whether or not academic research is supported by government funding.

There is a need for shared responsibilities. Strategies to manage dual use research will be most effective if investigators, institutions, the government, industry, editors, publishers, and the public are fully engaged in mitigating risks and supporting the sustained advancement of the life sciences.

In order to effectively advance the field of managing DURC internationally, the risk management agenda cannot be perceived as an agenda of the developed world being imposed on the developing world. Management strategies need to be sensitive to the unique situations and distinct needs and priorities of the developing world. These countries will need to be full players at the table as risk strategies are being considered and developed.

During the Roundtable several concrete follow-up actions were identified and were to be implemented soon. Refer to the following document for details of these and other relevant follow-up activities.

## IV. MAJOR POINTS

Throughout the presentations, plenary panels, breakout sessions, and informal discussions numerous common themes for the effective management of dual use research emerged during the two days of the Roundtable. While each country, region, scientific discipline, sector, institution, and investigator will need to consider issues associated with dual use research relevant to their specific interests, needs, and circumstances, there are common elements and considerations across the board. On behalf of the conference co-sponsors Dr. Amy Patterson, Acting Director of the NIH Office of Science Policy, presented key concepts that emerged throughout the two days of the Roundtable.

- *Science and society are inseparable.* Scientific progress takes place within society, is intended to serve society, and meets the needs of society. However, to fully realize the benefits that scientific progress offers for human health and well-being there is a need for public trust and confidence. The public wants assurance that scientists are taking every reasonable measure to assess and mitigate any risks posed by the misuse of information generated in life sciences research. Transparency in any mechanisms for the management of dual use research will be important to achieving public trust.

- *Existing frameworks.* It will be valuable to consider how existing frameworks can be employed to manage dual use research of concern. Introducing concepts of dual-use research into current education, professional responsibility, and review mechanisms may be an effective and efficient way to achieve the goals of managing DURC. Integrating risk management strategies into existing processes will serve the additional goal of increasing awareness and understanding within relevant communities. It will also prevent potential negative perceptions from the scientific community or others that management of DURC is an obstacle while still providing an appropriate and prudent mechanism for protection.

- *Continuums of risk and misuse.* It is critical to recognize that there are continuums of risk and misuse of knowledge, the latter based on intent ranging from research with unanticipated results which could be misused to intentional misuse. In addition, the perception of risk is based on local situations, including the natural occurrence of highly pathogenic disease and public health crises. Because of this, it is necessary to have a spectrum of risk management strategies suited to the local context.

- *Need for both flexibility and standardization.* Any risk management strategy will have to be flexible to keep pace with advances in technology and maintain relevance to the local context. However there is a simultaneous need for standards and consistency in management of dual use research. Regional approaches may be useful at this stage in establishing international standards while allowing appropriately flexible implementation at the local and national level.

Link to Wrap-up and Key Concepts slides presented at the closing plenary session.

## V. CONCLUSION

There are numerous important opportunities to advance the goals of sustaining progress in the life sciences and managing dual use research of concern. An important step will be the development of formal and informal mechanisms for sustained dialogue among all stakeholders. Collaborative, long-term relationships are critical. The establishment of networks will allow for the development and refinement of educational tools, codes of conduct, and for the sharing of best practices and expertise in, and procedures for, the analysis of any dual use potential in the review of research proposals, journal manuscripts, and other scientific communications.

APPENDIX A

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APPENDIX B

# Sustaining Progress in the Life Sciences: Strategies for Managing Dual Use Research of Concern

**CO-SPONSORED BY THE**
**WORLD HEALTH ORGANIZATION**
**AND**
**THE UNITED STATES GOVERNMENT**

**HOSTED BY THE**
**NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY**

Bethesda Marriott Hotel
5151 Pooks Hill Road
Bethesda, MD
November 5-6, 2008

**<u>Wednesday – November 5</u>**

8:30 a.m. – 8:45 a.m. **Welcome and Introduction to Program**

*Gerald W. Parker, D.V.M., Ph.D., M.S.*
Principal Deputy Assistant Secretary
for Preparedness and Response
Department of Health and Human Services
United States

*Ottorino Cosivi, D.V.M.*
Scientist
World Health Organization

*David Franz, D.V.M., Ph.D.*
Chair, NSABB Working Group on International Engagement

8:45 a.m. – 9:10 a.m. **Keynote Address**

*Alan I. Leshner, Ph.D.*
Chief Executive Officer
Executive Publisher, Science
American Association for the Advancement of Science

9:10 a.m. – 9:35 a.m. **Managing Dual Use Research Issues along the Research Continuum**

This presentation will review the NSABB *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* that has been submitted to the US Government for review and consideration. Special emphasis will be placed on the various points in the research continuum where interventions can be made to identify and manage dual use research of concern.

Presenter: *Paul Keim, Ph.D.*
Member, NSABB

9:35 a.m. – 10:00 a.m. **Break**

10:00 a.m. – 1:00 p.m. **Plenary Session I: Managing Dual Use Research of Concern: Practical Issues and Lessons Learned**

This session will focus on the steps taken by various nations and organizations to manage dual use research of concern (DURC). The presentations will describe relevant activities, including how they were developed and implemented. Presenters will focus on practical experiences and lessons learned, including why various approaches were selected and what challenges have been met and overcome in the execution of these approaches.

Co-moderators: *David Franz, D.V.M., Ph.D.*
Chair, NSABB Working Group on International Engagement

*Stanley M. Lemon, M.D.*
Member, NSABB

**National-level Advisory Bodies**

Presenters: *David Friedman, Ph.D.*
Coordinator
*Steering Committee on Issues in Biotechnological Research in an Age of Terrorism*
Israel

*Henri Korn, Ph.D.*
Editor
*Biological Threats*
French Academy of Sciences

*Koos van der Bruggen, Ph.D.*
Secretary
*Code of Conduct for Biosecurity: Report by the Biosecurity Working Group*
Royal Netherlands Academy of Arts and Sciences

**<u>Reviewing Research Proposals for DURC</u>**

<u>Presenters</u>: *Helen Thorne*
Director, Research Councils
United Kingdom Office in the United States

*Richard Frothingham, M.D.*
IBC Chair and Associate Professor
Duke University Medical Center

*Lukáš Holub, Ph.D.*
European Commission

**<u>Reviewing Scientific Communications (including publications) for DURC Content</u>**

<u>Presenters</u>: *Linda Miller, Ph.D.*
Executive Editor
Nature and the Nature Journals

*Jaclyn Fox*
Director of Communications and Publications
Center for Biosecurity of University of
Pittsburgh Medical Center

**<u>Training and Education</u>**

<u>Presenters</u>: *Chandre Gould, Ph.D.*
Institute for Security Studies
South Africa

*Michael Stebbins, Ph.D.*
Director, Biosecurity Project
Federation of American Scientists

**<u>Raising Awareness</u>**

<u>Presenters</u>: *Malcolm Dando, Ph.D.*
Professor of International Security
University of Bradford
United Kingdom

*Terence Taylor*
Director
International Council for the Life Sciences
United States

1:00 p.m. – 3:30 p.m. **Working Lunch/Concurrent Breakout Sessions I**

Over the course of the two sequential breakout sessions each group will address a series of questions to further explore activities and strategies for the management of dual use research of concern and the practical implications of developing and implementing management tools. Each group will first develop an inventory of various approaches used to manage DURC in the specific topic area of the breakout group and then consider the practical issues in developing and implementing these approaches. In addition, the breakout groups will review these approaches to identify common themes and principles for the management of DURC.

**A: Awareness Raising/Training and Education**

Co-chairs: *Michael Imperiale, Ph.D.*
Member, NSABB

*Malcolm Dando, Ph.D.*
Professor of International Security
University of Bradford
United Kingdom

Rapporteur: *Jo Husbands, Ph.D.*
Senior Project Director
Program on Development, Security, and Cooperation
National Research Council
United States

**B: Culture of Responsibility/Codes of Conduct**

Co-chairs: *Murray L. Cohen, Ph.D., M.P.H., C.I.H.*
Member, NSABB

*Koos van der Bruggen, Ph.D.*
Royal Netherlands Academy of Arts and Sciences

Rapporteur: *Neil Davison, Ph.D.*
Science Policy Manager
The Royal Society
United Kingdom

**C: Review of research proposals/Guidelines for review**

Co-chairs: *Stanley M. Lemon, M.D.*
Member, NSABB

*Richard Frothingham, M.D.*
IBC Chair and Associate Professor
Duke University Medical Center
United States

Rapporteur: *Jonathan B. Tucker, Ph.D.*
Professional Staff Member
Commission on the Prevention of WMD
Proliferation and Terrorism
United States

**D: Scientific communications/presentations and publications**

Co-chairs: *Paul Keim, Ph.D.*
Member, NSABB

*Jaclyn Fox*
Director of Communications and Publications
Center for Biosecurity of University of
Pittsburgh Medical Center
United States

Rapporteur: *Diane Scott-Lichter*
Publisher
American Association for Cancer Research

3:30 p.m. – 4:15 p.m. **Break**

4:15 p.m. – 5:45 p.m. **Plenary Session II: Interim reports from each Breakout group**

In this session each breakout group will briefly report on the status of their deliberations. There will be an opportunity for questions and discussion. This session will facilitate the breakout group deliberations on the second day.

Moderator(s): *Harvey Rubin, M.D., Ph.D.*
Member, NSABB

*Emmanuelle Tuerlings, Ph.D.*
Scientist
World Health Organization

*Amy Patterson, M.D.*
NSABB Executive Director

5:45 p.m. **Adjourn**

**Thursday, November 6**

8:30 a.m. – 8:35 a.m. **Welcome**

*David Franz, D.V.M., Ph.D.*
Chair, NSABB Working Group on International Engagement

8:35 a.m. – 9:20 a.m. **Plenary Session III: Progress at the National Level**

At the first USG/WHO International Roundtable in February 2007, representatives from a number of countries made presentations on the views and activities of their country which were relevant to the issues of DURC. This session will focus on updates on progress made in these activities.

The discussion session will afford an opportunity for other meeting participants
to make brief comments and updates on DURC related activities in their countries.

Co-moderators: *Anne K. Vidaver, Ph.D.*
Member, NSABB

*Barry J. Erlick, Ph.D.*
Member, NSABB

Presenters: *Professor Seumas Miller,* Australia
*George Chakhava, M.D., Ph.D.,* Georgia
*C. Kameswara Rao, Ph.D., M.Sc.*, India
*Professor Khalid R. Temsamani,* Morocco
*Andrzej Gorski, M.D.*, Poland
*Dr. Paul Nampala,* Uganda

9:20 a.m. – 10:00 a.m. **Discussion and Brief Comments by Countries**

10:00 a.m. – 10:20 a.m. **Break**

10:20 a.m. – 10:35 a.m. **Special Presentation: Harnessing the Benefits of the Biotechnology Revolution while Managing the Potential Risks: The Role of the United Nations**

This presentation will discuss the potential role that the United Nations, and specifically the Secretary-General, could play in helping to safely harness and disseminate the benefits of the revolution in biotechnology.

Presenter: *Robert Orr, Ph.D., M.P.A.*
Assistant Secretary-General for Policy Planning
Executive Office of the Secretary-General
United Nations

10:35 a.m. – 12:40 p.m.

**Plenary Session IV: Moving the field forward: Perspectives of Non-governmental Entities**

This session will explore the role of non-governmental entities in the management of DURC. The session will focus on how various non-government entities (e.g., intergovernmental organizations, science academies, industry, etc.) perceive their role in advancing the management of DURC – through 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.

Co-moderators: *Stuart Levy, M.D.*
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*Ottorino Cosivi, D.V.M.*
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**Biological Weapons Convention**

Presenter: *Ambassador Georgi Avramchev*
Permanent Mission of the Republic of Macedonia
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**Intergovernmental Organizations**

Presenters: *Emmanuelle Tuerlings, Ph.D.*
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*James Pearson, D.V.M.*
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**Scientific Academies**

Presenters: *Neil Davison, Ph.D.*
Science Policy Manager
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**Scientific Unions**

Presenters: *Angelo Azzi, M.D., Ph.D.*
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*Daniel Sordelli, Ph.D.*
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**Industry**

Presenters: *Rainer Wessel, Ph.D.*
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*John Mulligan, Ph.D.*
International Consortium for Polynucleotide
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12:40 p.m. – 1:00 p.m. **Break**

1:00 p.m. – 3:30 p.m. **Working Lunch/Concurrent Breakout Sessions II**

The same breakout groups will meet and continue discussions from day 1.

**A: Awareness Raising/Training and Education**

Co-chairs: *Michael Imperiale, Ph.D.*
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*Malcolm Dando, Ph.D.*
Professor of International Security
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Rapporteur: *Jo Husbands, Ph.D.*
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**B: Culture of Responsibility/Codes of Conduct**

Co-chairs: *Murray L. Cohen, Ph.D., M.P.H., C.I.H.*
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*Koos van der Bruggen, Ph.D.*
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**C: Review of research proposals/Guidelines for review**

Co-chairs: *Stanley M. Lemon, M.D.*
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IBC Chair and Associate Professor
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Rapporteur: *Jonathan B. Tucker, Ph.D.*
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**D: Scientific communications/presentations and publications**

Co-chairs: *Paul Keim, Ph.D.*
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Rapporteur: *Diane Scott-Lichter*
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American Association for Cancer Research

3:30 p.m. – 4:00 p.m. **Break**

4:00 p.m. – 4:15 p.m.

**Special Presentation: Promoting Global Health Research: Building Partnerships and Training the Next Generation**

Presenter: *Michael P. Johnson, M.D.*
Deputy Director
Fogarty International Center
National Institutes of Health

4:15 p.m. – 5:45 p.m.

**Plenary Session V: Moving Forward**

Each of the four breakout groups will report. The conference participants will join in a discussion of the major themes and recommendations for further activities.

Co-moderators: *Paul Keim, Ph.D.*
Member, NSABB

*Amy Patterson, M.D.*
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5:45 p.m. **Closing Remarks**

*Gerald W. Parker, D.V.M., Ph.D., M.S.*
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6:00 p.m. **Adjourn**

# APPENDIX C

**Sustaining Progress in the Life Sciences:**
**Strategies for Managing Dual Use Research of Concern**

***Co-sponsored by the***
***World Health Organization***
***and***
***The U.S. Government***

November 5-6, 2008

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# APPENDIX D

## *NSABB Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*[10]

## Brief Summary

### *1) Guiding Principles for Oversight*

- Free and open communication of life science research is essential to continued strong public health and national security.
- Oversight must balance the need for security with the need for continued research progress.
- Foundation of oversight includes investigator awareness, peer review, and local institutional responsibility.
- Responsible conduct and communication of DURC depends upon the individual.
- Research results are not always predictable; therefore there is a need for periodic evaluation for dual use potential.
- Effective oversight requires a harmonized federal approach, broad awareness of DUR issues, and ongoing public dialogue.
- Responsible communication of DURC is essential to public confidence in the scientific community.
- The oversight system must be periodically evaluated for effectiveness and impact on the research enterprise.

### *2) Key Features or Components of the Proposed Oversight System*

- *Federal guidelines.* Federal guidelines for oversight should be developed. These will assist scientists, institutions, other entities, and the federal government in determining and implementing safeguards regarding dual use research.
- *Awareness*. Researchers, research personnel, and research administrators should be fully aware of dual use research concerns, issues, and policies. 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.
- *Education*. Mandatory education about dual use research issues and policies will ensure that all individuals engaged in life sciences research are aware of the concerns and issues regarding dual use research and their roles and responsibilities in the oversight of such research. The federal government should develop training and guidance materials on federal requirements that can be used as educational resources at the local level. Furthermore, scientific societies, professional associations, and others in the private sector have an important contribution to make in promoting a culture of awareness and responsibility by educating broadly about dual use research, the associated tenets of responsible research, and the best practices in identifying and overseeing dual use research.

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[10] Full *Oversight Report* can be accessed at http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf

- *Local evaluation and review of research*. The initial review of research for dual use potential should be conducted by the investigator. Additional review at the local institution may also be appropriate. This local evaluation will ensure that those with the appropriate expertise and the best understanding of local personnel, facilities, and ethos are assessing research for dual use potential. And it will also demonstrate to the public that scientists and their institutions are attending to the biosecurity implications of dual use research and facilitate the timeliness of the oversight process.
- *Risk assessment and risk management*. Risk assessment and management should be the foundation for local oversight of dual use research of concern. This will help minimize the potential for misuse of dual use research information while minimizing any negative impact on the conduct of science and will facilitate the responsible conduct of life sciences research.
- *Periodic Evaluation*. It will be important to periodically evaluate the need for and effectiveness of oversight of dual use life sciences research.
- *Compliance*. There also needs to be mechanisms at both the federal and local level for ensuring compliance with policies for oversight of DUR.

***3) Roles and Responsibilities in Oversight***

- Researchers
- Research institutions, including institutional review entities
- NSABB
- U.S. Federal government

The *Oversight Framework* also acknowledges the important role of others, including the scientific communications community. The critical underpinnings of the oversight system will be education about dual use issues and all applicable policies as well as the provision of guidance and tools that facilitate compliance with the policies.

***4) Major Steps or Stages of Local Oversight***

Evaluation of life sciences research for its dual use potential should be done at the inception of any research and periodically throughout the research process. Research identified as being potentially dual use of concern should undergo institutional review, which should include assessment of any biosecurity risk(s) associated with the findings, technologies, or biological agents that might be generated from the research. Any dual use research of concern should be conducted in accordance with risk management strategies and should be communicated responsibly throughout the research process.

***5) Criterion and Considerations for Identifying Dual Use Research of Concern (DURC):***

*Definition: Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel.*

Applying the criterion is subjective and can be challenging. To assist in application of the criterion, NSABB identified categories and examples of information, products, or technologies that, if produced by research, might make that research DURC:

- Enhance the harmful consequences of a biological agent or toxin

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

***6) Evaluation of Life Sciences Research for Dual Use Potential***

In terms of evaluating life sciences research for its dual use potential, the PI should conduct the initial evaluation.  However, consultation with other scientists can be helpful and that it is quite possible that there will be differences of opinions, even among experts.

NSABB suggested  a formal attestation by researchers, on an annual basis, that they have been evaluating their work for DURC potential.

***7) Risk Assessment and Risk Management***

Once there is an initial decision that there may be dual use implications for a body of work or some results, the next step is a more formal institutional review that includes a risk assessment and the identification of ways to manage the risks. The institutional review should address the potential form and ways in which information could be misused to threaten aspects of national security; the likelihood of misuse; the potential impacts of misuse; and strategies for mitigating the risks of misuse. To facilitate this process, the NSABB developed a Guidance, “Points to Consider in Risk Assessment and Management of Research that is Potentially DURC.”

***8) Responsible Communication of Life Sciences Research with Dual Use Potential***

While there are concerns within the scientific community that oversight of DUR will lead to censorship and restrictions on communication of science, the NSABB *Oversight Framework* stresses that the default position should be the open and free communication of research results.  This is essential to a strong and robust scientific enterprise and continued advances in the life sciences and biodefense. But it must be done in a responsible fashion.

At the same time, the NSABB acknowledged that in very rare instances, it may not be appropriate to communicate certain findings.  It  is not necessarily a binary decision—publish or do not publish.  There may be ways to modify the content or the timing of publication that address biosecurity concerns.

The NSABB developed three communication tools:

- A set of principles for the responsible communication of research with dual use potential
- Points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information
- Considerations for the development of a communication plan for research with dual use potential

It is important to note that it is *not* the intent of the NSABB that every potential communication of research—be it an abstract, poster, seminar, or manuscript—be assessed using the communication tools. Rather, the tools may be utilized for the subset of life sciences research or research information determined to be dual use research of concern.

Just as research is not a discrete single activity with a predictable outcome – communication occurs at multiples points throughout the research process, and principles for the responsible communication at each point are integral to effective management of dual use life sciences research

***9) Considerations in Developing a Code of Conduct***

One of the foundations for effective oversight of DUR will be broad awareness within the scientific community of the issue and of policies pertaining to the conduct and communication of DURC.

Toward this end, and in direct fulfillment of one of its charges, the NSABB developed a resource for the life science community that includes:

- General considerations for a code of conduct
- Core responsibilities of life scientists with regard to dual use research of concern, and
- Specific responsibilities in the research process

The NSABB product can be adopted verbatim by professional organizations and institutions engaged in the conduct of life sciences research, or it can be tailored to address a specific group of scientists.

***10) Outreach and Education***

The final section of the *Oversight Framework* focuses on outreach and education. One of the charges to the NSABB is to advise on mandatory programs of education and training in biosecurity issues for all life scientists at federally funded institutions.

Although the educational content of training programs will derive in part from specific Federal policies and requirements, the NSABB nevertheless developed general recommendations for:

- Outreach during federal policy making process
- Communication during rollout of federal policy
- Ongoing educational and awareness-building strategies

NSABB recommend that outreach and education should have a broad reach. For example, it should be targeted not only at college and graduate levels, but also to high school and junior high school students, as well as internationally and including commercial researchers.

# Appendix E

## Acronyms

**BSL** Biosafety Level

**BWC** Biological and Toxin Weapons Convention

**BWG** Biosecurity Working Group of the InterAcademy Panel

**CDC** Centers for Disease Control and Prevention of the Department of Health and Human Services (US)

**CSE** Council of Science Editors

**DUR** dual use research

**DURC** dual use research of concern

**EC** European Commission of the European Union

**FBI** Federal Bureau of Investigation of the Department of Justice (US)

**GMO** Genetically Modified Organism

**IAP** InterAcademy Panel

**IASB** Industry Association for Synthetic Biology

**IBC** Institutional Biosafety Committee

**ICLS** International Council for the Life Sciences

**ICMJE** International Council of Medical Journal Editors

**ICPS** International Consortium for Polynucleotide Synthesis.

**ICSU** International Council for Science

**IUBMB** International Union of Biochemistry and Molecular Biology

**IUMS** International Union of Microbiological Societies

**NGO** Non Governmental Organization

**NIH** National Institutes of Health of the Department of Health and Human Services (US)

**NRC** National Research Council of the National Academies (US)

**NSABB** National Science Advisory Board for Biosecurity

**rDNA** Recombinant DNA

**RS** Royal Society of the United Kingdom

**UN** United Nations

**UNESCO** United Nations Educational, Scientific, and Cultural Organization

**USG** United States Government

**WAME** World Association of Medical Editors

**WHA** World Health Assembly of the World Health Organization

**WHO** World Health Organization