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

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

Brief Summary

I. Overview of the Roundtable

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. At 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 life sciences research issues primarily through presentations by countries and organizations that have taken concrete, practical steps to manage dual use research of concern. There was a focus on lessons learned where activities have been implemented.

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.

The agenda for the Roundtable is attached.

II. Participants

Over 130 scientists, government officials, and others from individual countries, non-governmental organizations, intergovernmental organizations, journal editors, philanthropic and funding organizations, 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 list of the Roundtable participants is attached.

III. Breakout Sessions

Each of the 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. Each of the four breakout groups reported on their findings and recommendations at the end of the conference.

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.

IV. Key Concepts

- *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 advancements in the life sciences.

- *Continuums of risk and misuse.* It is critical to recognize that there are continuums of risk and misuse of knowledge. There are continuums of biologic risk and a continuum of misuse 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. In light of this it is necessary to have a spectrum of risk management strategies suited to the local context. Any risk management strategy will have to be both transparent to engender public trust and flexible to keep pace with advances in technology and maintain relevance to the local context.

- *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 educational, 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.

- *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 includes legal, ethical, biosafety and security expertise as well as scientific expertise. Review mechanisms need to be transparent and include 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 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.

- *Moving Forward*. 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 between all stakeholders. Participants at the Roundtable were offered the opportunity to maintain communication through an email listserv facilitated by an NGO represented at the Roundtable. 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.

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

Wednesday – November 5

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

Reviewing Research Proposals for DURC

Presenters: *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

Reviewing Scientific Communications (including publications) for DURC Content

Presenters: *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

Training and Education

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

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

Raising Awareness

Presenters: *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.*
Vice-Chair, NSABB Working Group on International Engagement

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

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

Intergovernmental Organizations

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

James Pearson, D.V.M.
Expert Consultant
World Organization for Animal Health (OIE)

Scientific Academies

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

Scientific Unions

Presenters: *Angelo Azzi, M.D., Ph.D.*
President
International Union of Biochemistry
and Molecular Biology

Daniel Sordelli, Ph.D.
President
International Union of Microbiological Societies

Industry

Presenters: *Rainer Wessel, Ph.D.*
Board Member
BIO Deutschland
Germany

John Mulligan, Ph.D.
International Consortium for Polynucleotide
Synthesis
United States

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.*
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.*
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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. – 4:00 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.
NSABB Executive Director

5:45 p.m. **Closing Remarks**

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

Stuart Levy, M.D.
Vice-Chair, NSABB Working Group on International Engagement

6:00 p.m. **Adjourn**

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