

Update from the NSABB Working Group on International Engagement 3rd International Roundtable



**David Franz, D.V.M., Ph.D.
NSABB Board Meeting
December 10, 2008**



Previous Roundtables Hosted by NSABB

- ***International Roundtable on Dual Use Life Sciences Research***
 - ❑ Co-sponsored by WHO and USG
 - ❑ February 26-27, 2007

- ***Dual Use Issues in Life Sciences Research: A Roundtable on Strategies for Fostering International Engagement***
 - ❑ Sponsored by USG
 - ❑ October 10, 2007



3rd International Roundtable

- ***Sustaining Progress in the Life Sciences:
Strategies for Managing Dual Use
Research of Concern***
 - ❑ **Co-sponsored by USG and WHO**
 - ❑ **Hosted by NSABB**
 - ❑ **November 5-6, 2008**



Working Group on International Engagement

■ NSABB Members:

- Chair: David R. Franz, D.V.M., Ph.D.
- Vice Chair: Stuart B. Levy, M.D.
- Murray L. Cohen, Ph.D., M.P.H., C.I.H.
- Lynn W. Enquist, Ph.D.
- Barry J. Erlick, Ph.D.
- Stanley M. Lemon, M.D.
- Harvey Rubin, M.D., Ph.D.
- Anne K. Vidaver, Ph.D.

■ Agency Representatives:

- Tom Hopkins, Ph.D.
- George Herrfurth, M.A.
- Peter Jutro, Ph.D.
- Mary Mazanec, M.D., J.D.
- Robert Mikulak, Ph.D.
- Janet K.A. Nicholson, Ph.D.
- Polly R. Sager, Ph.D.
- Scott Steele, Ph.D.



3rd NSABB International Roundtable

- **Presentations by countries and organizations that have taken concrete, practical steps to manage dual use research of concern (DURC)**
- **Focus on lessons learned where activities have been implemented**



Objectives of 3rd Roundtable

- **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, institutions and organizations 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.**



Participants

- **Over 130 scientists, government and intergovernmental organization officials, journal editors, ethicists, and others**
- **Representation from 37 countries and over 72 organizations**



Areas of Special Concentration

- **Raising Awareness**
- **Training and education**
- **Codes of Conduct**
- **Reviewing research proposals for DURC**
- **Reviewing scientific communications (including publications) for DURC content**
- **Review and recommendations for managing DURC by national-level advisory bodies**



Overall Structure

- **Plenary Presentations:**
Individuals and Panels
- **Breakout sessions**
- **Plenary discussions**



Keynote: The Societal Context for Dual Use Research


Alan I. Leshner, Ph.D.

Chief Executive Officer

Executive Publisher, *Science*

AAAS

- Described the relationship between science and society, including the tensions that exist
- The important role of the scientific community in engaging the public
- AAAS's strategy for communicating with the public to
 - enhance their trust in science
 - ensure that research is responsive to the needs and priorities of the community



Managing Dual Use Research Issues along the Research Continuum

Paul Keim, Ph.D.

Member, NSABB

- Presented 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*



Harnessing the Benefits of the Biotechnology Revolution while Managing the Potential Risks: The Role of the United Nations

Robert Orr, Ph.D., M.P.A.

**Assistant Secretary-General for Policy Planning
United Nations**

- **Described 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 as a contribution to the Millennium Development Goals**



Moving the Field Forward: The Biological Weapons Convention

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

- Described the role and activities of the BWC in preventing biology from being used for malign purposes
- Explained how the BWC is engaging with the scientific community to develop a culture of responsibility
- Supported the need for scientists to retain the necessary freedom to advance science



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

Michael P. Johnson, M.D., M.P.H.

Deputy Director

Fogarty International Center

National Institutes of Health

- Described the role and activities of the Fogarty International Center in advancing global health, fostering international collaboration in science, training international scientists, and building capacity for health research



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

- This session consisted of multiple panels focused on the specific detailed steps taken by various nations and organizations to manage DURC
- Presenters focused on the areas of special concentration for the Roundtable
- Presenters concentrated on practical experiences and lessons learned
 - Why various approaches were selected
 - Challenges and how they have been met and overcome



Progress at the National Level

- **Updates on activities presented at the 1st Roundtable and new DURC related activities**
- **During the discussion session other meeting participants made brief comments on DURC related activities in their countries**



Some Activities Highlighted During National-Level Panel

- **Legislation**

- Australia
- Israel

- **Meetings**

- Georgia (December 2007)
- Poland (February 2008)
- Uganda (March 2008, July 2008 and January 2009)
- Philippines (July 2008)
- Pakistan (November 2008)
- Morocco (November 2008 and April 2009)
- China (December 2008)

- **Training**

- Brazil



Moving the field forward: Perspectives of Non-governmental Entities

- **Descriptions by various non-government entities (e.g., science academies, science unions, industry, etc.) and intergovernmental organizations on their role in advancing the management of DURC**
 - **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**
 - **reviewing scientific communications**



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Preparation for Breakout Sessions

- **Pre-meeting conference calls with co-chairs and rapporteur of each breakout group**
 - **Developed topic-specific questions**
 - **Identified useful topic-specific background materials**



Breakout Sessions

- **Each group**
 - explored activities and strategies for the management of dual use research of concern in its specific topic area
 - developed an inventory of various approaches used to manage DURC in its specific topic area
 - considered the practical experience of developing and implementing these management tools
- **Reviewed these approaches to identify common themes and principles for the management of DURC**
- **Developed suggestions for future management activities in their topic areas**



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Key Concepts

- ***Science and society are inseparable***
 - To fully realize the benefits that scientific progress offers there is a need for public trust and confidence
 - Public wants assurance that scientists are taking every reasonable measure to assess and mitigate risks posed by advancements in the life sciences

- ***Continuums of risk and misuse***
 - Continuums of biologic risk and misuse - ranging from research with unanticipated results which could be misused to intentional misuse
 - Perception of risk is based on local situations
 - Need a spectrum of risk management strategies suited to the local context

- ***Existing Frameworks***
 - Integrating risk management strategies into existing frameworks
 - Will serve the additional goal of increasing awareness and understanding within relevant communities
 - Prevent potential negative perceptions from the scientific community that management of DURC is an obstacle while still providing an appropriate and prudent mechanism for protection



Awareness Raising/Training and Education

- **Challenges to increased awareness of dual-use research include:**
 - diverse audience
 - various levels of training and professional development
 - many relevant disciplines
- **Proposed strategies to achieve goals include:**
 - development of standard components of educational programs
 - leveraging current educational efforts in various areas (e.g. ethics, biosafety, biosecurity, responsible conduct of research)



Culture of Responsibility/Codes of Conduct

- **Need to**
 - make codes relevant to the specific audience and context
 - customize existing codes
 - encourage the adoption of codes
- **Challenge: convincing individual scientists of the importance of attention to DUR issues and their ethical obligations to mitigate misuse of the results of their research**
- **Involvement of the life sciences community in developing and improving codes of conduct can also serve to educate the scientific community and raise awareness**



Review of Research Proposals/Guidelines for Review

- **Must occur across the research life cycle from project design to proposal review to publication**
- **Need 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

- **Need to ensure “upstream” review of research as well as review at the time of submission for publication**
- **Need for a consistent approach for the identification of DURC across various scientific publications**
- **Need to provide instructions to authors and manuscript reviewers for the identification and management of risks**
- **To facilitate the review of scientific publications**
 - **establish core systems for journals to share experience and best practices**
 - **advise smaller journals in the review of manuscripts**
 - **Consider developing a registry of experts for this review**



Moving Forward

- **Development of formal and informal mechanisms for sustained dialogue among all stakeholders**
- **Development and refinement of educational tools, codes of conduct, etc., including the sharing of best practices**
- **Sharing of best practices and expertise in and procedures for analyzing and managing any dual use potential in the review of research proposals and scientific communications**



Other Findings

- **A range of DURC management activities worldwide covering each of the areas of special concentration are already in place**
- **Transparency and public trust are very important**
- **Shared responsibilities**
- **Benefits of regional approaches**
- **Simultaneous need for standards and consistency coupled with need to tailor approaches to specific (i.e., local) context**
- **Sensitivity to distinct situations in developing countries**
- **Collaborative, long-term international relationships are critical**
- **Life sciences are a rapidly advancing field and approaches to managing DURC need to be flexible**



Follow-up to Roundtable

- **Federation of American Scientists (FAS) Listserv**
- ***Biosecurity and Bioterrorism* Journal**
- **Engagement with Fogarty International Center**
- **Summary provided to BWC Meeting of States Parties**
- **Council of Science Editors**

