

International Roundtable on Dual Use Life Sciences Research



In February 2007, the World Health Organization (WHO) and the United States (US) government cosponsored an International Roundtable on Dual Use Life Sciences Research. The Roundtable was convened in Bethesda, Maryland, USA, and was hosted by the National Science Advisory Board for Biosecurity (NSABB).

Background: Dual Use and the NSABB

The term "dual use" in conjunction with life sciences research is an acknowledgment that some of the very information and technologies used to advance human, animal, and plant health can also be used to threaten public health and safety. Because arguably most life sciences research has some potential for dual use, the term "dual use of concern" is sometimes used to delineate that subset of research that yields information or technologies that could be most readily used to cause significant harm to many.

The NSABB is an advisory body established by the US government to recommend ways to minimize the risk that information from legitimate life sciences research could be intentionally misused to threaten public health and other aspects of national security. One of the NSABB's major tasks is to recommend strategies for the efficient and effective oversight of dual use life sciences research. Another key charge is to recommend strategies for fostering international dialogues on dual use research issues. Towards this end, the NSABB planned the Roundtable to begin such a dialogue with scientists and representatives from interested countries, relevant intergovernmental organizations, and scientific professional associations.

Participants

Roundtable participants (see attached roster and photograph) came from the following countries: Australia, Argentina, Bulgaria, Georgia, India, Israel, Morocco, the Netherlands, the People's Republic of China, Poland, Spain, Switzerland, Uganda, the United Kingdom, and the United States. Although some of the participants had been identified by their governments as an official point of contact, none of the non-US guests participated as official representatives of their governments. The participants brought a diverse array of perspectives to the examination of the issue, including those of basic science, medicine, ethics, government scientific agencies, scientific journals, and national research councils. A number of key scientific associations were also represented, including the International Union of Biochemistry and Molecular Biology, the International Union of Microbiological Societies, the International Council for Life Sciences, and the American Society for Microbiology. The intergovernmental organizations represented included the WHO, the World Organization for Animal Health, and the Food and Agriculture Organization of the United Nations.

Purpose of the Roundtable

The objectives of the Roundtable (see attached agenda) included determining the scope of other countries' activities, interests, and concerns pertaining to dual use life sciences research; informing other countries and the international community about NSABB draft work products and obtaining feedback, establishing and maintaining communication with other countries and the international science and policy community on dual use research issues, and collaborating

with other countries and the international community to establish a larger, more robust dialogue on issues related to dual use life sciences research.

One of the sessions of the Roundtable was devoted to sharing NSABB work products with the participants. At the time, the NSABB had developed several draft work products—criteria for identifying dual use research of concern, elements for a code of conduct for life sciences researchers, and tools for the responsible communication of dual use research—which were in the process of being incorporated into a proposed framework for oversight of dual use life sciences research. In addition, the NSABB had developed a set of recommendations for addressing biosecurity concerns attendant to the rapidly advancing ability to synthesize viral and bacterial genomes.

NSABB members and staff presented these work products to the Roundtable participants and encouraged them to provide feedback on the products as well as to adapt any of them for use by the participants' home countries or scientific organizations. It was noted, however, that the work products were the draft recommendations of an advisory group and thus did not represent policies or requirements of the US government.

Roundtable Discussions

The Roundtable was successful in engaging individuals from different countries to share their perspectives about biosecurity and dual use research. Discussions were lively and revealed considerable variety in understanding and use of the term "biosecurity." A number of participants used the term interchangeably with biosafety. Many participants felt that the issues of biosafety and biosecurity needed to be addressed together, as they felt the two topics were inextricably linked.

Participants described how they viewed the possible role of codes of conduct for life scientists, and the various approaches underway in their countries for addressing the communication of research results with dual use potential. There was general appreciation for the importance of the dual use research issue, although there was significant variation in the priority that was given to the topic when it was compared to other public heath and security issues ongoing within the various countries.

The participants ultimately expressed general agreement on a number of principles:

- Life sciences research is essential to advancing the health and well-being of mankind. It is also true, however, that some of the very same materials, technologies, and information from the life sciences that are used to advance health and safety can also be intentionally misused to harm society.
- A productive life sciences enterprise must be maintained while simultaneously minimizing the risk that information from that research will be used for harmful purposes. The challenge is to prevent the use of science for harm while protecting scientific discovery and preserving scientific creativity.
- Heightened awareness of dual use research issues is necessary within the broader scientific community.
- Additional awareness and guidance on dual use research is needed, including a definition and discussion of the problems and challenges.
- A strengthened culture of responsibility is needed within the scientific community; scientists must be open to the dual use potential of their research and take steps to minimize the risk that information from their work will be misused.
- Since the life sciences are a global endeavor, and becoming more so, efforts to address the dual use aspects of this research must be global as well.

• Different approaches to addressing the dual use dilemma will be necessary given the differences in cultures around the world and in policies and practices for overseeing science.

Approaches to Addressing Dual Use Research Issues

Roundtable participants discussed a number of approaches for addressing dual use research issues, i.e., the steps necessary to develop a so-called "tool kit" for consideration of the dual use potential of life sciences research. The tool kit might contain:

- Criteria for identifying dual use research;
- Educational material for scientists, students of all ages, the public, government decision makers;
- Principles to be considered when developing a code of conduct for scientists
- Guidance for scientists and editors considering the publication of research;
- Oversight processes for dual use research; and
- Guidance for science funding agencies.

Options for Next Steps

The Roundtable participants identified a number of options for next steps, including:

- Further exploring the needs of individual countries regarding dual use research issues;
- Developing strategies for engaging the various stakeholders, which include researchers in academia and industry, government policy-makers, scientific journal editors and publishers, and the general public;
- Considering the development of an international communications network (web-based) for dual use research issues and activities;
- Identifying strategies for ongoing and expanded international dialogues on dual use research issues; and
- Considering development of a white paper on the Roundtable for submission to a scientific journal, to include an explanation of the dual use research issue and challenges, acknowledgment of previous and ongoing international discussions of the dual use issue, a description of the International Roundtable, and the proposed basic "tool kit" for addressing dual use research issues and the potential uses of the individual tools.



International Roundtable on Dual Use Life Sciences Research



February 26-27, 2007

PARTICIPANT LIST

Guests

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International Roundtable on **Dual Use Life Sciences Research**



Agenda

Monday, February 26

8:30 a.m. Welcome

David Franz, D.V.M., Ph.D.

Chair, NSABB Working Group on International Collaboration

8:35 a.m. **Opening Remarks**

Elias Zerhouni, M.D.

Director, US National Institutes of Health

8:55 a.m. Overview and Objectives of the Roundtable

David Franz, D.V.M., Ph.D.

Chair, NSABB Working Group on International Collaboration

Stuart Levy, M.D.,

Vice-Chair, NSABB Working Group on International Collaboration

9:05 a.m. Introduction of Roundtable Participants

David Franz. D.V.M., Ph.D.

Chair, NSABB Working Group on International Collaboration

9:20 a.m. Origins and Evolution of U.S. Considerations Regarding Dual Use Life Sciences Research:

An Overview of the National Science Advisory Board for Biosecurity (NSABB)

Amy Patterson, M.D.

NSABB Executive Director

9:50 a.m. **Break**

10:05 a.m.

Session 1: The Dual-Use Dilemma – What Is It and Why Does It Matter?

Objective: Determine the scope of countries' interest and concerns regarding dual use life

sciences research.

Ouestions to be addressed:

- What *concerns* do countries have about the potential misuse of life sciences research? What *criteria* does your country use to define "dual use"? How does your country *perceive* the dual use dilemma?
- Is there a need to develop and implement *safeguards/controls* for dual use life sciences research activities undertaken to address public health concerns, and if so, why? If not, why not?
- Is there a need for countries to work together to *increase awareness* in the international community about the potential misuse of legitimate life sciences research findings? If so, what mechanisms might be employed to enhance collaboration?

<u>Moderator</u>: *Ruth Berkelman, M.D.*

American Society for Microbiology (ASM)

Speakers: Emma Keuleyan, M.D., Ph.D.

Ministry of the Interior, Bulgaria

Khalid R. Temsamani, Ph.D.

National Coordinator of Material Sciences Ministry of Higher Education, Morocco

Geoffrey L. Smith, Ph.D., FRS

Virology Dept., Faculty of Medicine

Imperial College of London, United Kingdom

11:05 a.m. Roundtable Discussion: Participants' Views

Moderators: David A. Relman, M.D.

Member, NSABB Working Group on Synthetic Genomics

Li Huang, Ph.D.

Chinese Academy of Sciences, China

12:30 p.m. Lunch

2:00 p.m. Session 2: Recognizing Dual Use Potential While Advancing Global Health Research

Objective: Determine the scope of countries' initiatives in dual use life sciences research.

Questions to be addressed:

• What *national initiatives/objectives* has your country developed, or is planning, to protect collaborative (i.e., trans-border) life sciences research from potential misuse for malevolent purposes?

- What *mechanisms* have countries employed, or are currently developing, to balance national security concerns with the need to advance collaborative life sciences research to address global public health priorities?
- What is the appropriate *locus of responsibility* (e.g., individual researchers, institutions, national governments) for safeguarding against malevolent uses of collaborative life sciences research activities?
- How does your country implement its national objectives given that science is conducted in a *collaborative*, *international environment*?

Moderator: Daniel Sordelli, Ph.D.

President-Elect, International Union of Microbiological Societies

Speakers: *Mina Teicher, Ph.D.*

Chief Scientist

Ministry of Science and Technology, Israel

Souleymane Mboup, Pharm.D., Ph.D. Laboratoire de Bacteriologie Virologie Cheikh Anta Diop University, Senegal

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Rob Floyd, Ph.D.

Assistant Secretary, Chemical, Biological, Radiological & Nuclear Security,

National Security Division

Department of the Prime Minister and Cabinet, Australia

Seumas Miller, Ph.D.

Director, Center for Applied Philosophy and Public Ethics

Australia National University

3:00 p.m. **Break**

3:15 p.m. Roundtable Discussion: Participants' Views

Moderators: *Barry J. Erlick, Ph.D.*

Member, NSABB Working Group on International Collaboration

James Pearson, D.V.M., M.S.

Consultant, World Organization for Animal Health (OIE)

4:45 p.m. Closing Remarks

David Franz. D.V.M., Ph.D.

Chair, NSABB Working Group on International Collaboration

5:00 p.m. Adjourn

8:00 a.m. Opening Remarks/Summary of Day 1

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

8:30 a.m.

Session 3: Balancing Public Health Priorities and National Security Concerns:
Addressing the Dual Use Dilemma

Objective: Establish a dialogue on the "dual use issue."

Questions to be addressed:

- What are some of the key *challenges* to balancing national health/scientific imperatives with national security concerns?
- Is *transparency* critical for researchers to communicate and exchange information? Why or why not?
- How have *codes of conduct* been effective in enhancing a culture of responsibility in your country? How can they serve as bridges to collaboration?
- Should the *public* play a role in helping to address concerns related to dual use life sciences research? If so, how should that role be defined?
- How can countries work together to *foster international collaboration* on addressing concerns regarding the potential misuse of life sciences research findings?

Moderator: *Stuart Levy, M.D.*

Vice-Chair, NSABB Working Group on International Collaboration

Speakers: George Chakhava, M.D., Ph.D.

Secretary General, Georgian Society of Neurologists

Georgian State Medical Academy, Georgia

Andrzej Gorski, M.D.

Vice President, Polish Academy of Sciences, Poland

Peter Ndemere, Ph.D.

Executive Secretary

Uganda National Council for Science and Technology, Uganda

Koos van der Bruggen, Ph.D.

Royal Netherlands Academy of Arts and Sciences

9:30 a.m. Roundtable Discussion: Participants' Views

Moderators: Angelo Azzi, M.D., Ph.D.

President-Elect

International Union of Biochemistry and Molecular Biology

C. Kameswara Rao, Ph.D., M.Sc.

Executive Secretary

Foundation for Biotechnology Awareness and Education, India

11:00 a.m. Break to Pick Up Lunch (Working Lunch)

11:30 a.m.

Session 4: U.S. Initiatives in Dual Use Life Sciences Research

Objective: Obtain input on draft work products US National Science Advisory Board for

Biosecurity.

Moderator: Amy Patterson, M.D.

Executive Director

US National Science Advisory Board for Biosecurity

Panelists: Anne K. Vidaver, Ph.D.

Member, NSABB Working Group on International Collaboration

Liaison to the NSABB Criteria Working Group

Murray L. Cohen, Ph.D., M.P.H., C.I.H.

Member, NSABB Working Group on International Collaboration

Liaison to the NSABB Code of Conduct Working Group

Harvey Rubin, M.D., Ph.D.

Member, NSABB Working Group on International Collaboration Liaison to the NSABB Synthetic Genomics Working Group

Paul S. Keim, Ph.D.

Chair, NSABB Working Group on Communication of Dual Use Research

12:30 p.m. Roundtable Discussion: Participants' Views

Questions for roundtable discussion:

- Would the U.S. proposed oversight framework for dual use research present any challenges for scientific collaboration with your country?
- Are there any elements of this proposed oversight framework initiatives that might be of particular interest to your country?
- Do you think your country may be interested in collaborating to address dual use issues in life sciences research?

Moderators: Emmanuelle Tuerlings, D.Phil., MSc.

Scientist, Biorisk Reduction for Dangerous Pathogens Department of Epidemic and Pandemic Alert and Response

World Health Organization

David Franz, D.V.M., Ph.D.

Chair, NSABB Working Group on International Collaboration

Stuart Levy, M.D.

Vice-Chair, NSABB Working Group on International Collaboration

1:30 p.m. Summary of Meeting and Identification of Next Steps

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

Stuart Levy, M.D.

Vice-Chair, NSABB Working Group on International Collaboration

1:45 p.m. Adjourn