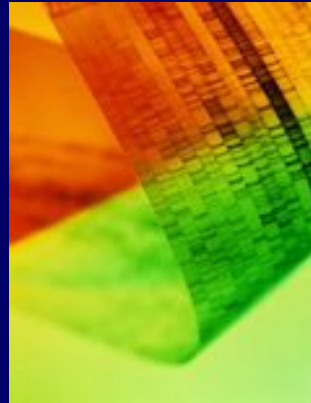


NSABB Working Group on International Engagement Update



NSABB Meeting
December 15, 2011

Tab 4

Roster

Voting Members

- David R. Franz, DVM, PhD, Co-chair
- Stuart B. Levy, MD, Co-chair
- Kenneth I. Berns, MD, PhD
- Murray L. Cohen, PhD, MPH, CIH
- Michael J. Imperiale, PhD
- Stanley M. Lemon, MD
- Randall Murch, PhD
- David A. Relman, MD
- Anne K. Vidaver, PhD

Agency Representatives

- Parag Chitnis, PhD
- Franca Jones, PhD
- Amanda Dion-Schultz, PhD
- Dennis M. Dixon, PhD
- Peter Jutro, PhD
- Teresa Lawrence, PhD
- Janet K.A. Nicholson, PhD
- Christopher Park
- Dana Perkins, PhD
- Jessica Petrillo, PhD
- Jessica Tucker, PhD
- Edward H. You

NSABB IWG Charge

Developing and supporting the implementation of strategies to foster international engagement on issues related to dual use life sciences research

- **Raise awareness internationally**
- **Gain perspectives on and monitor the status of international issues and activities**
- **Expand the international network**

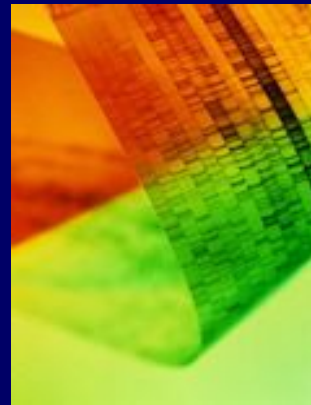
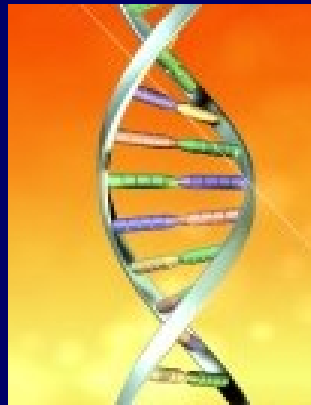
IWG Approaches

- **Conduct International Events**
 - Focus on DUR/C awareness raising
 - Focus on topics of USG/NSABB interest
- **Facilitate International Engagement Activities**
 - To support other NSABB efforts
 - To convene face-to-face international discussions
 - To facilitate participation at international meetings



The Intersection of Science and Security: a Case Study Approach

Continuing the global dialogue with the scientific and science policy community with a focus on Asia and the Western Pacific



WORKSHOP
NIH campus/Bethesda
December 9, 2011

Objective and Scope

■ Objective

- To give attendees a greater understanding of dual use research, including an awareness of strategies for managing dual use research of concern and an appreciation of how these issues are being addressed around the globe. To learn regional perceptions and strategies for managing dual use research from our colleagues from Asia and the Western Pacific.

■ Purpose

- Provide examples of dual use research of concern that highlight issues needing to be considered by investigators, institutions, journal editors, governments, and the scientific and security policy communities
- Facilitate discussions among all panelists on global science and security issues



Asia and the Western Pacific Workshop Format

- Brief presentations and guided discussions using case studies of published scientific research that raise security concerns relevant to Asia and the Western Pacific region and globally
 - Panel 1: Discussion of science and security issues utilizing an article on Mousepox and IL-4 as a case study
 - Panel 2: Discussion of science and security issues utilizing an article on a SARS-like virus as a case study
 - Panel 3: General discussion of science and security globally with an emphasis on Asia and the Western Pacific



Workshop Panelists

- *Dr. Murray Cohen*
NSABB Member
Safety Foundation, Ltd., Atlanta, GA
- *Dr. Mark Denison*
Vanderbilt University, Nashville, TN
- *Dr. Robert Floyd*
Australian Safeguards and Non-proliferation Office,
Canberra, Australia
- *Dr. Dave Franz*
NSABB Member
Midwest Research Institute, Frederick, MD
- *Dr. Chan-Wha Kim*
President, Asia-Pacific Biosafety Association
Korea University, Seoul, South Korea
- *Dr. Stuart Levy*
NSABB Member
Tufts University School of Medicine, Boston, MA
- *Dr. Jeffery Miller*
NSABB Member
University of California - Los Angeles, Los Angeles, CA
- *Dr. H. V. Murugkar*
Indian Veterinary Research Institute, Bhopal, India
- *Dr. Amy Patterson*
National Institutes of Health, Bethesda, MD
- *Dr. Ian Ramshaw*
Australian National University, Canberra, Australia
- *Dr. Za Hussein Reed*
Regional Emerging Diseases Intervention Center,
Singapore
- *Dr. Masayuki Saijo*
National Institute of Infectious Diseases, Tokyo, Japan
- *Dr. Michael J. Selgelid*
Monash University, Clayton, Australia
- *Dr. Herawati Sudoyo*
Eijkman Institute for Molecular Biology, Jakarta,
Indonesia President, Indonesian Biorisk
Association, Jakarta, Indonesia
- *Dr. Zhiming Yuan*
Wuhan Institute of Virology, Chinese Academy of
Sciences

Panel I Discussion Questions

- What might the researchers and others (journal editors and government authorities) have done differently to address the security issues inherent in the research at the time the research was conducted? What would happen today?
- What role should the Institutional Biosafety Committee/reviewing body have in evaluating research with potential biosafety and biosecurity concerns?
 - What systems have been established in countries in the region to regulate biosafety and biosecurity issues? How is potential for Dual Use in research evaluated?
- What lessons can be learned from this case study?

Panel II Discussion Questions

- **What role should an Institutional Biosafety Committee/reviewing body/ consultative group have in evaluating research with potential biosafety and biosecurity concerns? How prepared are institutional biosafety committees to make determinations of dual use research of concern and to provide guidance for research design and evaluation?**
 - **What systems have been established in countries in the region to regulate biosafety and biosecurity issues? How is the potential for dual use in research evaluated?**
 - **Should plans be discussed in regards to unexpected outcomes from the research? When?**
- **What is the best way to approach journals about a publication based on research of potential dual use research of concern?**
- **What lessons can be learned from this case study?**

Panel III Discussion Questions

- **What should/could be done going forward to address security concerns in science? By government officials, scientists, journals, etc.?**
- **How can we ensure critical information is exchanged between the scientific and security communities to help inform determinations of dual use research of concern and questions surrounding publication?**
- **What are the best ways to engage the scientific and security community to manage the security risks of DURC?**
- **What current science and security educational/training resources are available globally, and in Asia and the Western Pacific region, including on the Internet?**
 - **What resources are needed to address the gaps which are not currently addressed globally and in this region?**
- **What are the best platforms to address security issues, i.e. educational modules, specialized training, etc., formation of specialized committees?**
 - **Should this be done through extant bioethics or biosafety training? Or should new courses and other resources under a specific biosecurity umbrella be established?**
- **How should the trusted insider/insider threat be dealt with? How can those with access to the resources that would use them for malevolent purposes be managed?**
- **How can a culture of responsibility be established? How can personnel reliability best be assured?**
- **What regulations or strategies exist for managing research involving synthetic biology in countries in this region?**

Workshop Observations

- Case study approach focused and facilitated discussion
- Strengthened by having senior authors of the case studies present
- Experts knowledgeable regarding DURC from key countries in the region contributed effectively to the discussions
- Event was well attended by a diverse audience



Workshop Take-home Messages

- Need for multiple disciplines to collaborate in addressing biosecurity risks
- Recommend extant IBC structure for biosecurity review
 - Part of the scientific review process
 - Include education on biosecurity for IBC members
- Stress the importance of leadership
 - Trust, awareness and transparency are important for promotion of safe science
- Education on biosecurity at all professional levels is key to promoting responsible research conduct
- There is a need for guidelines and principles to manage science and communication of science
- Ultimately DURC is an informed judgment call
- “Web of Prevention” – intervention must occur at different places throughout the research process through varying mechanisms
- DURC is a global problem best addressed through global engagement and is not a concern unique to the U.S.