



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

National Institutes of Health

Building 10, Masur Auditorium December 9, 2011, 1:00 pm-4:30 pm

AGENDA

At-A-Glance

1:00 pm	Welcome and opening remarks
Panel I: Discussion of science and security issues utilizing an article on	
	Mousepox as a case study
1:20 pm	Background and presentation on Mousepox publication
1:30 pm	Panel discussion and questions from the audience
Panel II: Discussion of science and security issues utilizing an article on a	
	SARS-like virus as a case study
2:05 pm	Background and presentation on SARS-like virus publication
2:15 pm	Panel discussion and questions from the audience
Panel III: General discussion of science and security globally with an emphasis on Asia and the Western Pacific	
3:05 pm	General background
3:20 pm	Panel discussion and questions from the audience
4:15 pm	Concluding remarks
4:30 pm	Meeting adjournment

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

BACKGROUND:

On December 9, 2011 the United States Government is sponsoring a workshop, *The Intersection of Science and Security: a Case Study Approach, Continuing the global dialogue with the scientific and science policy community: focus on Asia and the Western Pacific.* This event is a workshop aimed 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. The workshop will utilize case studies, involving Mousepox and SARS, as examples of dual use research of concern that highlight issues which investigators, institutions, journal editors, governments, and the scientific and security policy communities need to consider. In addition to presentations of the case studies, there will be discussions among all panelists and attendees on global science and security issues as well as those of special interest within Asia and the Western Pacific, including information on training and education resources currently available.

PROGRAM:

1:00 pm Welcome and opening remarks

Dr. Amy Patterson Associate Director for Science Policy National Institutes of Health, Bethesda, MD

Dr. Za Hussein Reed Assistant Director for Clinical Research Regional Emerging Diseases Intervention (REDI) Center, Singapore

Dr. Dave Franz NSABB Member Vice President and Chief Biological Scientist MRIGlobal, Frederick, MD

1:20 pm

Panel I –Discussion of science and security issues utilizing an article on Mousepox as a case study

Background:

Scientific research is a vital social undertaking that yields innumerable and immeasurably important benefits. At the same time, good science can be put to bad uses, and even a single misuse of certain information, knowledge, or technology could have far reaching and devastating effects. Over the past ten years, there has been a growing recognition that some information, knowledge, or technologies resulting from scientific research, in the wrong hands, can be misused to pose a threat to public health

and national security. Research yielding new technologies or information with the potential for both benevolent and malevolent applications is referred to as "dual use research" (DUR) and a subset of the most problematic research is termed "dual use research of concern" (DURC). An example of DURC was reported in a February 2001 publication where researchers inadvertently developed a lethal mousepox virus. The researchers in Australia inserted a gene into the mousepox virus hoping ultimately to induce infertility in mice by using the product as a pest control agent for the overpopulation of mice in Australia. The results of the experiment were that the altered virus was capable of killing both naturally resistant mice and those that had been vaccinated against ordinary mousepox. After publication and widespread publicity, many were concerned that the article was not only alerting potential terrorists to a possible novel biological orthopox virus weapon (such as modified smallpox), but also providing them with detailed instructions on how to construct it. The purpose of this session is to have the mousepox research and article presented by the principal investigator in order to stimulate a discussion about the science and security issues it raises, including the rationale for the research and the issues surrounding the publication of the results, as well as the public health, ethical and security concerns and implications for scientists everywhere.

Moderators:

Dr. Herawati Sudoyo Deputy Director Eijkman Institute for Molecular Biology, Jakarta, Indonesia President, Indonesian Biorisk Association, Jakarta, Indonesia

Dr. Jeffery Miller NSABB Member Professor and Chair, Department of Microbiology, Immunology & Molecular Genetics, David Geffen School of Medicine University of California - Los Angeles, Los Angeles, CA

Discussion Questions:

- What might the researchers and others (journal editor 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 dual use research evaluated?
- What lessons can be learned from this case study?

Presenter:

Dr. Ian Ramshaw
 Director, National Centre for Biosecurity
 The John Curtin School of Medical Research, Australian National University
 Canberra, Australia

Panelists

- Dr. Robert Floyd
 Director General
 Australian Safeguards and Non-proliferation Office, Canberra, Australia
- Dr. Michael J. Selgelid
 Senior Lecturer and Deputy Director, Centre for Human Bioethics
 Monash University, Clayton, Australia
- Dr. Chan-Wha Kim
 President, Asia-Pacific Biosafety Association
 Professor, College of Life Sciences and Biotechnology,
 Korea University
 Seoul, South Korea
- Dr. H. V. Murugkar
 Senior Scientist (VPH) cum Biosafety Officer
 High Security Animal Disease Laboratory
 Indian Veterinary Research Institute
 Bhopal, India
- Dr. Zhiming Yuan
 Professor, Deputy Director
 Wuhan Institute of Virology, Chinese Academy of Sciences
 Wuhan, China

1:30 pm Panel discussion and questions from the audience

2:05 pm

Panel II - Discussion of science and security issues utilizing an article on a SARS-like virus as a case study

Background:

The recognition of potential dual use research has increased over the last decade and some institutions are working directly with their scientists to assess and manage potential dual use research of concern. In one example two U.S. scientists were conducting research to synthetically generate a non-cultivatable bat virus genetically related to a severe acute respiratory syndrome coronavirus (Bat-SARS-like CoV). The overall goals of the research were to establish strategies for recovery, testing, and attenuation of the potential pandemic non-cultivatable viruses, and to determine pathways of Bat-CoV host-species movement and adaptation. The research was considered highly significant since it could enable more timely response to potential species jumps and more rapid and effective public health intervention. The investigators determined that the proposed research would constitute dual use research of concern as it fell within two of seven NSABB categories to consider for potential DURC. The researchers therefore established a consultative working group consisting of the biosafety committees from both investigator institutions as well as experts from the "Policy, Ethics and Law" core from a NIH-sponsored Regional Center of Excellence. Criteria were established and intermittently reviewed for experimental design, commercial gene synthesis, material transfer, biosafety, biosecurity, termination of

research, publication, and public response and media communication. The investigators also maintained communication with public health and grant program officials throughout design and performance of experiments. The purpose of this session, following the presentation by the senior author, is to discuss the case of a synthetic Bat SARS-like coronavirus and how it relates to science and security, particularly addressing the biosafety and biosecurity oversight of the research, in addition to ethical and publishing considerations.

Moderators:

Dr. Michael J. Selgelid Monash University, Clayton, Australia

Dr. Dave Franz NSABB Member MRIGlobal, Frederick, MD

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?

Presenter:

Dr. Mark Denison
 Craig-Weaver Professor of Pediatrics
 Departments of Pediatrics and Microbiology and Immunology
 Vanderbilt University
 Nashville, TN

Panelists

- Dr. Murray Cohen
 NSABB Member
 President and Chairman, Frontline Healthcare Workers®
 Safety Foundation, Ltd.
 Atlanta, GA
- Dr. Za Hussein Reed
 Regional Emerging Diseases Intervention Center, Singapore

- Dr. Herawati Sudoyo
 Deputy Director
 Eijkman Institute for Molecular Biology, Jakarta, Indonesia
 President, Indonesian Biorisk Association
- Dr. Jeffery Miller
 NSABB Member
 University of California Los Angeles, Los Angeles, CA
- Dr. Masayuki Saijo
 Director, Department of Virology 1
 National Institute of Infectious Diseases, Tokyo, Japan
- 2:15 pm Panel discussion and questions from the audience
- 2:50 pm Break
- 3:05 pm

Panel III - General discussion of science and security globally with an emphasis on Asia and the Western Pacific

Background:

As concerns about terrorist activities and threats have become a global issue, the need for international communication and collaboration have become more apparent. Undertaking a biological attack using naturally occurring or genetically manipulated pathogens in many cases remains relatively easy, inexpensive, and the necessary information and materials often are widely available. To address this issue, the scientific community needs to consider biosecurity as well as biosafety concerns.

Traditionally, biosafety committees within an institution or organization are responsible for managing biosafety issues and training, but a means of dealing with biosecurity at the local level does not appear to be broadly recognized or have a widely accepted structure. The purpose of this panel discussion is to identify the current status of science and security requirements and best practices, and educational/training resources globally, including on the Internet, and to identify additional tools that need to be developed. There will be a special focus on resources available in Asia and the Western Pacific and any gaps that need to be filled.

Moderators:

Dr. Stuart Levy BIO

NSABB Member

Director, Center for Adaptation Genetics and Drug Resistance

Professor of Molecular Biology/Microbiology and Medicine

Tufts University School of Medicine, Boston, MA

Dr. Robert Floyd BIO
Australian Safeguards and Non-proliferation Office, Canberra, Australia

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?

Panelists:

- Dr. Murray Cohen BIO
 NSABB Member
 Frontline Health Care Workers
 Safety Foundation, Ltd., Atlanta, GA
- Dr. Mark Denison BIO
 Vanderbilt University, Nashville, TN
- Dr. Dave Franz BIO
 NSABB Member
 MRIGlobal, Frederick, MD
- Dr. Chan-Wha Kim BIO
 President, Asia-Pacific Biosafety Association
 Korea University, Seoul, South Korea
- Dr. Jeffery Miller BIO
 NSABB Member
 University of California Los Angeles, Los Angeles, CA
- Dr. H. V. Murugkar BIO
 Indian Veterinary Research Institute, Bhopal, India

- Dr. Amy Patterson BIO
 National Institutes of Health, Bethesda, MD
- Dr. Ian Ramshaw BIO
 Australian National University, Canberra, Australia
- Dr. Za Hussein Reed
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 National Institute of Infectious Diseases, Tokyo, Japan
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- Dr. Zhiming Yuan BIO
 Wuhan Institute of Virology, Chinese Academy of Sciences

3:20 pm Panel discussion and questions from the audience

4:15 pm Concluding remarks

Dr. Amy Patterson National Institutes of Health, Bethesda, MD

Dr. Za Hussein Reed Regional Emerging Diseases Intervention Center, Singapore

Dr. Dave Franz NSABB member Midwest Research Institute, Frederick, MD

4:30 pm Meeting adjournment

MEETING MATERIALS:

- RONALD J. JACKSON, ALISTAIR J. RAMSAY, CARINA D. CHRISTENSEN, SANDRA BEATON, DIANA F. HALL, AND IAN A. RAMSHAW (2001). Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox.
- Michael J. Selgelid & Lorna Weir (2010). *The mousepox experience: An interview with Ronald Jackson and Ian Ramshaw on dual-use research.*

- Rachel Nowak (2001). Killer Virus.
- Michelle M. Beckera, Rachel L. Grahamb, Eric F. Donaldson, Barry Rock, Amy C. Sims, Timothy Sheahan, Raymond J. Pickles, Davide Corti, Robert E. Johnston, Ralph S. Baric, and Mark R. Denison (2008). Synthetic recombinant bat SARS-like coronavirus is infectious in cultured cells and in mice.
- Yudhijit Bhattacharjee (2009). Life Scientists Cautious About Dual-Use Research, Study Finds.
- WHO Guidance document, Responsible life sciences research for global health security.
- Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons.
- Biotechnology Research in an Age of Terrorism, "Fink Report".
- NSABB documents:
 - o Culture of Responsibility report
 - Synthetic biology report
 - Oversight Framework report
 - Outreach and Education reports :
 - Strategies to Educate Amateur Biologists and Scientists Outreach and Education .
 - Outreach and Education
 - Reports of the International Roundtables on Dual Use Life Sciences Research
 - Responsible Communication of Life Sciences Research with Dual Use Potential