

Dual-use Issues in Life Sciences Research: A Roundtable on Strategies for Fostering International Engagement

October 10, 2007
NIH Campus, Building 31-C

Summary of Roundtable Meeting

Welcome and Overview

David R. Franz, D.V.M., Ph.D. (NSABB Working Group Chair); Stuart B. Levy, M.D. (NSABB Working Group Vice-Chair); and Amy P. Patterson, M.D. (Executive Director, NSABB)

Drs. Franz and Levy welcomed the roundtable participants. Dr. Franz offered a short history of real and perceived biological risks since 9/11 and placed the work of the NSABB on dual use research of concern (DURC) in that context. He described the international nature of the issue and the significant regional variation in perception and response. While the rest of the NSABB focuses on the United States, the international panel is tasked with fostering awareness, understanding, and communication internationally; building relationships; and worldwide discussion of relevant issues and actions. Finally, Dr. Franz mentioned the February 2007 workshop of the international panel and the consensus points developed by the group, which included representatives from 17 countries. Dr. Levy explained that the international panel was formed to ensure that global networks, collaborations, and communications are built through professional societies, governments, and nongovernmental organizations. The initial thrust has been to find out which groups are already collaborating and communicating outside of their usual constituents, and to figure out how to communicate and share the information on dual-use research as well as codes and guidelines on how best to reduce the potential for harm in carrying out dual use research.

Dr. Patterson reviewed the overall goals of this roundtable – to advance the dialog already begun, to review and synthesize efforts already underway, and to identify options for actions – and noted that four panels will describe relevant activities and plans. Questions and issues to be addressed by each panelist in Sessions I through IV were:

- Scope of and goals for current activities
- Mechanisms used to carry out those activities
- Partners in those activities
- Challenges
- How the success of those activities are measured and evaluated
- Lessons learned and advice you would give to others planning activities
- The unmet needs in this area
- Future plans

Expected outcomes from this Roundtable were shared insights and perspectives on strategies to enhance scientific progress while minimizing the potential for misuse of research methodologies and information, with specific activities to raise awareness and understanding and to foster further

communication and collaboration. It was also expected that the deliberations of this Roundtable would provide an important conceptual backdrop for a report from the NSABB to the U.S. Government regarding proposed strategies to foster international engagement.

Dr. Patterson explained that “dual use research of concern” (DURC) had been defined by the NSABB in the “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information” (NSABB Report, June 2007) as “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.” There is now a consensus within the NSABB that essentially all research might in some way be considered ‘dual use’; the board has chosen to focus on that subset more likely to be misapplied, thus the designation DURC. The probability of misuse is unknown but even if small, the potential consequences for public health, safety, security, and public trust are significant. While DURC is of global concern, the priority that any given nation places on dual use research issues will depend in large part on the other issues that the nation faces.

Session I: Academies

Moderators: Drs. Harvey Rubin and Anne Vidaver (NSABB Working Group)

Responsible Stewardship of Advances in Life Sciences Research: Engaging the International Scientific Community – Jo Husbands, Ph.D., U.S. National Academy of Sciences

Dr. Husbands described the work of the National Academies in dual-use issues and provided some background information about international organizations. The National Academies has a long history of working on biological weapons issues, having been engaged in dual-use issues before 9/11 and the anthrax mailings in October 2001. Two particular points of concern are the potential for misuse and the potential negative impact on research if heavy-handed regulations are enacted.

The Fink Report (2003), the Falkow Report (2004), and the Lemon-Relman Report (2006) contained four common messages (1) the scientific community has the responsibility to help reduce the risks of misuse, (2) scientific societies and associations play a critical role in educating their members about dual-use issues, (3) forums should be created to ensure communication between scientists and policymakers on how best to develop and harmonize standards for addressing dual-use issues, and (4) whatever is done needs to be international as well as national in scope.

Some of the key international science organizations include the International Council for Science (ICSU), founded in 1931, with a global membership that includes both national scientific bodies (112 members) and international scientific unions (29 members); the InterAcademy Panel, a network of 97 of the world’s science academics, created in 1993; and the InterAcademy Medical Panel, a network of 64 of the world’s academies of science and medicine, created in 2000. An effort is underway to coordinate these various networks, recognizing the increasing capacity of academies to be effective advisors on scientific and technical issues that affect policy choices as well as on policies that affect how science is supported and conducted.

On the policy side, there exists an equally diffuse set of international intergovernmental organizations each with potentially relevant roles and varying experience with scientists, with security issues, and with each other, including the Organization for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the United Nations (UN), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), and Interpol. In addition, benefit is derived from the

international laws and norms established by the Biological and Toxin Weapons Convention (BWC) and the Chemical Weapons Convention (CWC).

Current activities at the National Academies include the International Biosecurity Project, which has been working since 2004 to promote implementation of the Fink committee's international recommendations. The best source of information on other activities is the National Academies' biosecurity Web site at <http://www7.nationalacademies.org/biosecurity/index.html>.

The relevant issues are too complex and the stakeholders are too varied for any single organization to lead, so that many different kinds of groups must be involved and many different approaches must be utilized. For the sciences, biosecurity is best framed as part of the "social responsibility of science"; for example, the OECD refers to "responsible stewardship" and others (including the NSABB) refer to fostering a "culture of responsibility." Ultimately, a network of networks is most likely to be effective as a form of "governance" that would mix formal (including legal and regulatory) and informal regulations, and would include biosafety and laboratory biosecurity as essential elements, an important role for funding organizations, and a key role for "soft law" such as norms and codes of ethics. Communication, coordination, and collaboration will be key to success.

International Partners, UK Partners, and Challenges Ahead – Alastair Hay, Ph.D., U.K. Royal Society *(by videoconference)*

Dr. Hay summarized the activities of the Royal Society (RS). The RS has a standing committee that is considering the scientific and technical aspects of international security, such as arms control, counter terrorism, nonproliferation, and reducing the risk of the misuse of scientific research. Recent activities of the RS include an October 2004 workshop cosponsored by the Wellcome Trust on reducing the potential for the misuse of life science research, a June 2005 meeting of experts of the Biological and Toxin Weapons Convention (BWC) in Geneva, a September 2006 international workshop on science and technology developments relevant to the BWC, and in November 2006 the Sixth BWC Review Conference seminar.

The InterAcademy Panel on International Issues released a statement on biosecurity that was drafted by academies from the Netherlands, Cuba, the United States, the United Kingdom, China, and Nigeria. This statement was released in November 2005 and was signed by 69 national scientific academies. It presents guiding principles for formulating codes of conduct including awareness, safety and security, education and information, accountability, and oversight.

A September 2006 meeting was convened to discuss scientific and technological developments relevant to the BWC; 86 individuals participated from a wide range of countries. The key conclusions were that risk management should be improved, openness and transparency should be stressed and over-restriction avoided, education and awareness raising should be emphasized, and scientific input into the BWC should be reinforced through strengthening the independent scientific advisory panels and regional scientific meetings and networks, allowing the scientific community to provide input more regularly into the BWC regime, and helping keep track of the rapid pace of technological developments.

Regional networks are useful for promoting cooperation and for coordinating resources and efforts on issues that are truly international in scope, such as the BWC. One such example is the European Academies Science Advisory Council (EASAC), which provides scientific advice to European policymakers by drawing on the memberships and networks of the national academies of the European Union member States. The EASAC stresses scientific cooperation and coordination across Europe on various bioscience and public health issues.

The U.K. Government Chief Scientific Adviser instituted an ethical code in 2006 among government scientists; in September 2007, this code was urged to be adopted by all U.K. scientists. The code says, in part:

- Act with skill and care and keep skills up to date.
- Prevent corrupt practice and declare conflicts of interest.
- Respect and acknowledge the work of other scientists.
- Ensure that research is justified and lawful.
- Minimize impacts on people, animals, and the environment.
- Discuss issues science raises for society.
- Do not mislead; present evidence honestly.

Challenges and next steps include creating a web of prevention, engaging all levels of the scientific community, and taking advantage of educational opportunities. Dr. Hay noted that many members of the U.K. scientific community already feel over-regulated.

Biosecurity-Related Activities at the InterAcademy Panel – Li Huang, Ph.D., InterAcademy Panel/Biosecurity Working Group and China Academy of Sciences

Dr. Huang provided an overview of the IAP Biosecurity Working Group, the biosecurity-related activities at the InterAcademy Panel (IAP), and the Chinese Academy of Sciences (CAS) and its biosecurity-related activities.

The IAP executive council has made biosecurity a priority initiative and established a Biosecurity Working Group (BWG) in 2004 to coordinate its activities in this area. The lead academy is The Royal Netherlands Academy for Arts and Sciences, and other members include academies of China, Cuba, Nigeria, the United Kingdom, and the United States. The goal of the BWG is to enhance the capacity of member academies to promote policies that support both international security and continuing scientific progress. Past and current activities of the BWG include preparation of a statement on biosecurity, sponsorship or cosponsorship of biosecurity forums and workshops, monitoring national and regional developments related to biosecurity, development of a biosecurity tool-kit, and participation in the BWC process.

In 2005, the BWG prepared a statement on biosecurity that included principles that should be considered in developing codes of conduct, including awareness, safety and security, education and information, accountability, and oversight. To date, 69 IAP member academies from all parts of the world have endorsed this statement. A survey of IAP members indicates that the statement has been translated into six languages and has been posted on the Web sites of 13 academies, and 15 academies have presented the statement to their national authorities.

To carry out its activities, the BWG offers meetings and teleconferences, identifies lead academies within the BWG for each activity, stresses cooperation with member academies, and coordinates with other international organizations. A partnership among the IAP, the InterAcademy Medical Panel (IAMP), and the ICSU resulted in cosponsoring the first international forum on biosecurity, held in Como, Italy, in March 2005. In addition, the IAP and the International Union of Microbiological Societies (IUMS) will co-sponsor the second international forum on biosecurity in early 2008.

Challenges include a general lack of appreciation of the importance of the dual-use issues, the fact that regulatory measures are not readily acceptable to scientists, and significant differences among nations in the perception of biosecurity. To address these challenges, the BWG plans to engage more directly with individual academies and regional networks to increase their capacity to serve as sources of expertise and advice on biosecurity. To do so, the BWG is sponsoring the second

international forum on biosecurity, biosecurity surveys in sub-Saharan Africa, and a biosecurity workshop in Beijing, China. To continue enabling the IAP to represent the scientific community in international biosecurity forums, the BWG plans to participate in the BWC process and other biosecurity activities sponsored by other international organizations.

The CAS was founded in 1949. As the most prestigious academic institution and the major national advisory body in science and technology in China, it is composed of 89 research institutes and 44,000 staff members, including 13,000 senior researchers and 38,000 visiting scholars, postdoctoral fellows, and graduate students. In 1997, the CAS Academic Divisions established the Moral Construction Committee and in 2001 the committee formulated the “Self-Discipline Rules for Academicians.” International cooperation has included participation in international biosecurity activities and hosting of the 2008 Beijing biosecurity workshop.

The principles in international science and technology ethics cooperation, as espoused in 2005 by the president of CAS, were as follows:

- Scientists, engineers, lawyers, and social scientists should join in discussion of the ethical issues.
- Principles of equality, equity, reciprocity, and transparency should be insisted and emphasized in the face of ethical issues.
- Various communities of the society should make joint efforts in achieving harmony between the development of science and technology and the improvement of ethics.
- Science and technology ethics education should be promoted, especially among young students.

Session II: International Science Unions

Moderators: Drs. Stuart Levy and Anne Vidaver (NSABB Working Group)

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

Dr. Sordelli provided a brief history of the IUMS. Founded in 1927 as the International Society of Microbiology, the IUMS evolved into the International Association of Microbiological Societies in 1967 and then acquired independence in 1980, and the IUMS became a Union Member of the ICSU in 1982. IUMS is one of the 29 Scientific Unions of ICSU, representing 65 countries in its 113 member societies and 14 associate members. To implement its scientific activities, the IUMS sponsors congresses every 3 years with the next congress occurring in Istanbul, Turkey, in 2008.

The major goal of the IUMS is to promote research and the open exchange of scientific information for the advancement of the health and welfare of humankind and the environment, while strongly discouraging any uses of knowledge and resources to the contrary. The IUMS strives to promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons. All member societies are asked to adopt or develop a code of ethics to prevent misuse of scientific knowledge and resources; the IUMS has developed its own “Code of Ethics Against Misuse of Scientific Knowledge, Research, and Resources.”

At present, the IUMS has not formed any specific partnerships; however, in the future, the IUMS would like to partner with other unions to begin to address the unmet needs of awareness of the importance of dual-use issues and realization of the importance of multinational initiatives. Future plans include: a) seeking partnership with a group of organizations to engage in international projects (for example, an initiative to prevent misuse of biological tools and methods); b) enhancing the vertical flow of information both upstream to the ICSU and downstream to member societies; and c) engaging

with other scientific unions in educational projects relevant to raising awareness on the risks emerging from scientific research dual use.

Role of the International Union of Biochemistry and Molecular Biology in Issues of Dual-use Research – Bettie Sue Masters, Ph.D., D.Sc., M.D. (Hon.)

Dr. Masters provided an overview of the International Union of Biochemistry and Molecular Biology (IUBMB). As one of the 29 scientific unions of the ICSU, the IUBMB represents the disciplines of biochemistry and molecular biology. Its mission is “to foster and support the growth and advancement of biochemistry and molecular biology as the foundation from which the biomolecular sciences derive their basic ideas and techniques in the service of mankind.” Strategies to achieve its mission include promoting international cooperation and high standards in research, discussion, application, and publication, and through international standardization of methods, nomenclature, and symbols.

The IUBMB sponsors international congresses every 3 years and international conferences in the intervening years. Symposia and workshops are also sponsored. Journals published by the IUBMB help to disseminate research and educational information. The IUBMB assists the biotechnology industry in the areas of sustainable development, wealth creation, and improvements in the quality of life. The 11th IUBMB Conference, in conjunction with the 33rd FEBS Congress, will be held in Athens, Greece, in 2008; the 21st IUBMB Congress will be held in Shanghai, China, in 2009. Wood-Whelan Fellowships, sponsored by the IUBMB, provide for young scientists to travel to qualified laboratories to perform research not possible in their own countries.

The IUBMB can contribute to the dual-use research issue by disseminating biochemical and molecular biological education to Africa, Asia, and South America through regional organizations, cooperative projects, and exchange programs and fellowships. IUBMB has offered financial support to the Board on International Scientific Organizations (BISO) of the National Academies for a symposium in the field of biosecurity. Publication of articles relating to dual-use research in IUBMB journals will raise the level of awareness of the journal’s readership. Because fear can become rampant once awareness is raised, education must follow in order to ward off some of that fear.

While the IUBMB’s current plans are achievable using current resources, expanding IUBMB activities to promote the dual-use agenda will require raising additional funds, which is currently underway. The IUBMB recently incorporated an entity in the Commonwealth of Massachusetts and a fundraising campaign is being planned. Dues, paid primarily by the adhering bodies of the most scientifically developed nations, have supported all previous activities. This level of support is not adequate to launch new initiatives, since it is a struggle to maintain the activities already supported by the IUBMB, thus necessitating new sources of funding.

International Union of Pure and Applied Chemistry – John Malin, Ph.D.

Dr. Malin provided background information about the International Union of Pure and Applied Chemistry (IUPAC). The mission of the IUPAC is to advance the worldwide aspects of the chemical sciences and to contribute to the application of chemistry in the service of humankind. This mission is supported by promoting norms, values, and ethics of science; advocating free exchange of scientific information and access of scientists; and addressing global issues as a scientific, international, nongovernmental, objective body. The IUPAC consists of nine international divisions and four major committees, of which the Chemical Research Applied to World Needs (ChemRAWN) is one. Activities of the IUPAC include congresses, workshops, and meetings; publications; setting international standards (for example, element naming); and a young observers’ program to assist in attending congresses.

Several workshops related to the dual use of chemicals have been held in recent years. The Bergen workshop in 2002 (79 participants from 34 countries) provided scientific advice to inform operations of the CWC review conference in 2003 and discussed agrochemicals, biotechnology, new catalytic processes, terrorism risks to chemical industry, and new analytical methods. The Zagreb workshop in 2007 (68 participants from 30 countries) discussed trends in the CWC, chemical synthesis, analysis, production, nanotechnology, and decontamination, and will inform the CWC's second review conference, scheduled for April 2008. Goals of the IUPAC-sponsored Kuala Lumpur Workshop, held in August 2007, were to identify gaps in chemical security/safety in South and Southeast Asia, to investigate joint programming to fill those gaps, and to raise awareness of the potential for chemical terrorism threats in the region.

The IUPAC is working with the chemical industry through its Company Associates program, which fosters relationships between the Union and internationally based industrial corporations and scientific businesses, allowing for the exchange of information regarding current issues influencing chemistry and industry. The IUPAC's Committee on Chemistry and Industry (COCI) has direct involvement with Company Associates.

In regard to chemical weapons, dealing with economically disadvantaged countries, developing new analytic procedures, and remediation are the primary challenges seen by the IUPAC, which will measure the success of its activities by the actions of its constituent organizations. Future plans include development of a Chemical Safety Program, which would train priority country personnel to enhance chemical safety practices, to meet developed world standards, to promote security and threat perception, to provide risk/vulnerability assessments, and to increase transparency and accountability for dangerous chemicals and technologies. An educational Web site has been established to raise public awareness and understanding of chemical weapons.

The IUPAC supports development of international guidelines, and a group is presently forming to come up with guiding principles for member organizations to consider. Once the guidelines are drafted, there will be an extensive period of consultation and draft guidelines will be produced for member organizations, with assistance in translating them within their own countries.

Session III: Intergovernmental Organizations

Moderators: Drs. David Franz and Murray Cohen (NSABB Working Group)

Life Science Research and Global Health Security – Ottorino Cosivi, D.V.M., M.Sci., World Health Organization

Dr. Cosivi discussed activities of the WHO, beginning with two resolutions of the World Health Assembly (WHA) in 1967 and in 2002. No WHA resolution to date specifically deals with biosecurity, although both of these resolutions touch on the issue.

The objective of the project called Life Science Research and Global Health Security is to inform and provide guidance to member States on the prevention of accidental or potential misuse associated with the outputs of life science research – from expected or unexpected products (tangible products) to skills and tacit knowledge (intangible factors). Supported by the Sloan and Ford foundations, this project seeks to map the issue and establish the network (Phase 1) then establish a Scientific Working Group, online consultation, and hold one regional workshop on capacity-building (Phase 2). Plans include the development of guidelines and information/training material, and further regional activities. Project outputs will include reports, actions, regional activities, and raised awareness.

The Scientific Working Group has recommended five areas for action within this project: education and training, preparedness for a possible major outbreak of disease, development of risk assessment methodologies, engagement of all stakeholders in the life science community and guidelines for oversight, and capacity building at the country level, to include ethics, clinical practice, laboratories, and research.

The WHO project has been contributing to regional activities on laboratory biosafety and laboratory biosecurity (Tehran, Iran, 2006 and Nairobi, Kenya, 2007), with the goal of exchanging information and evaluating the needs of the different WHO regions. Other similar workshops will be conducted in 2008 and 2009. A regional Workshop on Research Policy and Management of Risks in Life Science Research for Global Health Security will be held in Bangkok, Thailand, in December 2007.

The WHO's plans are to develop the guidelines by utilizing the regional activities and peer review in a review process and through field testing. The information/training material will be developed, and regional activities (from information exchange to capacity building) are planned to take place in Africa, Latin America, and the Commonwealth of Independent States (CIS; formerly the Soviet Union). A Scientific Working Group meeting will be held at the end of 2009. The next phase will be to offer technical support to countries.

Biosecurity in the OECD's International Futures Program – Michael Osborne, Ph.D., Organization for Economic Co-operation and Development

While acknowledging that the primary mandate of the OECD is focused on economics, Dr. Osborne discussed the DURC-related activities of his organization. The OECD's focus is on discerning the DURC issues among the governments, and the organization's biosecurity guidelines were released in March 2007.

The OECD's International Futures Program (IFP) provides an early warning of emerging issues, pinpoints major developments, and analyzes key longterm concerns to help governments map strategy. In service of its mission, the IFP uses a variety of tools including multiyear projects, high-level conferences, expert workshops, and consultations; a futures-oriented online information system; and a network of contacts from government, industry, academia, and civil society.

The IFP's Web site, www.biosecuritycodes.org, covers biosecurity (though not biosafety) issues. The goals of this Web site are to provide a comprehensive information portal for general biosecurity information as well as more focused information on codes of conduct and regulatory oversight mechanisms for the life sciences within OECD and non-OECD countries; to raise awareness about biosecurity among government officials, scientists, and the public; and to build an appetite for voluntary agreements and harmonization of public and private efforts. The intended audiences are the public, scientists, and government decisionmakers, and the hope in the near future is to adapt the site to the needs of the media. To date, the Web site has generated more than 2,500 unique visitors per month and nearly 200 subscribers from 6 continents have signed up to receive the online newsletter. One of the problems has been how terminology translates behaviorally into different languages, for example, the meanings of "voluntary" and "mandatory." Evaluation of this Web site has shown that one possible change would be to improve terminology; a Wiki or Web2 approach to using this site might make it a more useful tool and would create buy-in among users.

The OECD sees three major challenges for DURC issues – the need for broad consensus by all interested parties that something should be done; better interaction at the international level among active bench scientists and engineers in public and private research, private-sector product developers, and regulators; and more involvement of key globalizing economies.

Regarding next steps, the OECD echoes the Fink Report's admonition that international coordination and cooperation will be necessary to make effective any effort to mitigate the risks of bioterrorism. Cost/benefit analyses should measure the efficiency and effectiveness of voluntary compared with mandatory approaches, by geographic region, and best/better practices at the international level should be identified.

Intergovernmental Organizations – Robert Mikulak, Ph.D., Biological and Toxins Weapons Convention and The Chemical Weapons Convention (U.S. Department of State)

Dr. Mikulak discussed working with international nonproliferation organizations – the CWC, the BWC, the Australia Group (AG), and UN Security Council Resolution 1540.

The CWC bans weapons relying on the toxic effects of chemicals, highlighting dual-use issues. A total of 182 States have joined the CWC. The Organization for the Prohibition of Chemical Weapons (OPCW), located in The Hague, The Netherlands, is the treaty secretariat for the CWC. The OPCW assists member States with national legislation and regulations, promotes technical and economic cooperation, and provides an active forum for issues at the interface of security and peaceful chemical activities.

The BWC bans biological and toxin weapons; activities not justified by peaceful purposes are prohibited. A total of 159 States have joined the BWC. There is no treaty secretariat but there is a small implementation support staff in Geneva, Switzerland. Annual meetings are held on dual-use issues, at which discussion topics include national legislation, codes of conduct, pathogen security, and disease surveillance.

While based on political commitment and not a legally binding agreement, the Australia Group consists of 40 countries plus the European Commission and coordinates national export controls on chemical and biological items. China, Russia, and India are not member States. The AG control lists are becoming the *de facto* international standard for export controls. An annual meeting encourages exchange of information about relevant technical developments, national policies, and proliferation concerns among a broad community. Next spring, the AG is expected to issue a set of best practices for export of synthetic oligo- and polynucleotides. Under the AG there has been a continuing effort to address intangible transfers of technology, including documentation and the kind of know-how that is communicated when, for example, someone visits a laboratory. The United States has placed a lot of emphasis on that, and concern has been growing particularly in Europe, Germany, and the United Kingdom.

The UN Security Council Resolution 1540 (2004) requires States to take steps to prevent acquisition of nuclear, chemical, and biological weapons by non-State actors, an attempt to keep these weapons out of the hands of terrorists. The Resolution is legally binding on all member States. Initial followup to this Resolution is focused on data collection and analysis prior to assisting countries in filling the gaps. An extensive regional and subregional outreach program is underway.

Dual-use issues related to the life sciences are already under discussion in international nonproliferation organizations with foreign ministries, defense ministries, and science and technology ministries; the focus of these discussions has been on security. The convergence of chemistry and biology is prompting a growing interest in synthetic biology. Under the CWC, there is a strong working relationship with the scientific community and industry; under the BWC, there is positive cooperation with science academies, the WHO, and the OECD.

Session IV: Foundations

Moderators: Drs. David Franz and Barry Erlick (NSABB Working Group)

Paula Olsiewski, Ph.D., Alfred P. Sloan Foundation

After providing a brief history of the Sloan Foundation, Dr. Olsiewski discussed the Sloan Foundation's goals and strategies regarding dual use research, the importance of an international approach, how to raise awareness, practical steps to minimize risk, and future plans. The Foundation operates under five program areas; "Selected National Issues" is the area under which dual-use research is contained.

In the late 1990s, the Sloan Foundation identified bioterrorism as an issue of importance. The Foundation's goal is to reduce the threat of bioterrorism, address issues of potentially dangerous research, and encourage citizen and business preparedness; the strategy to address issues of potentially dangerous research is to raise awareness within the scientific community and then find practical steps to minimize risk. While most Sloan grants are given to U.S. institutions, the Foundation recognizes that scientific research is internationally collaborative and that information is shared worldwide.

Awareness is being raised by working directly with the life scientists; embracing a broad range of approaches with a premium on looking for creativity and new ideas. Sloan recognizes that the problems are so vast that it is important to work with everyone – national academies, universities, international organizations, and industry. Finding metrics by which to measure success is difficult; data is needed to determine if progress is being made.

One example of a practical step to minimize risk is with the synthetic biology community – screening DNA orders for hazardous sequences. Sloan is currently funding a screening algorithm and has invited a proposal to support the development of the elements of an annotated database.

The Sloan Foundation will continue its current awareness-raising efforts and will look for new ideas and opportunities to raise awareness. The Foundation also will continue its domestic work on synthetic genomics and will examine the international situation. To date, the Sloan Foundation has been limited only by ideas and not by funds.

Patricia Nicholas, Carnegie Corporation of New York

Ms. Nicholas discussed the Carnegie Corporation's grantmaking in biological weapons nonproliferation as it has evolved during the past 7 years. The beginning of the Corporation's grantmaking in the biological weapons arena was in the late 1990s, when it was recognized there would be an opportunity to affect the biological weapons treaty review conference of 2001, specifically the verification protocol. It was an arms control mindset that launched the Carnegie Corporation into biological weapons nonproliferation support.

Following the events of September 11, 2001, the Corporation's grantmaking focus was to support the training of a community whose experience would be at the nexus of bioscience and international security. The goals of that training strategy were threefold: to ensure that people who became aware of inappropriate biological research would know how to stop dangerous science and would know how to react, to cultivate more sophisticated participants in the debate over biological weapons policy, and to attract some percentage of that expertise to work directly in the policy field. In response to these goals, the Corporation took on two complementary sets of activities – bringing security context to the science community and bringing science into the policymaking community. In 2004, the Corporation created and solely funded the "Biosecurity Integration Initiative," which supports training programs at

several targeted American universities and has resulted in a small consortium of the principal investigators of those grants who meet annually to share best practices and suggest improvements. Managed by the Federation of American Scientists, the Corporation-created programs at various universities have trained approximately 250 scientists.

The Jefferson Science Fellows Program was funded with the MacArthur Foundation. It is a program for policymakers to interact with career scientists by placing tenured academic bioscientists in yearlong assignments in U.S. foreign policy agencies, mostly at the U.S. Department of State. Participants translate their research into language that is understandable to policymakers and they respond to policymakers' needs for information. After 1 year, fellows return to their home universities and remain available to the Government for a 5-year consultation period. Twenty-six Jefferson Science Fellows have been placed at the Department of State; recently, the Department of State has taken over as the funder of the Jefferson Science Fellows Program.

Lessons learned from the Corporation's 7 years of funding biological weapons nonproliferation include:

- It is nearly impossible to take what was learned from nuclear nonproliferation and overlay it onto biological weapons issues.
- Success is the result of interplay between the science community and the policymaking community as well as industry and thinktanks; one sector cannot succeed alone.
- The power of individuals can far outlast the power of written reports. An oft-cited adage in philanthropy says that "if you want prosperity for a year, invest in wheat; if you want prosperity for a decade, invest in trees; but if you want prosperity for a lifetime, invest in people."
- The remaining funding needs are huge, and even though money is dwindling from major foundations, the smaller foundations are stepping in to pick up the slack. Projects should be leveraged wherever possible and collaboration, coordination, communication, and cooperation are all crucial.

Ms. Nicholas announced that the Corporation has culminated its work on biological weapons nonproliferation, having made a final round of grants at its September 2007 board meeting.

Enhancing Biological Safety and Security: Connecting the Scientists and the Policymakers – Terrence Taylor, International Council for the Life Sciences, Global Health and Security Initiative

Mr. Taylor explained the missions of the Global Health and Security Initiative (GHSI) and the International Council for the Life Sciences (ICLS). Both organizations are designed to help ensure global public health, safety, and security by safeguarding the opportunities offered by advances in the life sciences and their application through the promotion of best practices, standards, and codes of conduct. GHSI and ICLS take a full-spectrum approach to countering biological risks in order to engage all the sectors necessary for effective action. They engage in programs that counter risks along the spectrum from naturally occurring disease through laboratory accidents to deliberate misuse of the life sciences and their associated technologies.

The GHSI makes grants and manages projects, but is not currently funding projects within the United States and does not fund single-venture projects. Three elements underlie the GHSI approach: there must be "action at the front line" (scientists must be actually doing the work and asking for a safety and security paradigm), partnerships must be developed (empowering groups or networks, having expertise to undertake the projects, and supplying funds or in-kind equipment or training), and sustained engagement should be planned (specific outcomes to look for and establishing a regional training center).

The GHSI is a major supporter of the ICLS. The ICLS's priority action areas are the promotion of international biosecurity and biosafety best practices and training, and risk assessment. One of the main vehicles for this activity is the development and promotion of International Advisory Groups (IAGs) of biosafety and biosecurity experts to assist countries or regions through sustained engagement on issues of common interest.

The GHSI's programs focus more on enhancing infectious disease surveillance in key areas of the world. The emphasis in the infectious disease surveillance projects is on enhancing early detection and identification and capacity building. The GHSI is currently supporting two consortia. The Middle East Consortium on Infectious Disease Surveillance (MECIDS) is a cooperative venture among Israel, the Palestinian Authority, and Jordan – Israelis and Arabs working together to enhance their capacities for infectious disease surveillance. Funding partners for the MECIDS include the World Bank, the government of the United Kingdom from their Global Opportunities Fund, and the Bill and Melinda Gates Foundation. In addition, the private sector is involved in the form of a partnership with IBM, which is developing novel software for a Web-based data sharing system so that all three partners are looking at the same data set and map. Also partnering in this consortium is a laboratory equipment supply company – Becton, Dickinson & Company – which is donating equipment. Key achievements to date include that partners send samples to each other for laboratory confirmation and quality control, countries have common data formats, participant countries have developed common procedures for influenza outbreaks, and daily contact occurs in times of urgency.

The other consortium being supported by the GHSI, along with the Rockefeller Foundation as the major partner, is the Mekong Basin Disease Surveillance Network, which is the same idea as MECIDS and includes Cambodia, China, Laos, Myanmar, Thailand, and Vietnam. While this group has its own executive board that makes decisions on policy, the GHSI concentrates on delivering expertise and equipment, where needed, and discussing issues such as proper operation of laboratories.

In support of its mission to promote best practices, standards, and training, the ICLS will hold a regional meeting in Abu Dhabi in November 2007, primarily for representatives from countries in the Middle East, the Persian Gulf, and North Africa. Experts from other regions will also be invited. Participants will be scientific and policy experts from academia, governments, and the private sector. Two outcomes are anticipated from the meeting in Abu Dhabi: creation of a standing international advisory group and development of a regional training center with simulated BSL-2 and BSL-3 laboratories in order to conduct safety and security training. This regional meeting will include representatives from the private sector, which the ICLS suggests is best effectuated by engaging the CEO of a company.

Session V:

Roundtable Discussion: Opportunities to Foster International Engagement

Moderators: David R. Franz, D.V.M., Ph.D.; Stuart B. Levy, M.D.; Amy P. Patterson, M.D.

A major goal of this Roundtable was to identify and discuss the challenges, opportunities, and lessons learned by other organizations that have looked at biosecurity, biosafety, and dual use research issues internationally. Toward this end, this session of the Roundtable focused on the current activities and gaps and the potential role that some of the tools, already developed by the NSABB and others, might play in facilitating international engagement on dual use research issues.

COMMENT

This session was a free-flowing discussion of key dual-use issues that built upon the earlier presentations and discussion periods following each panel. Some issues were explored in detail, others only touched on by one or two participants, and others raised in the panel presentations were not dealt with at all. There was no attempt to reach a consensus. The following are some of the shared insights and perspectives and major points made in the final session and comments from the brief discussion periods that followed the earlier panel presentations. They are grouped by major category in this summary for ease of review and to highlight the areas covered:

UNDERLYING CONCEPTS AND CHALLENGES IN DEVELOPING A DUAL USE RESEARCH INTERNATIONAL ENGAGEMENT STRATEGY

- Science is a social contract between scientists and society. Science is a critical component of public health and well being, and therefore a precious resource that needs to be protected against misuse.
- Lack of awareness of the importance of the DUR issue is widespread.
- As a culture of responsibility in science is increasingly encouraged, developed and accepted the risk of harm coming from an incident related to DUR will be reduced.
- Dual use research is a complex issue with many pieces and many stakeholders.
- The intersection of science and harmful intent can involve the public and/or private sectors.
- In biology, traditionally, the security and enforcement communities have not communicated closely with the science or science policy communities.
- While the “scientific community” is diffuse there is general uniformity in a lack of appreciation of dual use issues.
- The scientific community has little experience with security issues and has a reluctance to engage in them.
- The scientific community already feels over-regulated and would not readily accept additional oversight measures.
- Industry---and other components of the private sector---and funding organizations have an important role to play in the dual use research arena and should be actively engaged.
- The issue of funding will be very important in the future because meetings, activities, publications, and other methods of communicating, collaborating and disseminating information about dual use issues will require substantial funds.
- Dual use educational/training products should be developed and made suitable/attractive to various target groups.
- Dual use research issues are too complex and stakeholders too varied for any single organization to lead.

- There is no single “international scientific community.” Instead there is a wide array of organizations with disparate memberships and mandates. Additionally, there is a diffuse set of intergovernmental organizations and treaty regimes with variable involvement with scientists, security issues and each other.
- Dual use issues are considered by some countries as relatively esoteric because they view issues such as health, poverty, and clean water as more pressing concerns.
- It is very important to examine science-related concerns, norms, and guidelines that have received global attention in the past and prompted successful international action as potential precedents for dual use research actions. Examples include: Human Subjects Protection in research (The Declaration of Helsinki of the World Medical Association) and Recombinant DNA Oversight (The OECD Blue Book, "Recombinant DNA: Safety Considerations.")
- Biosafety and biosecurity, while not universally defined terms, are important concepts that are intrinsic to discussion of dual use research.

DEFINITIONAL PROBLEMS CONFOUND THE USE OF TERMS SUCH AS DUAL USE RESEARCH, BIOSAFETY, AND BIOSECURITY IN INTERNATIONAL AND NATIONAL SETTINGS

- “Biosafety,” “biosecurity,” and “dual use” are different concepts, and they require different approaches but they are, to varying degrees, inter-related.
- There is no readily understood or harmonized lexicon of dual use-related terms. Not only is there a lack of understanding as to what "dual use research" means, but the terms "biosafety" and "biosecurity" mean different things to different people and organizations.
- Standardized definitions are needed for dual use research, dual use research of concern, biosafety, biosecurity, and risk assessment and risk management. The definitions need to be meaningful in multiple languages.
- Terminology and the clarity and interoperability of language and definitions are key to garnering international support for actions to address dual use issues.
- The term “dual use” is an obstacle to dialogue in many parts of the world. Some believe that the term dual use cannot be used successfully internationally, at the present time.
- International discussion needs to center on terms that do not have any perceived political agenda attached to them. Dual use is seen by many as primarily an American issue.
- There is a universal concern internationally that technology can be used for malevolent purposes as well as for the good of humanity. How that concern is addressed in different countries will have to be individualized, to some degree, because the cultures are different.
- To cast the dual use message in terms that may be most palatable to the international community, “the responsible conduct of science” should be used. The entire scientific community wants to protect itself against misuse and would like to be viewed as made up of responsible scientists. It is a bit like airline safety where it is in each nation’s best interest if there is a common approach to specific aspects of safety.

PROMOTING AWARENESS OF DUAL USE RESEARCH ISSUES

- Raising awareness of dual use research issues among the public and in the scientific community is a key early step in shaping international cooperation and collaboration.
- There are caveats, however, in raising awareness. Merely raising awareness about dual use research issues could result in fear among the public. People will wonder why there are no safeguards now to prevent misuse. Scientists will be worried that their research will be disapproved and/or they will be unable to publish. Thus, education and training must accompany awareness efforts.
- It can be difficult to get foreign audiences, particularly in developing countries, to talk explicitly about biosecurity and security of pathogens and laboratories, if effective biosafety practices and procedures are not already in place in the research or public health laboratory setting.
- Effective information dissemination and outreach includes using the media and encouraging all stakeholders to participate in dual use discussions and actions. Media is key to disseminating information and engaging the public in dual use issues. Part of the challenge in talking and working with the media is figuring out how to convey the critical set of dual-use issues in a way that is transmittable both quickly and clearly. Nuclear issues, for example, are more readily apparent. Biology is more difficult to talk about, and the risks in biology are more difficult to define.
- The “messengers” i.e., who will be delivering the DURC messages, are important. International and national scientific organizations will be likely the best groups to convey information to scientists. Opportunities for that kind of engagement abound through professional societies.

PROMOTING EDUCATION AND TRAINING IN DUAL USE RESEARCH ISSUES

- Education and training need to follow awareness-raising. As stated above, merely raising awareness could stimulate fear. Education and training should include consideration of assessment and management of dual use risk.
- To be effective, dual use activities in education/training/oversight must be international in scope.
- Dual use educational/training products need to be developed and made suitable/attractive to various target groups.
- Educational and as well as awareness-raising activities, guidelines and codes need to include “Top-down” and “Bottom-up” approaches
- Regional as well as international scientific and security organizations need to be engaged in dual use research issues.
- Training should include veterinary and agricultural issues because similar risks are involved.

PROMOTING COMMUNICATION AMONG DUAL USE RESEARCH INTERESTED PARTIES

- Without a broadly and easily available and free means of communication, initiating and sustaining cooperation, coordination, and collaboration among relevant parties will be very difficult.
- At a recent OECD-sponsored meeting in Holland, one of the primary recommendations was the creation of an open, searchable, and some-parts-secure computer architecture that would allow for that access.
- A repository for information and a surveillance mechanism are needed and would be well accepted.
- The UN is considering the implementation of a single comprehensive database containing information on events where biocontainment failures have occurred that will complement the database established by Interpol.
- Networks and networks of networks are needed. Networks will facilitate cooperation and collaboration. A web portal that could serve as an important source of information and input is currently under consideration by OECD and the Federation of American Scientists.
- The UN is considering the implementation of a database containing information events where biocontainment failures occurred.

APPROACHES TO COORDINATION AND COLLABORATION

- Conferences and meetings that bring together international groups that influence international and national policies are good mechanisms for developing coordination and collaboration. Academies and Unions have a variety of upcoming congresses, workshops, and other meetings with their national and regional representatives that offer excellent opportunities for DUR-related discussions and policy development.
- A near term opportunity for engagement on dual use issues will be the intersessional meeting for the BWC in 2008; one of the topics will be the broad definition of research oversight, education, and awareness-raising. This will give scientific groups some focus and a way to engage their own governments in dual use-related discussions.
- The discussion of DURC fits into the already-underway activities of the WHO and the IAP, OECD and others at an upcoming WHO training workshop (December 2007 in Bangkok) and at the 2nd International Forum on Biosecurity (IAP and others, March 2008 in Budapest) which will attempt to raise awareness about DURC.
- There is a need to create new international, regional and national fora that include scientists and policymakers in order to harmonize "standards" for dual use research
- As a way to begin to operationalize some of these ideas, one strategy would be to gather groups through OECD or the Australia Group – where there exists some consensus on DUR issues. Attempts at achieving some degree of harmonization in that forum could then be followed by expanding from that core group.
- National governments should move forward quickly. Changes in national Administrations that are concerned about dual use research, whether or not the new Administration is of the same

or different political party, will slow down the movement of decision making. Intergovernmental organizations will only act in a vigorous and decisive manner if member states band together to develop resolutions to be adopted by their governing bodies. This is usually a lengthy process so the sooner draft resolutions are crafted by like-minded governments and brought to the governing bodies, for example the WHO Executive Board, the better. Regardless, current projects managed by intergovernmental organizations are very important. Highlighting dual use research ties to such projects and related programs, as biosafety and biosecurity, implementation of WHO's International Health Regulations, and UN Resolution 1540 activities should be pursued and dual use research-related activities/concepts incorporated into such extant programs.

- The United Nations Headquarters in New York would be a better venue for discussion of DUR issues than Resolution 1540 regional workshops.

THE NEED FOR INTERNATIONAL GUIDANCE, GUIDELINES AND STANDARDS

- Guidelines are important tangible products. There is a need to develop appropriate risk assessment and risk management methodologies as part of an internationally relevant "tool-kit." NSABB work products/tools might be utilized internationally. They are now available on the NSABB web site and have been submitted to the US Government. They are still under review and thus do not now necessarily reflect official US Government policy. (These documents are the: "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" and "Addressing Biosecurity Concerns Related to the Synthesis of Select Agents.")
- When working on codes of conduct, it is essential to have as many people as possible involved in the process so that they take ownership of those codes. For example, the IUPAC is considering a small fund to sponsor a working group to develop guiding principles for member organizations to consider in developing a Code of Conduct. Guiding principles will be drafted, followed by an extensive period for consultation because of the sensitivity of these issues. After the period of consultation, it is hoped that a draft set of guiding principles will be produced that will inform member organizations and help them to translate these principles within their own countries.
- A framework document contains a set of principles/topics, such as the NSABB work products. The IAP biosecurity group began by discussing the drafting of a code of conduct; however, it became clear that a set of principles would be more useful to an international body than would an actual code. The framework document for a code of conduct is a useful set of principles and topics that any country or any group must consider; a good place to start the dual-use conversation. Success would be discovering that the international discussions cover all of the points in the framework document. Publication and review of proposals are topics for discussion; the actual form taken would reflect each nation's needs, but at least the same set of problems is being discussed. Process is equally as important as product.

METRICS

- There is a need to catalogue what different countries already have in place and there is great interest in how the codes of conduct now in place are working.
- It will be difficult to measure the effects of awareness activities, codes of conduct, and international relationship-building; however, there is a need to determine success. Success

will be difficult to measure. What can be measured is which communities and constituencies have been reached, and whether they are considering dual use issues themselves

- One measure of success, albeit a soft measure, is whether international collaborations on dual-use issues are enhanced and not inhibited. Communicating is valuable; if walls are built and communication is not occurring, there is harm. While it might not be testable that a certain number of lives were saved as a result of generating codes and policies, the process of developing those codes and policies is important because it is communication – talking together about a difficult problem
- The issue of metrics in implementing DURC codes or policies is important in two ways: (1) measuring the level of awareness among the scientific community and the public and (2) measuring the extent to which harm is not done to the scientific enterprise. There currently exists some ability to measure the level of awareness of dual-use issues among the scientific community and the public, but it will be increasingly necessary to know if and how those messages have been received. The other important metric will be not doing harm to the scientific enterprise; metrics will be needed to measure whether the appropriate balance has been struck such that DURC codes or policies are not slowing down research or unduly burdening scientists.

COMMENT

The expected outcomes from this Roundtable as set out by Dr. Patterson at the outset of the meeting were met. Many participants shared insights and perspectives on strategies to enhance scientific progress while minimizing the potential for misuse of research methodologies and information, and specific activities to raise awareness and understanding and to foster further communication and collaboration were articulated and discussed. The deliberations of this Roundtable will provide an important conceptual backdrop for a report from the NSABB to the U.S. Government regarding proposed strategies to foster international engagement.

Appendix A: List of Participants

Presenters

Ottorino Cosivi, D.V.M.

Project Leader
Program for Deliberate Epidemics
World Health Organization
Geneva, Switzerland

Alastair Hay, Ph.D.

UK Royal Society
Professor of Environmental Toxicology
School of Medicine
University of Leeds
Leeds, United Kingdom

Li Huang, Ph.D.

InterAcademy Panel/Biosecurity Working
Group
Director, State Key Laboratory of Microbial
Resources
China Academy of Sciences
Beijing, People's Republic of China

Jo Husbands, Ph.D.

Senior Project Director
Policy and Global Affairs Division
National Academy of Sciences
Washington, DC

John Malin, Ph.D.

Chair, ChemRAWN Committee
International Union of Pure and Applied
Chemistry
American Chemical Society (Retired)
Washington, DC

Bettie Sue Masters, Ph.D., D.Sc.

International Union of Biochemistry and
Molecular Biology
The Robert A. Welch Distinguished Professor
in Chemistry
The University of Texas Health Science Center
at San Antonio

San Antonio, TX

Robert Mikulak, Ph.D.

Director, Office of Chemical and Biological
Weapons Threat Reduction
Bureau of International Security and
Nonproliferation
U.S. Department of State
Washington, DC

Ms. Patricia M. Nicholas

Program Associate, International Program
Carnegie Corporation of New York
New York, NY

Michael Osborne, Ph.D.

Director
OECD Global Science Forum
Organization for Economic Co-operation and
Development
Paris, France

Paula Olsiewski, Ph.D.

Director, Bioterrorism Program
Alfred P. Sloan Foundation
New York, NY

Daniel Sordelli, Ph.D.

President-Elect
International Union of Microbiological Societies
Full Professor, Department of Microbiology
School of Medicine
University of Buenos Aires
Buenos Aires, Argentina

Mr. Terence Taylor

Director
Global Health & Security Initiative
The Nuclear Threat Initiative
President and Director,
International Council for Life Sciences
Washington, DC

Discussants

Ronald Atlas, Ph.D.

American Society of Microbiology
Dean, Graduate School
University of Louisville
Louisville, KY

Kavita Berger, Ph.D.

Senior Program Associate
Center for Science, Technology and Security
Policy
American Association for the Advancement of
Science
Washington, DC

Kenneth K. Bernard, M.D.

Former Special Assistant to the President for
Biodefense
Monterey, CA

Gerald Epstein, Ph.D.

Senior Fellow for Science and Security
Center for Strategic and International Studies
Washington, DC

Margaret A. Hamburg, M.D.

Chair
Board on Global Health
Institute of Medicine
National Academy of Sciences
Washington, DC

Gabriele Kraatz-Wadsack, D.V.M., Ph.D.

Chief
Weapons of Mass Destruction Branch
United Nations Headquarters
New York, NY

Canice Nolan, Ph.D.

First Counselor, Head of Food Safety, Health,
and Consumer Affairs
Delegation of the European Commission to the
U.S.A.
Washington, DC

Robert E. Palazzo, Ph.D.

President, Federation of American Societies
for Experimental Biology
Provost
Rensselaer Polytechnic Institute
Troy, NY

James E. Pearson, D.V.M.

World Organization for Animal Health
Paris, France

Michael Stebbins, Ph.D.

Director of Biology Policy
Federation of American Scientists
Washington, DC

Mr. Terence Taylor

Director
Global Health & Security Initiative
The Nuclear Threat Initiative
President and Director
International Council for Life Sciences
Washington, DC

Jonathan B. Tucker, Ph.D.

Senior Fellow
James Martin Center for Nonproliferation
Studies
Monterey Institute of International Studies
Washington, DC

NSABB Members

David R. Franz, D.V.M., Ph.D. (Chair)

Vice President and Chief Biological Scientist
Midwest Research Institute
Frederick, MD

Stuart B. Levy, M.D. (Vice Chair)

Director
Center for Adaptation Genetics & Drug Resistance
Professor of Molecular Biology, Microbiology and Medicine
Tufts University School of Medicine
New England Medical Center
Boston, MA

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

President and Chairman
Frontline Healthcare Workers® Safety
Foundation, Ltd.
Atlanta, GA

Barry J. Erlick, Ph.D.

President
BJE Associates, Inc.
Alexandria, VA

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

Director, Institute for Strategic Threat Analysis and Response
Professor of Medicine, Microbiology, and Computer Science
University of Pennsylvania
School of Medicine
Philadelphia, PA

Anne K. Vidaver, Ph.D.

Professor and Head
Department of Plant Pathology
University of Nebraska, Lincoln
Lincoln, NE

Federal Agency Representatives

Dennis Dixon, Ph.D.

Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institutes of Health
Bethesda, MD

Tom Hopkins, Ph.D.

Assistant to the Secretary of Defense
Nuclear and Chemical and Biological Defense Programs (Acting)
Department of Defense
Washington, DC

Peter Jutro, Ph.D.

Deputy Director
National Homeland Security Research Center
U.S. Environmental Protection Agency
Washington, DC

Mary Mazanec, M.D., J.D.

Acting Director
Office of Medicine, Science & Public Health
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Washington, DC

Jeff Miotke

Deputy Assistant Secretary for Science and Health
U.S. Department of State
Washington, DC

Janet K.A. Nicholson, Ph.D.

Associate Director for Laboratory Science
National Center for Infectious Disease
Centers for Disease Control and Prevention
Atlanta, GA

Scott Steele, Ph.D.

NSTC Representative
Office of Science and Technology Policy
Executive Office of the President
Washington, DC

NIH Office of Biotechnology Staff

Amy P. Patterson, M.D.

Executive Director
National Science Advisory Board for Biosecurity
Director
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health
Bethesda, MD

Mary Groesch, Ph.D.

Senior Advisor for Science Policy
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health
Bethesda, MD

Ronna Hill

Program Assistant
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health
Bethesda, MD

Stuart L. Nightingale, M.D.

Consultant
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health
Bethesda, MD

Allan Shipp, M.P.H.

Director of Outreach and Education
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health
Bethesda, MD

Appendix B: Acronyms

AG	Australia Group
BISO	Board on International Scientific Organizations
BWC	Biological and Toxin Weapons Convention
BWG	Biosecurity Working Group
CAS	Chinese Academy of Sciences
ChemRAWN	Chemical Research Applied to World Needs
CIS	Commonwealth of Independent States (formerly the Soviet Union)
COCI	Committee on Chemistry and Industry, IUPAC
CWC	Chemical Weapons Convention
DURC	dual-use research of concern
EASAC	European Academies Science Advisory Council
IAMP	InterAcademy Medical Panel
IAP	InterAcademy Panel on International Issues
ICLS	International Council for the Life Sciences
ICSU	International Council for Science
IFP	International Futures Program, OECD
IHRs	International Health Regulations
IUBMB	International Union of Biochemistry and Molecular Biology
IUMS	International Union of Microbiological Societies
IUPAC	International Union of Pure and Applied Chemistry
MECIDS	Middle East Consortium on Infectious Disease Surveillance
OECD	Organization for Economic Co-operation and Development
OPCW	Organization for the Prohibition of Chemical Weapons
RS	Royal Society
UN	United Nations
UNESCO	United Nations Educational, Scientific, and Cultural Organization
WHA	World Health Assembly
WHO	World Health Organization

Appendix C: Upcoming Meetings Scheduled by Organizations Represented at the Roundtable

Upcoming Conferences, Congresses, Forums, and Workshops

The following were mentioned at this Roundtable and are scheduled during the next 12 months:

- November 12-14, 2007 – Biosafety and Biosecurity International 2007: A Seminar for the Life Sciences and Policy Communities in the Gulf, Middle East, and North Africa; Abu Dhabi; www.biosafetyandbiosecurity-2007.org (Dr. Taylor)
 - November 2007 – Workshop on laboratory biosafety and biosecurity, Ouagadougou, Burkina Faso, (WHO, Dr. Cosivi)
 - December 2007 – Workshop on Research Policy and Management of Risks in Life Science Research for Global Health Security, Bangkok, Thailand (WHO, Dr. Cosivi)
 - January 2008 World Health Organization Executive Board
 - March 30 – April 2, 2008 – 2nd International Forum on Biosecurity, Budapest, Hungary; IAP, IAMP, IUMS, IUBS, and IUBMB the co-conveners. (Dr. Husbands)
 - April 2008 – CWC second review conference (Dr. Malin)
 - May 2008 – World Health Assembly, annual meeting (Dr. Cosivi)
 - August 2008 – IUMS next scientific conference will take place in Istanbul, Turkey (Dr. Sordelli)
 - August 2008 – BWC Intersessional Meeting of Experts
 - 2008 – 33rd FEBS Congress/11th IUBMB Conference, Athens (Dr. Masters)
 - 2008 – International Biosecurity workshop in Beijing (CAS, Dr. Huang)
 - 2009 – 21st IUBMB Congress, Shanghai (Dr. Masters)
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