CONTROLLING DANGEROUS PATHOGENS PROJECT

Regional Workshop on Dual-Use Research

Teresopolis, Brazil

December 8-10, 2006

Meeting Report by Elisa D. Harris[1]

The Controlling Dangerous Pathogens Project of the Center for International and Security Studies at Maryland (CISSM) held its second Regional Workshop on Dual-Use Research in Teresopolis, Brazil from December 8-10, 2006. As with CISSM's previous regional workshop, the meeting in Brazil had two primary purposes: to help raise awareness among key stakeholders about the dual-use issue; and to obtain feedback on the governance proposal that we have developed for managing the most consequential areas of dual-use research.

Nearly two dozen scientists, academic researchers, government science ministry officials, security experts, and industry representatives participated in the workshop, from 8 Latin American and Caribbean countries. The keynote address was given by Dr. Joxel Garcia, Senior Vice President and Senior Medical Advisor at Maximus, Inc, and former Deputy Director of the Pan American Health Organization. Dr. Roque Monteleone-Neto of the UN 1540 Committee and Ms. Ana Tapajos of the Brazilian Ministry of Health kicked off the discussion with presentations on the basic problem of dual-use research and the challenges associated with defining the most consequential areas of such research. Dr. John Steinbruner of CISSM then provided a presentation on recent developments in the United States on the dual-use issue, with particular emphasis on the Fink Committee report, the National Science Advisory Board for Biosecurity, and the work of the Controlling Dangerous Pathogens Project. This was followed by presentations on developments in Latin America and internationally related to dual-use research by Dr. Mario Soberon of the Universidad Nacional Autonoma de Mexico and Dr. Carlos Mendoza of the Peruvian National Institute of Health. Ms. Maria Espona of the National Defence School of Argentina then provided a presentation on the efforts of various international scientific and health organizations to help mitigate the risks from dual-use research. Finally, Prof. Roberto Fernandez of the Instituto Pedro Kouri of Cuba and Dr. Walter Mendoza, a UN Population Fund consultant from Peru considered various aspects of the dual-use issue as it relates to Latin America and the Caribbean specifically, including whether there are different perceptions of the threat from dual-use research both within Latin America and between Latin America and the United States, whether existing oversight arrangements in Latin American countries are adequate, and whether there are legal and cultural differences that would have to be addressed as part of any effort to strengthen research oversight within Latin America.

[1] This report is intended as a summary of the workshop discussion and not a consensus document reflecting the views of the workshop as a whole.

There was general agreement among workshop participants that policies aimed at reducing the risk from dual-use research must apply not only to academic institutions but also to government and industry laboratories, where consequential research also is being carried out. Strong arguments were made for ethical codes for scientists, guidelines for carrying out dual-use research, formal research oversight requirements, and education and training programs to help address dual-use concerns, building on existing biosafety requirements. The importance of regional and international harmonization of dual-use policies was also emphasized, both to ensure a level playing field between countries and to achieve maximum effectiveness. Particular attention was also given to the issue of capacity building both to help developing countries implement biosecurity and biosafety rules and to strengthen their public health infrastructure.

Specific Issues

Definitional Issues: Workshop participants pointed out that the term dual-use generally refers to items or activities that could have both beneficial and harmful effects. There is less agreement on what constitutes dual-use research, at least in terms of the types of activities that are of greatest potential consequence. This is reflected in the Fink Committee's "experiments of concern," the National Science Advisory Board for Biosecurity's "criteria for identifying dual-use research and results," and the tiered research oversight categories developed by CISSM's Controlling Dangerous Pathogens Project. An agreed definition is needed to guide policy development. This will be influenced by a variety of factors, including the policy objective (e.g., preventing inadvertence or deliberate malfeasance) and target of concern (e.g., individual scientists or state or non-state actors). It will need to avoid being so narrow that it neglects consequential areas or so broad that it is unworkable. And it will need to emerge from a process that involves all the relevant stakeholders internationally.

Threat Perceptions: Workshop participants pointed out that there are different perceptions of the threat from dual-use research both within the scientific community as a whole and between US scientists and scientists in Latin America and other parts of the developing world. Many scientists are not even aware of the potential for destructive consequences from their work. Even among those scientists who are sensitive to the dual-use issue, there are different perceptions of the risk. US concerns about dual-use research are not broadly shared in Latin America, where infectious agents are endemic and the diseases caused by them are serious public health problems. Nevertheless, decisions taken in the US on the dual-use issue are likely to have a spillover effect because of the close links between US and Latin American research institutions and could jeopardize research that is pertinent in the latter countries. Participants agreed that research oversight and other measures to address concerns about the misuse of life sciences research should be pursued in conjunction with efforts to promote beneficial applications of such work.

State vs. Non-state Threats: Participants noted that a distinction must be made between the threat from non-state activities and from state-level activities, both defensive and offensive. Non-state actors are unlikely to use advances in technology to develop more

dangerous pathogens, focusing instead on known pathogens for which standard public health practices such as surveillance and response are possible if not yet fully developed. The same is not true for national programs. Threat assessment research involving advanced pathogens, although intended for legitimate defensive purposes, risks stimulating corresponding work in other countries, leading to the development of pathogens for which no public health response is available. State level research on and development of advanced pathogens for offensive purposes is a different problem that needs to be addressed through compliance mechanism under the 1972 Biological and Toxin Weapons Convention.

Nuclear vs. Biotechnology: Participants pointed out that there are important similarities as well as differences between nuclear technology and biotechnology. Both clearly have the potential for causing mass destruction, unlike any other existing technology. But society has come to accept the legitimacy of using nuclear technology for military purposes. This is not the case for biotechnology. No country asserts a right to use biotechnology to develop or produce biological weapons. The norm against destructive applications of biology is in fact well established, and is reflected in the prohibitions of the BWC. In addition, the economic implications of biotechnology are much more significant than nuclear. Biotechnology is growing at a phenomenal rate, thus increasing both its importance and the challenges associated with preventing its misuse.

Dual-Use Implications: Participants noted that the dual-use issue has implications for individual scientists, the scientific enterprise, and society itself. Concerns about over-regulation could discourage scientists from engaging in consequential areas of research or lead to the destruction of rare or dangerous pathogens in culture collections, thus affecting progress in specific areas of research. Over regulation could also interfere with the freedom to inquire and to be creative, which are the essence of the scientific process. At the same time, exaggerated assessments of the biological weapons threat could lead not only to unnecessary expenditures on biodefense or bioterrorism research but also the diversion of funds from traditional areas of public health. Ultimately, the public needs to be reassured that effective policies for managing risk are in place if it is to support funding for life science research. One way of thinking about this is as a social contract, whereby scientists agree to adhere to certain rules concerning the conduct of consequential research in return for society's support for such work.

Biosafety vs. Biosecurity: A number of participants noted that biosafety and biosecurity are not separate issues, but are in fact closely linked. In some languages such as Spanish, the same word is used in both cases (*bioseguridad*). Both biosafety and biosecurity are designed to help individual scientists pursue their research interests with minimal risk. Both demonstrate to the public and policymakers that good laboratory practices are being followed. Both are most effective when they are broadly adhered to by researchers in as many countries as possible. And both require scientists to think and conduct their work in a fundamentally different way, as part of what one participant called a "culture of safety."

The Media: Participants noted the impact of the media on the issue of dual-use research. Misinformation about or exaggeration of the risk from particular research projects can fuel public concern. But the media can also play a constructive role, helping to educate the public about the importance of advanced research in addressing the health and other needs of society. Promoting the dissemination of accurate and timely information about dual-use research is a challenge for both developed and developing countries.

Policy Responses: Participants discussed a range of measures to address the dual-use issue, and agreed that no single measures will be sufficient on its own. These measures include ethical codes for scientists, guidelines for carrying out dual-use research, formal research oversight requirements, and education and training programs. Among the questions that were discussed were: Can non-binding measures such as ethical codes and guidelines reduce the risk from dual-use research? Is it possible to implement binding research oversight requirements without interfering with the scientific process? Are enforcement provisions necessary to ensure compliance with dual-use requirements? At what point should dual-use risks be addressed – at the research funding stage or later? Who should make the decisions on dual-use risks, and how can the public interest be represented? When should academic courses on the social implications of science be required – at the undergraduate or graduate level?

Voluntary vs. mandatory measures: Workshop participants discussed the value of both voluntary and mandatory measures in responding to the dual-use problem. Some participants were optimistic that voluntary measures like ethical codes, research guidelines, and education and training programs would be sufficient to address the risks from dual-use research. Others were skeptical that scientists would conduct themselves differently in the lab unless they were legally obligated to do so. Recent reports in the US of the failure of many research institutions to comply with the NIH guidelines underscored these concerns.

Transparency: Participants emphasized that the ability to replicate and build upon the research efforts of others is critical to the scientific process. This requires openness rather than secrecy in research. The issue of openness is viewed differently, however, in both industry and military programs, where secrecy often is the norm to protect proprietary business or national security information. This poses a challenge for efforts to develop and implement any oversight system that includes international regulation.

Priorities for Developing Countries: It was noted that the growth in the world population, especially in developing countries, is posing new challenges in terms of ensuring access to food and clean water, managing disease, and preventing the sort of radicalization that leads to terrorism and other forms of violence. Advances in biotechnology clearly can both help address these fundamental problems and provide new opportunities for causing harm. Several participants argued that developing countries are more dependent than developed countries on scientific knowledge and technology to help solve problems affecting the poor, and are therefore likely to put more weight on the benefits rather than the risks of dual-use research. Others doubted that developing countries are so dependent on access to cutting edge technology

There was, however, broad agreement among participants that developing countries are in an asymmetrical position vis a vis developed countries with respect to the dual-use issue. Developing countries both enjoy fewer of the benefits of consequential research and face greater risk because of their more limited disease surveillance and response capabilities. Over-regulation of research in developed countries could lead to even greater risk for developing countries if dangerous research is carried out there instead, without adequate oversight mechanisms in place. Over-reaction to the dual-use issue in developed countries also could be used to justify trade restrictions or other policies that could hamper scientific progress in developing countries. How to narrow the gap between developed and developing countries on both benefits and risks is a crucial issue.

The Relevance of Existing Biosafety Requirements: Participants pointed out that there already are rules in many countries for prior review of recombinant DNA and other types of research. These rules must be adhered to in order to receive government funding for proposed research projects. Other regulations exist to prevent the spread of disease between countries. Under the Cartagena Protocol, for example, living modified organisms resulting from modern biotechnology may not be exported to another country without that country's advance informed consent. One hundred and thirty eight countries are currently party to the Cartagena Protocol, including 24 in Latin America and the Caribbean.

In Brazil, adherence to the Cartagena Protocol led to the adoption of a new biosafety law in 1995. Under this law, all research and handling of genetically modified organisms (GMOs) must be reported to and approved by either a local institutional review committee or national biosafety committee, depending upon the degree of risk involved. All labs and personnel conducting GMO work must also be certified by the national biosafety committee. At the outset, technical visits were carried out at institutions to train researchers to meet these new biosafety requirements. After more than 10 years, Brazil's biosafety committee is now reaching out to African countries to share their biosafety experience.

Similar legislation requiring prior review and approval of GMO research has been enacted in Mexico and other Latin American countries. In Cuba, new biosafety laws and regulations also have been adopted, including licensing requirements for the import or export of certain biological agents, for the construction of new biological research facilities and for research on new biological agents. These experiences demonstrate that carefully crafted regulations have an important role to play in reducing risk and promoting ethics in science. They also provide a foundation on which measures to address the dual-use issue can be built.

Capacity Building: Participants emphasized that new rules and regulations aimed at addressing the dual-use issue will not be effective unless institutional arrangements are put in place at the local and national level to support implementation. Both technical and financial assistance will be required to build the capacity for overseeing dual-use research and sharing experiences. This is especially the case for developing countries, which lack the resources to implement biosecurity measures on their own. A parallel capacity

building effort also should be undertaken in developing countries to enhance disease surveillance, laboratory research and analysis, and response capabilities. Capacity building in these areas is important both for strengthening public health and for responding to disease outbreaks that may result from dual-use research. The increasing cooperation among certain Andean countries on epidemiological surveillance, while far from complete, was discussed as an example of this type of regional capacity building.

Incremental Steps: Participants noted that this is a good time to address the dual-use issue in Latin America, given the biosafety training courses now being initiated in the region by the United Nations Industrial Development Agency in support of the Cartagena Protocol. Some focused on measures for addressing the dual-use issue, arguing for a "step-wise approach" in which dual-use requirements evolve in parallel with the capacity for implementation. Under this approach, research guidelines would be developed first, followed later by legally-binding arrangements. Others emphasized targets of concern, arguing for priority attention to threat assessment and other biodefense research, followed by consequential research in other types of labs.

Harmonization: Participants agreed on the importance of both regional and international harmonization of policies for reducing the risks from dual-use research, as is happening in other areas of biology. Both the WHO's work developing laboratory biosafety guidelines and the OECD's standards for biological resource centers were cited as examples of important international harmonization efforts. The Global Health Security Action Working Group is also working to harmonize laboratory biosafety and biosecurity standards across member states. Broad adherence to agreed standards and rules is essential given the global scope of life sciences research. It is also sensible from an economic perspective, as it helps level the playing field for, and perhaps even gives a competitive advantage to, those who adhere to internationally agreed rules.

Ownership: Participants agreed that the dual-use issue is a multi-disciplinary problem that can only be addressed in a multi-disciplinary fashion. Scientists cannot address the issue on their own, either individually or collectively, given the need to assess security risks. Policymakers likewise lack the knowledge to develop effective responses without input from the scientific community. Public health agencies such as WHO and PAHO also have a critical role to play if common standards and greater harmonization between countries are to be achieved. FAO and OIE must also be part of the process, given the need to include research with plant and animal pathogens in any oversight arrangement.

The Risk of Inaction: Participants noted the importance of being proactive on the dual-use issue, before a consequential event occurs and possible restrictions on the conduct of science are imposed. The handling of transgenic corn in Mexico was discussed as an example both of how public concern can lead to adverse consequences for science and of how scientists and policymakers working together can devise effective policies for managing risk and restoring public confidence. In this case, following an initial ban on transgenic corn, a new law regulating research on GMOs was drafted by the Mexican government in consultation with recognized biotechnology research scientists. The law requires case by case review, risk assessment, monitoring, research support, and penalties

for noncompliance. This is one model for how research oversight could be pursued in the dual-use area.