Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science
Volume 7, Number 1, 2009 © Mary Ann Liebert, Inc.
DOI: 10.1089/bsp.2009.1018

MEETING REPORT

SUSTAINING PROGRESS IN THE LIFE SCIENCES: STRATEGIES FOR MANAGING DUAL USE RESEARCH OF CONCERN—PROGRESS AT THE NATIONAL LEVEL

ON NOVEMBER 5-6, 2008, A MEETING was held in Bethesda, Maryland, hosted by the National Science Advisory Board for Biosecurity and co-sponsored by the World Health Organization and the U.S. government, titled "Sustaining Progress in the Life Sciences: Strategies for Managing Dual Use Research of Concern." Participants came from more than 35 countries, and many spoke on the activities in their countries aimed at addressing the issue of dual-use research of concern (DURC). Here we present edited transcripts of the reports from 10 countries.

AUSTRALIA

Seumas Miller

I will speak briefly about what is happening in Australia in relation to dual-use issues. Probably the major development in Australia is a piece of legislation called the National Health Security Act of 2007, which has established a national authority, namely, the Australian government's Department of Health and Aging to administer the Security Sensitive Biological Agents Regulatory Scheme [www.health.gov.au/ssba]. Previous regulatory schemes focused essentially on biosafety. This takes matters into the area of security, and specifically the concern is with countering bioterrorism through pathogen security.

The regulatory scheme was introduced in January 2009, and it comprises various elements—for example, a list of the security-sensitive, highly pathogenic biological agents. There's a national register of entities (comprising their facilities, which are mainly laboratories). There are also provisions in relation to the security status of those who would be involved in the handling and transportation of such agents, and there's a raft of regulations concerning the storage, handling, and transport of those agents. There is provision for inspection and monitoring processes, and also there are penalties in relation to noncompliance, including criminal sanctions. There is also a provision for an education and awareness-raising campaign in relation to the regulatory scheme. In a sense, it is analogous to the select agents rule in the U.S.

Obviously, this new legislation constitutes only a partial response to the dual-use issue. There are dual-use issues outside the scheme, such as whether or not to allow certain research proposals to go forward; issues to do with publication and dissemination are not covered; and there are the issues arising out of the new synthetic genomics. They are not covered because that list of agents is essentially in relation to existing biological agents rather than new genetic constructs.

That is basically where we are with the dual-use response in terms of the Australian government. They are considering various new policies and reflecting on what they need to do. They are well aware they need to do more. They commissioned a report, *Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences*, which was published in December 2007 in the journal *Science and Engineering Ethics* (and now it has been published as a book by Springer); it is a report written by myself in conjunction with some scientists and security people.

There is other academic activity ongoing. Particularly worthy of note is the establishment of a new center for biosecurity, which is a joint venture of the Australian National University and Sydney University. The activities of that organization include research and education in relation

Seumas Miller, PhD, is a Professor at the Center for Applied Philosophy and Public Ethics, Charles Sturt University and the Australian National University, Canberra, Australia.

to all matters to do with biosecurity, including but obviously not restricted to dual-use issues. And there are various other activities connected with centers that are connected with that center—like my own center, the Centre for Applied Philosophy and Public Ethics. So there is quite a lot of activity amongst academics and between academics and industry, and between academics and government in Australia in relation to these issues.

BRAZIL

Leila Macedo Oda

The Brazilian Biosafety Association—ANBio—is a nonprofit scientific society with the aim of supporting biosafety awareness and capacities in Brazil. It was founded in 1999 and since that time has developed a capacity-building program on biosafety and more recently on biosecurity in all regions of the country. ANBio has established a network with research institutes, public health laboratories, agriculture laboratories, and stakeholders in Brazil in health, agriculture, environment, science and technology, and education, as well as with the private sector and the national biosafety committees in all Latin American countries.

In 2000 Brazil launched a program to include biosafety as a discipline in post-graduate courses with the scientific support of ANBio, and recently Brazil has started a national program called Sensible Goods, which gives support to institutions to fulfill the requirements of the BWC.

In 2007 ANBio launched its biosecurity program within the biosafety framework. This program has the support of the Biosecurity Engagement Program from the U.S. Department of State and has so far trained about 250 researchers working with biological organisms. The training sessions were open to participants from other Latin American countries, and individuals from 6 countries have taken part.

In regulatory affairs, ANBio has advised the stakeholders in Brazil in establishing biosafety regulations and, more recently, on biosecurity measures that are being put in place. Since 1995 Brazil has had a biosafety law that establishes procedures and mechanisms of control for DNA technology. However, there is no formal mechanism to control the safe use of other biological materials or to control dual-use research in academia, but this subject is under discussion now among government stakeholders. In addition, the Ministry of Health has established a national program for enhancing the capacities of public health laboratories.

Brazil currently has 12 BSL-3 labs for the health sector and 7 BSL-3 enhanced labs for the agricultural sector. A new facility to handle BSL-4 organisms has been proposed.

Brazil has to deal with many different realities. On one hand, we have top research in the field of DNA technology; on the other hand, we have many health problems that we should face, such as dengue, which now is increasing in Brazil, and other challenges for public health and agriculture.

Biosafety is not a new issue in Brazil. We have been developing some capacity and strengthening the laboratories in Brazil in all aspects of biosafety. We comply with the WHO biosafety guidelines, and we have had support from CDC for many years for training people in Brazil. But *biosecurity* is a new issue in Brazil. We have begun training on biosecurity, starting last year with BSL-3 and some BSL-2 labs and the scientists and workers who are working in those labs. We also made the training available to some people on the biodefense side and some in the Ministry of Agriculture, Health and Science Technology. Since last year we have organized 3 courses, one a national course and the others with a local approach.

The main challenges remaining are enhancing awareness within the scientific community; capacity building on biosecurity; and personal reliability programs. What is on the horizon? Recently, there has been the possibility of a new framework under discussion to be implemented for biosafety and biosecurity measures in those labs that are dealing with select agents.

GEORGIA

George Chakhava

I represent the Georgian Association of Medical Specialists and also the Tbilisi State Medical University. I will present an overview of existing regulations on biosafety and biosecurity in Georgia.

In the past, Georgia, as a part of the Soviet Union, shared all of the Soviet legislation, including regulations on biosafety. But not all biosafety legislation has been adapted to new situations. Progress on market reforms and democratization has been made in the years since Georgia became independent, but this progress has been complicated recently by the Russian occupation of 2 breakaway regions of Georgia: Abkhazia and South Ossetia. These 2 territories remain outside the control of the central government and are ruled by unrecognized de facto governments.

Our current regulations are based on the main issues that are well-known in the world:

- *Laboratory Biosafety Manual,* World Health Organization [WHO/CDS/CSR/LYO/2003.4]

Leila Macedo Oda, PhD, is President of the Brazilian Biosafety Association in Rio de Janeiro, Brazil.

George Chakhava, MD, PhD, is head of the Strategic Development Center, Tbilisi State Medical University, Tbilisi, Georgia.

- *Biosafety in Microbiological & Biomedical Laboratories* [U.S. CDC,4th ed, May 1999]
- U.S. *Federal Register* [Vol 240, No 67, Rules and Regulations, Part IV, DHHS 42 part 73]
- *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens*, WHO [WHO/EMC/97.3]

The regulations comply with the law of Georgia on Health Care [10.12.1997]; the law of Georgia on Export Control of Armament, Military Techniques and Products of Bilateral Purpose [28.04.1998]; and the law of Georgia, Georgian Sanitary Code [08.05.2003].

The package of lab biosafety and biosecurity legislation consists of 4 documents:

- Select Agents Rule
- Rules of Import, Export, Containment, Transfer and Handling of Cultures of Infectious Diseases' Causative Agents, Protozoa, Mycoplasma and Genetic Materials, also Toxins and Poisons of Biological Origin
- Sanitary Norms for Labs Working with Especially Dangerous Pathogens
- Guidelines for Safe Transportation of Infectious Substances and Diagnostic Materials

The need for new Georgian regulations on biosafety and biosecurity is evident. The main institutions working on these problems in Georgia are (1) the National Center for Disease Control and Medical Statistics of Georgia (NCDC Georgia) of the Ministry of Labor, Health and Social Affairs of Georgia, which carries out surveillance on especially dangerous infections; (2) Biokombinat in Tabakhmela, which produces live vaccines for cattle for anthrax, foot-and-mouth disease, etc; and (3) the Eliava Institute of Bacteriophage, which manufactures vaccines for rabies, anthrax, etc. The new legislation will be agreed upon by all of the agencies involved, including the Central Sanitary Inspection of the Ministry of Labor, Health and Social Affairs of Georgia.

The Center for Strategic Development and Research in Medical Education has established some priorities: ethics in science, risk assessments, openness and transparency, and education and awareness raising. Three types of ethics committees exist currently in Georgia: the National Council on Bioethics and also research and clinical (medical) ethics committees.

The Swiss Nobel laureate Richard Ernst said that it is insufficient to simply train specialists in science and technology; ethics and social responsibilities must be considered as important as scientific skills, knowledge, and understanding or there is "a loss of the accepted ethical foundations of research." The context of science is changing: we now need to take into account hostile and dual use, political pressures, economic pressures, pressures to publish, and scientific misconduct.

To what extent are researchers free to choose their subject of research? Are universities obliged to create opportunities for research that is not prima facie relevant to society or industry? If universities are obliged to do so, to what extent? What is the balance between basic research and revenue-generating interests?

What do we need? A higher level of information to be in control, a code of conduct, and also competition or cooperation, or both.

At the Tbilisi State Medical University, our priorities at the international level are the European Research Area, the Bologna Architectural Study for Medical Education, and the EU Code of Conduct for Recruitment.

We hold some international conferences—for example, "The Technical Enablers and Challenges of Biological Terrorism" was a conference held last December. We have also written or contributed to some recent publications. And we have participated in WHO online consultation on life sciences research and development and global health security.

In the future, planned activities include international consultations on dual-use life sciences research; an analysis of existing codes of conduct; and a critical comparative analysis of strengths and weaknesses of policy on dual-use life sciences research.

We also plan to hold an international conference to take into account identified needs and priorities in the regional level in a coordinated manner and to promote the role of ethics in the formulation and evaluation of development strategies and programs. This conference will be one of the steps in the process of identifying needs and priorities, identifying a network of partners and interacting with them, and learning from progress to date.

Further, we plan to establish an advisory committee on the duality of life sciences research and international concerns at the Tbilisi State Medical University—a very important step.

We believe that the process of working together internationally across the spectrum of biological challenges will both reduce the impact of already existing naturally occurring disease threats and also reduce the likelihood of intentional misuse of life sciences research. Among the possible solutions that we are pursuing are advanced medical education, a code of conduct, and raising awareness.

INDIA

C. Kameswara Rao

During the past year or so, there have been many significant new policy initiatives in India in the areas of health re-

C. Kameswara Rao, PhD, DSc, is a Professor at the Foundation for Biotechnology Awareness and Education, Bangalore, India.

search and biosecurity regulation of genetically engineered organisms and their products, which have a bearing on dual-use research of concern (DURC).

Research in life sciences related to health is carried out primarily under the aegis of the Indian Council of Medical Research of the Department of Health, Ministry of Health and Family Welfare. There are 22 National Research Institutes and 6 Regional Medical Research Centers under the council, and a large number of central or state universities, autonomous research institutions, medical colleges, and other academic institutions involved in advanced medical research.

The Indian pharmaceutical industry has an export component of about 58%. Its revenue in 2007-08 was US$1.75 billion, a 70% share of total biotech industry revenue. About 47% of pharmaceutical revenues come from vaccines. Of the top 20 companies in Asia-Pacific, 14 are Indian.

rDNA technology is being widely deployed both in the agricultural and pharmaceutical sectors. The actual component of modern biotechnology-derived biopharmaceuticals is small, as the bulk of them are being produced through conventional technologies, but by jumping on the bandwagon of biotechnology. Vaccines are the major component of the Indian pharma industry, and since vaccines are administered to healthy people to prevent them from contracting a disease, their dual-use potential is minimal.

The focus of the national health policy is the development of drugs, vaccines, and diagnostics relevant particularly to HIV, TB, malaria, and emerging and re-emerging infections, through modern biotechnology. This continues to be the major activity of both the public and private sector R&D, but there is an accelerated interest in therapeutics based in stem cells and nanotechnology.

The strategies and programs of health research are designed to develop into a National Health Research System, managed by a National Health Research Management Forum. To facilitate this, the government recently released several policy documents with bearing on biomedical research: a national health research policy, guidelines for stem cell research and therapy, and ethical guidelines for biomedical research.

India's biosecurity regulatory regime for genetically engineered products is among the most stringent in the world, operating through the coordinated activities of the Recombinant DNA Advisory Committee (RDAC), the Institutional Biosafety Committees (IBCs), the Review Committee on Genetic Manipulation, and the Genetic Engineering Approval Committee. The RDAC reviews national and international developments in biotechnology to advise the government on policy imperatives.

Every organization involved in research in any area of modern biotechnology functions under the supervision of an IBC specifically constituted for an area of research in that institution. IBCs are the first and most critical phase in designing, evaluating, and monitoring a biosecurity regime. IBCs are the stage for recognition of DURC and to regulate the intent, content, and direction of research.

Based on several decades of experience in implementing a biosecurity regulatory regime, the representations from different stakeholders, and the criticism faced by the present regulatory regime, the Indian government has initiated several policy changes rooted in the new National Biotechnology Development Strategy (2007). The most significant change is the establishment of the National Biotechnology Regulatory Authority.

In India, the awareness of the term and importance of DURC is low even in scientific circles, as reflected by its absence in any official or scientific documents. The terms *bioterrorism* and *biowarfare* are used occasionally but in broad general terms. The recent biological disaster management guidelines will in the course of time enhance the level of awareness but only in conventional contexts.

The identification and monitoring of DURC presently depends on the level of awareness in the IBCs, which is patchy. There is no concern or mechanism now in place for funding agencies to identify projects with DURC implications or for the journal editorial system to identify them at the stage of peer review. These gaps need to be addressed, keeping in mind the international consensus that there should be no restrictions on the kind of research one undertakes or on international communication of advances in science, but intent on only the identification of the risk and means of mitigating it.

MOROCCO

Khalid R. Temsamani

I am going to talk about the ongoing activities on biosafety and biosecurity in Morocco. We have had a national debate in Morocco about what should be the high-priority areas of scientific research. From this debate emerged the 2025 strategy, the National Reform of Public Scientific Research. In terms of scientific research at the university level, this reform allows us to create some centers for doctoral studies. We associated with that a thesis charter; article 17 of this charter talks about science, ethics, and codes of ethics. Most

Khalid R. Temsamani, PhD, is National Coordinator, Materials Science; Representative of Morocco to the NSF; and Advisor to the Ministry on Biosafety and Biosecurity and Science Ethics, Moroccan Ministry of Education, Training, Higher Education and Scientific Research, Rabat, Morocco.

of the public funding at the university comes from the government: around 95% of the budget comes from the state and the rest comes from either international cooperation or partnerships with the private sector.

To be eligible for funding, there is a peer review process of the research project, and the researcher must work inside the framework of the priority areas for the country. These are environment, health, competitive entrepreneurship and industry, water management, land preparation and management, cultural heritage, information technology, and agriculture. Thus, there is already screening at that level. Also, in order to perform research, you need to have an accredited lab. Accreditation takes place first at the university level and then at the ministry level.

In general, in Morocco 73% of the funding that goes to either the private sector or the public sector for research comes from the government (private sector: 22%, public/public partnership: 1%, public/private partnership: 1%). International cooperation is around 3%, and for that we need to abide by the criteria of the organization with which we interact—for example, the European Union—in terms of the program framework research.

We have some debate taking place at the university level, not about dual-use research of concern, but more about biosafety and infrastructure. In the medical field, at the medical school, we have some national bioethics committees. This is well organized. And we have science commissions in every school of science that will screen the research project and the research results; sometimes this is a determining step for having approval for funding. But assessment is not based on dual-use research of concern, so this is something that we have to do something about.

In a study conducted recently by our Ministry of Higher Education and Scientific Research, we had to revise the percentage that goes from our GDP to scientific research, and it is only 0.64%. This is not a lot of money that goes for research, and because of that the biotechnology activity that is taking place is very poor. Only a few research teams work on biotechnology activity, and this activity is more or less classical biotechnology. We have almost no modern biotechnology activity at the moment. It may come in the next few years, but for the moment there is no activity.

In terms of high-containment labs, all the work done on dangerous pathogens is done under government control. We have 3 different BSL-3 labs for human health and 1 lab for animal health. Last summer during a sheep plague outbreak, this lab for animal health made a vaccine by themselves in 2 months, and now they are vaccinating sheep all around Morocco. They are doing a very good job. Unfortunately, at the university level there is no classification in terms of labs. This is work that will need to be done, but we do not have Level 3 labs at the university.

Within a few weeks we will have an inter-ministerial committee that will meet to draw the roadmap for the national priorities in terms of scientific research for the next year or so. Two items are on the agenda: (1) the creation of a National Commission for Science Ethics and (2) the National Commission for Biosafety and Biosecurity. The projects will include a code of science ethics and a code of conduct for researchers.

We have many different cooperative activities with the United States and other parts of the world, and we have been involved in a study conducted by the National Academies of Science on assessing Morocco's capability to control potential biological threats and the Moroccan perspective on the potential for unintentional or intentional release of pathogens, highlighting the progress Morocco has made in this field. The report will be released in early 2009 by NAS, and it will be an important tool for us to use in improving our system.

There are many other activities in which we have been involved—for example, a joint U.S.-Morocco workshop on biosecurity in Rabat. On April 2-3, 2009, we will host BBIC-09, Biosafety and Biosecurity International Conference in Casablanca. We are also partnering with the International Council for the Life Sciences, the Jordanian Royal Society, and the Emirate Environmental Agency for that. The key elements of the strategy drafted for this conference are capacity and capability building, governance, scientific responsibility, and ethics-based codes. Those are some elements that we will discuss, and we hope that this will contribute to progress in our region in terms of dual-use research and biosafety and biosecurity.

Some perspectives for international cooperation: We still need to have implementation of the concept of DURC at our university level, and we hope that through international cooperation we can achieve this. There is still a great need for inclusion of biosafety and biosecurity curricula at the university, and Morocco, of course, is ready to play an active role at the regional level in implementing a center for biosafety and biosecurity education and creating a regional biosafety association.

Also, it is desirable for us to set up international standards in the field of DURC that take into account freedom of mobility for scientists and for materiel; scientists in Morocco are struggling with the difficulties in acquiring strains to perform their research because of the international health regulations. For example, they sometimes cannot put in place or develop new diagnostic tools because of an inability to acquire strains. This is something that is very serious for countries like mine. And, finally, Morocco will continue to share and learn from best practices of other advanced countries.

NORWAY

Filippa Lentzos

There are no BSL-4 facilities in Norway, and there is one BSL-3 facility, which forms part of the national biological defense R&D program. This facility is located at the Institute of Microbiology, Armed Forces Medical Services in Oslo. It focuses on both human and veterinary microbiology and is wholly funded by the Ministry of Defense. All work on human and animal diseases related to defense activities is published in open, international journals. There are other BSL-3 facilities at the Norwegian Institute of Public Health, the National Veterinary Institute, and the Ullevål hospital.

There have been no major lab accidents or shipment/transportation incidents involving biological agents in recent years, nor have there been outbreaks of unusual diseases caused by select agents.

Norway has legislation relating to the development, production, stockpiling, acquisition, or retention of biological agents, toxins, weapons, equipment, and means of delivery as specified in the BWC, as well as legislation relating to the export and import of biological agents. Research on human pathogens is regulated under the Working Environment Act and its Regulation on Protection against Biological Agents, implemented by the Norwegian Labour Inspection Authority.

The genetic modification of organisms is regulated through a separate act, the Gene Technology Act. The competent authority for deliberate releases is the Ministry of the Environment (and the Directorate for Nature Management), and the competent authority for approval for contained use is the Ministry of Health and Social Affairs (and the National Institute of Public Health). The purpose of the act is "to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment." Thus, in addition to incorporating considerations of health and the environment, the act also requires an emphasis on ethical and social concerns, making it more restrictive than comparable legislation in other European countries.

The act also establishes the Norwegian Biotechnology Advisory Board. The Board organized a meeting on bioterror and biological weapons together with the Norwegian Red Cross and the Norwegian Zoonosis Center. (More info about the Board is available at www.bion.no.)

Norway and Det Norske Veritas contributed to the development of the Laboratory Biorisk Management Standard (CWA 15793), released by the European Committee for Standardization in 2008.

Filippa Lentzos, PhD, is Senior Research Fellow at the BIOS Centre, London School of Economics, London, England.

PAKISTAN

Anwar Nasim

I work as an advisor of science with the OIC committee, so my interest is not only in Pakistan but in all the 57 Islamic countries for which I am supposed to give advice about science. I also chair the National Commission on Biotechnology.

Pakistan has been very active in the area of biotechnology, particularly in the areas of agriculture and health. We have an infrastructure in place. There is a National Commission on Biotechnology. The Higher Education Commission set up a national core group on life sciences, and there we worked very closely with the International Council for the Life Sciences and with Dr. Terry Taylor. For the past 2 or 3 years, there have been a number of activities in this area. We have held a number of workshops on biosafety for training, and I think we will continue to do that.

There will be a meeting on biosafety and biosecurity in Karachi, where we have a very strong Center of Bioethics. We have invited a number of colleagues, but travel restrictions make it difficult for some to attend; therefore, I feel that there's a need for this forum and other organizations to look at alternative mechanisms such as video conferencing or access through electronic mail so that these activities can continue in spite of the difficulties that we face.

The government for the last 4 or 5 years has placed a very high priority on science and technology, in general, and on biotechnology in particular.

Anwar Nasim, PhD, is Science Advisor for COMSTECH in Islamabad, Pakistan.

PHILIPPINES

Irma Reyes Makalino

I would like to share what is happening in my country with respect to biosafety and biosecurity. Over the past 3 years, we have been collaborating with the U.S. Department of State Biological Engagement Program (BEP) to raise awareness with respect to biosafety and biosecurity. Within the University of the Philippines Manila, after the initial meet-

Irma Reyes Makalino, MD, is a Professor at the Manila College of Medicine, University of the Philippines, Manila.

ing with the BEP team, the chancellor created our institutional biosafety committee (IBC). Through this committee and in partnership with the U.S. BEP team, a plan to create an institutionalized program to "train the trainers" in biosafety has been laid out. UP Manila, through a grant from the Department of Science and Technology, through the Director of the Institute for Biotechnology at the National Institutes of Health, is working toward putting up a BSL-3 lab. It is envisioned that this laboratory, while housed inside the UP Manila, may be used by researchers who are using the tools of biotechnology in the process of drug development.

Outside of UP Manila, there have been strong collaborations between the BEP team and certain sectors of the Department of Health, such as the Research Institute of Tropical Medicine (RITM). Meetings have been held with the U.S. BEP team to increase the current capability of the laboratory, which is a BSL-2 lab with BSL-3 practices. The Department of Health through its own initiatives has been drafting a National Policy Guideline for Biosafety. BEP sponsored a symposium on BSL-3 laboratories in Manila in July 2008, where a multi-stakeholder team was called upon. At this meeting, we were able to engage the defense sector as well, because we invited the Philippine National Police; this opened up the possibility of doing some work with them in the area of biodefense. The BEP team has also been working with the Department of Agriculture and particularly with the Bureau of Animal Industry. We have also established the Philippine Biosafety and Biosecurity Association, Inc., with Dr. Edith Tria as president of the organization.

A seminar-workshop on Biosecurity and the Dual Use of Research was held in Manila in October 2008 through the Philippine Biotechnology Association, headed by Professor Nina Gloriani, PhD, who is currently the Dean of the College of Public Health of UP Manila. The meeting was held in partnership with the Department of Science and Technology.

I was invited to participate in a meeting on dual-use research in Budapest in March 2008. I have also been teaching the students in the Master in National Security Administration program of the National Defense College of the Philippines their 3-hour module on bioterrorism over the last 3 years.

POLAND

Andrzej Gorski

I represent the Polish Academy of Sciences, which is the national academy of science for Poland, with 350 elected members, corresponding and foreign members, and almost 100 scientific committees. There are domestic branches in 7 major Polish cities as well as stations abroad in Paris, Vienna, Berlin, Rome, Moscow, and Brussels. We also have almost 80 research institutions. What is important about these institutions is that, according to the most recent government evaluation, 80% of them have been ranked as belonging to category 1, which is the highest ranking—in other words, we believe that we do quality research at those institutions. Those institutions are divided or subdivided into 7 divisions of the Polish Academy of Sciences, which are responsible for sponsoring and management, although the funding comes from the Ministry of Science. We are almost entirely funded by the Polish government. The Polish Academy of Sciences provides independent advice on science issues to the government, to the public, and to the society.

Biosafety and biosecurity issues are very relevant at our institutes, and I can give you an example from the Institute of Immunology and Experimental Therapy (where I was director for 2 terms), located in Wroclaw in Lower Silesia. We used to have a collection of microorganisms and we also had a collection of phages; there are 2 centers in the world that carry on the phage therapy of antibiotic resistant infections, one in Georgia and the other one in Poland. Despite some skepticism, we are getting interesting results in patients, from Poland and abroad. So, we have a weapon against bioterrorism in terms of bacteria. For example, our collection of phages covers more than 80% of staph bacteria, including MRSA.

The awareness and knowledge of dual use in Poland is not very high, and I think this also applies to countries of my region. I mentioned that science in Poland is almost entirely funded by the Polish government and, more specifically, by the Ministry of Science and Higher Education, but this institution until recently was inactive in the field of dual use and possible applications. Thus, our first step was to organize a forum to disseminate knowledge and information on dual use. (We thank the U.S. National Academy of Sciences for their help in organizing this conference.) We had many renowned speakers, and the presentations from this conference are available on the website of the Polish Academy of Sciences.

Another event was my presentation at the forum of national ethics committees of the European Union (Lubliana, Slovenia, February 2008), done with the help of my younger associate lawyers and doctors, on the issue of whether or not the existing code of ethics adequately addresses the issue of dual use. And finally, 2 months ago we had convened our first formal meeting with possible stakeholders, where there was a lively discussion of what to do and the potential directions. The Ministry of Foreign Affairs proposed compiling a list of DURC areas, appointing security officers at each scientific center, and introducing a

Andrzej Gorski, MD, is Vice President of the Polish Academy of Sciences in Warsaw, Poland.

code of conduct related to DURC. But this initiative was not supported by some meeting participants, who stressed that monitoring and restrictions on research are controversial and could be considered unconstitutional. It was concluded that a meeting with representatives of academic and scientific institutions will be organized to discuss these matters.

A lesson learned is that joint efforts and activities are necessary to achieve any progress, at least in this region. Conferences with well-known international authorities as speakers are helpful in attracting public attention and in promoting awareness and understanding that DURC is a real threat to society that requires appropriate attention.

UGANDA

Paul Nampala

I want to share with you what is happening in Uganda, which may be representative of sub-Saharan Africa with the exception of South Africa. There are many concerns in our country about dual-use research of concern, including the issues of agriculture productivity and the increased proximity of modern biotechnology research to populated areas. We are working on issues of genetically modified crops, and this research is now moving from the laboratory to the fields. This is also true with vaccines in the pharmaceutical industry. Our laboratories are not very well developed, and so the biosafety programs at many institutions and universities and in the private sector may be dysfunctional. An increasing number of institutions are handling hazardous work because of the rapid growth of biotechnology laboratories.

In the Great Lakes Region we have a problem of infectious disease threats. In Uganda in 2002, 2005, and 2007, we had outbreaks of Ebola and Marburg, caused by highly pathogenic viruses. They pose a lot of challenges. We are grateful to WHO, which has always come to our rescue, but we probably cannot continue with just external assistance, because we want to support rapid response to outbreaks by accurately characterizing these pathogenic viruses within our national program. So, there are measures that are underway to try and prevent outbreaks, although many times we are just firefighting. We are focused when an outbreak occurs, and we get up in arms to try and deal with it. But we need to concentrate on measures that will help to *prevent* outbreaks of these highly infectious diseases.

There are efforts to increase awareness. The Uganda National Academy has piloted efforts with help from the Sloan Foundation, which helped us in March 2008 initiate a project on promoting biosafety and biosecurity within the life sciences. In July we had a follow-up meeting on planning, managing, and sustaining biocontainment laboratories in Africa; this was with our key partners, the U.S. National Academies under the African Science Academy Development Initiative. Following this meeting, we now have a program that we are implementing supported by the U.S. Department of State, again through our partners the National Academies, and in January 2009 we will be conducting an international meeting on standards and general good laboratory practices for managing safe, secure, and sustainable laboratories from the perspectives of public health and security. For us, the biosafety issues are of more concern than the biosecurity issues.

There also are legal aspects and challenges. There is a serious concern whether the existing legal framework takes consideration of the biosafety and biosecurity issues. We are undertaking activities to analyze the internal legal frameworks to see whether they take into consideration all these issues. This is the case in many African countries: yes, the legal framework exists, but it is not clear whether it is all-encompassing.

We need to examine the current system for biosafety and biosecurity oversight, including the national and institutional biosafety committees. These have been established for Uganda. The code of conduct and ethics research or review committees are also in place, but the capacity to deal with the complex issues in biosecurity are not very clear, and in many situations we need to look again at these issues. We need to identify any gaps with regard to dual-use research of concern, and we also need to develop options and strategies for addressing these gaps. We very much look forward to collaboration with potential partners in these important issues of DURC.

Paul Nampala, PhD, MSc, is Executive Secretary of the Uganda National Academy of Sciences, Makere University, Kampala, Uganda.