

Countering Biological Threats

Challenges for the Department of
Defense's Nonproliferation Program
Beyond the Former Soviet Union

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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Committee on Prevention of Proliferation of Biological Weapons in States
Beyond the Former Soviet Union

Office for Central Europe and Eurasia
Development, Security, and Cooperation
Policy and Global Affairs

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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**COMMITTEE ON PREVENTION OF PROLIFERATION OF
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who offered their time and expertise over the course of the study's development. Appendixes A and B identify many of the individuals and organizations that provided important insights for the committee. Also, we would like to single out the excellent support provided by Shawn Cali, manager of the Biological Threat Reduction Program, who responded on short notice to many requests from the committee for information.

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Weapons in States Beyond the Former Soviet
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Summary

The National Defense Authorization Act of 2008 called for a study by the National Academy of Sciences (NAS) on the prevention of proliferation of biological weapons. The study was to consider several issues concerning U.S. cooperation in this field with developing countries other than states of the former Soviet Union (FSU) within the framework of the Cooperative Threat Reduction (CTR) Program that is administered by the Department of Defense (DOD). Specifically, Congress requested that the study (a) assess the capacity of developing countries to control dual-use technologies, (b) assess cooperative nonproliferation approaches used in the FSU that could be used in other countries, (c) review other international programs that may contribute to nonproliferation, and (d) recommend steps for integrating DOD's nonproliferation activities with other relevant U.S. government programs outside the FSU.¹

DOD has supported biological nonproliferation activities in seven countries of the FSU during the past 12 years at a cost of about \$800 million within the framework of the CTR Program. These activities, referred to as the Biological Threat Reduction Program (BTRP), are scheduled to continue in the FSU for at least 5 years. At present, the largest activity is establishment of the

¹ For the purposes of this summary as well as the full report, *biological weapons* include any biological pathogens and associated toxins that could be deliberately misused to cause significant harm to humans or agricultural resources. *Biosecurity* encompasses all direct and indirect measures that contribute significantly to (a) preventing inappropriate persons from gaining access to materials, equipment, or technology that could be used in producing biological weapons; or (b) detecting, characterizing, or responding to outbreaks of diseases that involve biological pathogens. It encompasses, but is much broader than, *biosafety*. *Biosafety* covers the application of knowledge, techniques, and equipment to prevent personnel, laboratory, or environmental exposure to potentially infectious agents or biohazards. "Developing countries" include more than 130 low- and middle-income countries outside the FSU, as defined by the World Bank.

Threat Agent Detection and Response (TADR) system. This system is devoted to upgrading capabilities of partner governments to detect, characterize, and respond to outbreaks of infectious diseases, and particularly diseases associated with especially dangerous pathogens. BTRP also assists partner governments in developing biosecurity policies and regulations at the national level and provides training and technical assistance at the facility level. Finally, it supports cooperative research programs.

DOD anticipates reaching an annual level of BTRP expenditures of about \$250 million during the next 5 years, including funding for activities in developing countries beyond the FSU. In this regard, DOD has begun considering efforts directed to Afghanistan, Pakistan, and the Democratic Republic of the Congo, although no commitments to these countries have been made.

This summary sets forth principal findings and recommendations of the study using primarily information available as of November 30, 2008. The importance of strengthening existing health and agriculture disease surveillance and response capabilities of partner governments, which overlap in many ways with systems for preventing and reducing the impact of bioterrorism incidents, is a recurring theme of this summary and the full report. Poor countries cannot afford a separate surveillance system for pathogens of bioterrorism concern and a surveillance system for other disease agents. Also, several U.S. government departments and agencies have relevant international activities and capabilities, and the importance of BTRP operating within an interagency framework is an essential aspect of much of the discussion. The full report elaborates on the findings and recommendations and presents additional observations.

SECURITY CONTEXT

In low-income countries and many areas of middle-income countries, the primary security issue for hundreds of millions of people is survival—enough food and water, adequate shelter, and tolerable levels of diseases. Unemployment and underemployment are high in many areas of the world. Sometimes impoverished populations also must cope with insurgents, terrorists, and gangsters—and even full-scale wars—that force them to move to unfamiliar surroundings. Neither the governments nor the populations in these circumstances can give priority to combating bioterrorism, which until now has not become a significant threat in their countries. However, they do know that naturally occurring diseases cause suffering and deaths and can have debilitating impacts on society (see Box S-1).

Meanwhile, many international specialists have highlighted the urgency of addressing bioterrorism on a broad scale (see Box S-2). An attack with roots in a developing country could claim victims within or outside the country. It could be a serious setback for positive aspects of the country's political and economic agendas by diverting resources to yet another impediment to development.

BOX S-1
Spread of Especially Dangerous Pathogens in
Sub-Saharan Africa

- Ebola has been present in Sudan and the Republic of the Congo since 1976.
- Marburg has been present in Kenya, Uganda, and Angola since 1980.
- Yellow fever and dengue now exist in Kenya, Sudan, and Somalia.
- Rift Valley fever reappeared in Kenya, Somalia, and Tanzania in 1997 and in 2006.
- West Nile disease is present in Africa.

SOURCE: Virologist, Central Veterinary Laboratory, Tanzania, presentation in Washington, D.C., July 2008.

More broadly, the worldwide psychological impact of a major bioterrorism incident would be traumatic.

The infrastructure required to support a bioterrorism attack is relatively small, but the infrastructure for countering an attack is complex. A variety of factors are important in detecting and responding both to naturally occurring and to malevolently instigated outbreaks of diseases. Some pathogens found in nature, as well as other genetically engineered disease agents, could be dispersed by terrorist organizations or by individuals motivated by personal animosity or financial considerations. Major responsibilities to counter biological threats, whatever the source, usually rest with the same scientists and practitioners. Therefore, the strategies to combat both naturally occurring and deliberately released pathogens should be well integrated. Some aspects of early warning systems for these two types of threats may differ (for example, intelligence systems to identify bioterrorism plots and epidemiology systems designed to identify outbreaks of nature). But most aspects of effective human health and agricultural surveillance and response systems, including detection, diagnosis, and therapy, are important in countering infectious disease threats in general.

In efforts to reduce the proliferation of biological weapons, the international community has developed many important international treaties, regulations, agreements, and codes of conduct that provide a framework for actions on a global basis. The development and implementation of appropriate laws, regulations, and guidelines at the national level are vital. For example, the International Health Regulations, while still in the early stage of implementation, not only provide a legal framework but also define public health events of international concern. National actions should also emphasize the development

BOX S-2 Threat of Biological Pathogens

"There are many ways for terrorists to obtain deadly pathogens. They can buy or steal them from universities, research labs, pharmaceutical companies, military stockpiles, or commercial supply houses; acquire them from 'friendly' states or sympathizers; buy them on the black market; or produce the agents on their own. It is also becoming ever more possible for them to produce the pathogens as the volume and sophistication of the necessary information become increasingly accessible through publications, the internet, and other sources."

SOURCE: Robert K. Noble, Secretary General, Interpol. P. xvii in Kellman, B. 2007. *Bioviolence: Preventing Biological Terror and Crime*. New York: Cambridge University Press.

of appropriate physical and personnel infrastructures to prevent bioterrorism in accordance with international obligations. This task is difficult in resource-poor developing countries. BTRP can help—in some countries as the lead U.S. program and often as support to other agencies that would lead U.S. or broader international efforts.

Recommendation 1-1: DOD should, within the U.S. government's evolving global biological engagement strategy, promptly expand BTRP into selected developing countries beyond the FSU. BTRP is the largest biological non-proliferation program in the world. The United States and the broader global community can benefit from a geographical expansion of BTRP within an appropriate U.S. interagency framework on a sufficient scale to significantly reduce the threat of bioterrorism outside the FSU. A reasonable target is for BTRP to begin biosecurity engagement, as the lead or as a supporting U.S. government program, in at least 10 countries outside the FSU during the next 5 years. This is a reasonable number given the magnitude of the global threat, the complexities of effective engagement, and the resources likely to be available to BTRP. The type of engagement should depend on local threats and vulnerabilities, local capabilities to effectively implement enhanced biosecurity measures, and those aspects of biosecurity engagement that are strongly embraced by the countries of interest. At the same time, BTRP should not divert its available resources that are needed for completion of important biosecurity enhancements in the FSU to support new efforts in additional countries.

Recommendation 1-2: BTRP's initial engagement activities in any developing country outside the FSU should be planned to last for up to 5 years, with

consideration given to extending engagement activities for another 5 years depending on initial successes in reducing biological threats and the future importance of continued engagement. Thus, from the outset, BTRP will be required to launch programs without the years of delay that too often have characterized the initiation and conduct of biosecurity activities in the FSU. Also, BTRP will need to emphasize the development of *sustainable* programs and the necessity for host governments to attract multiple international partners to the long-term task of enhancing local capabilities. At the same time, too many countries have severe biosecurity vulnerabilities for BTRP to use its limited resources to fix secondary problems that pose minor risks. But BTRP can carry out priority biosecurity upgrades and jump-start others on a broad basis while being a catalyst for complementary actions by other parties, and particularly actions by local organizations in the countries of interest.

CAPACITIES OF DEVELOPING COUNTRIES TO COUNTER BIOLOGICAL THREATS

Biology-related capabilities in each of the more than 130 developing countries are different. However, few developing countries have adequate capabilities to counter biological threats on a broad basis. In some countries, particularly in Africa, capabilities to cope with infectious diseases are severely limited.

With international support, most developing countries have for decades been upgrading their national systems for reducing disease burdens and for preventing disease agents from limiting agricultural production or contaminating exported or imported food products and commodities. But progress is slow and uneven. Capabilities to address bioterrorism depend on these same systems while also requiring additional security arrangements.

Some challenges such as deficiencies in the number of qualified scientific personnel are present throughout developing countries, although they differ in scope and severity. For example, Pakistan, despite an enormous brain drain, has a significant cadre of good scientists, largely with Western training. In Indonesia, the situation is bleaker, with only a limited number of specialists, many of whom were trained in Australia. Still of greater concern is the situation in the Philippines, where the capabilities of the higher education system lag behind appropriate training opportunities in other countries of the region.

Similarly, policies and financial resources that determine the directions of biological activities vary significantly among countries. For example, Brazil is in a class by itself in pressing forward with biotechnology in Latin America. Singapore and Malaysia are becoming biomedical hubs in Southeast Asia. Turkey and Egypt are well ahead of many other nearby countries in the life sciences. South Africa stands out as a biotechnology leader in Africa.

Also, biosecurity conditions vary within countries. For example, in Thailand, several modern biotechnology centers stand apart from many more lim-

ited facilities in the country. In Pakistan, the level of effective security at the country's dozens of bioscience and biotechnology facilities varies dramatically.

The list of vulnerabilities to biological threats in developing countries is long. Many countries have good biosafety regulations, but enforcement is generally weak. Governments may have little capability to diagnose and confirm suspected human or animal outbreaks. Many laboratories are poorly equipped, and some are barely functioning. Pathogen collections are often scattered throughout the country but are poorly documented, maintained, and secured. Reliability of electricity, communications, and basic water and sanitation networks is questionable at best. The number of trained technicians and scientists is inadequate. From well-qualified security guards to experienced laboratory managers to competent research scientists to responsible biotechnology entrepreneurs, there are opportunities for BTRP to address shortfalls and thereby contribute to the betterment of science, reduction of threats of bioterrorism, and improvement of public health (see, for example, Box S-3).

Recommendation 2-1: BTRP should continue to emphasize to partner governments the importance of their strengthening on a broad basis the infrastructures necessary to address human, animal, and plant diseases and the underlying scientific capabilities of the countries as essential foundations for addressing threats of bioterrorism. Biology-related activities depend on many aspects of a nation's physical infrastructures, its human resources base, and its policy commitments to reducing disease burdens. In particular, health and agriculture disease surveillance systems and associated research facilities are important. The security services play significant roles and require their own types of support. Transportation networks and communication capabilities are essential.

TRANSFERABILITY OF APPROACHES TO BIOLOGICAL THREAT REDUCTION ADOPTED IN THE FSU

BTRP capabilities and approaches have been well tested in the FSU, and many can be readily adjusted for circumstances in other countries. Most importantly, BTRP now realizes that partnerships rather than foreign assistance relationships with counterparts are essential in obtaining necessary buy-in for sustainable cooperative activities. These partnerships should begin from the outset of engagement and be reflected in the initial strategies and plans for BTRP-supported activities. Then BTRP will have opportunities to draw on its many training, engineering, biosafety, and other well-honed approaches.

Cooperative research has not been a strong aspect of BTRP, but other U.S. government organizations and several universities are assisting BTRP. Thus, BTRP has focused local attention on important research challenges such as investigations of brucellosis and plague, which are readily recognized by coun-

BOX S-3
**Systemic Weaknesses in Addressing the
Risk of Disease Threats**

Most developing countries have limited ability to

- monitor disease patterns,
- identify new organisms,
- investigate outbreaks and routes of transmission,
- stockpile and mobilize commodities,
- rapidly respond with trained staff,
- educate the public on prevention and care seeking,
- regulate unsafe animal rearing, transport, and selling, and
- coordinate routine and emergency operations among health, animal, and other sectors.

SOURCE: USAID briefing to the committee, November 3, 2008.

terparts as local threat agents. Together they have used collaborative research as a basis for developing good rapport not only with scientists but also with local officials.

BTRP has encountered some administrative difficulties in delivering products. At times, the chain of command for implementing projects from DOD through DTRA, through contractors, and through subcontractors to individual implementers of projects has been inefficient. While BTRP has made considerable progress in reconciling DOD procedural requirements with conditions on the ground, simplification of procedures is needed.

As to impacts, BTRP is now developing an overdue system of appropriate metrics, but expanded efforts in this regard are still needed.

The following approaches are essential to address the above concerns.

Recommendation 3-1: As BTRP moves beyond the FSU, the theme of partnerships with counterpart organizations in host countries should be a guiding principle. The governments of some developing countries associate foreign funds with foreign aid. But if they can be convinced through both words and actions that BTRP wants them as true partners, the path to success of BTRP will be wide and the likelihood of sustainability will be increased.

Recommendation 3-2: BTRP should develop in cooperation with each partner government a Strategic Plan that describes the security situation and particularly vulnerabilities relevant to biological assets in the country, disease burdens

and trends, local capabilities to detect and respond to outbreaks, and plans for cooperative threat reduction activities within the context of national plans and capabilities of both countries. BTRP's experience in developing country-specific "Science Plans" in the FSU is a starting point. The Strategic Plan should be developed jointly with host-country partners and within the framework of the U.S. government's evolving overall strategy for biosecurity engagement in the country of interest. The plan should of course take into account the near-term security-related developments that are relevant to effective use of the country's biological capabilities. Emphasis should also be placed on long-term goals that require sustained efforts, including efforts after BTRP's departure from the country. The plan should address containment of pathogen collections, assessment of disease burdens and trends, development of local capabilities to detect and respond to disease outbreaks, enhancement of research laboratories and joint research opportunities, allocation of financial resources available from local and international sources, engagement of organizations that will sustain BTRP-supported initiatives, and BTRP's exit strategy. The strategic plans should be regularly reviewed, as individual plans and as a set of plans with common goals.

Recommendation 3-5: BTRP should support cooperative biological research in countries where it engages, even if local research capabilities are limited.

Cooperative research involving local and U.S. scientists over an extended period of time can enhance transparency and build trust as to BTRP's overall intentions while upgrading local capacity to investigate problems of local concern. Regional networks of BTRP-supported investigators working on similar topics in different countries may in time offer important approaches to sustainable international research relationships.

Recommendation 3-7: DOD should streamline its chain of command for implementing BTRP and simplify the operational process within DOD to enhance efficiency, reduce misunderstandings, and increase transparency concerning U.S. intentions toward the host governments.

Given likely sensitivities to DOD's involvement in programs in some developing countries, misunderstandings and false expectations should be avoided to the fullest extent possible. While DOD has well-established management procedures for drawing on contractors as implementers of programs, the special procedures developed for BTRP have been unnecessarily complex and too Washington-centric. DOD should, of course, ensure that policy requirements are satisfied. Nevertheless, DOD needs to reduce the time to approve plans and the delays in implementation of projects while ensuring that U.S. government officials, rather than contractors, are in the forefront in engagement with host governments.

Recommendation 3-9: BTRP should continue to develop improved metrics

that will help guide evaluations of the impacts of BTRP and provide information for setting priorities for activities designed to reduce proliferation of biological weapons as well as related risks from naturally occurring contagious disease agents. BTRP should continue to track the number of facility upgrades, consolidated pathogen collections, and research projects completed; number of trainees; quantity and quality of scientific publications; sustained linkages between U.S. and partner institutions; and other identifiable results attributable in part to BTRP. But additional indicators that reflect impacts in enhancing U.S. security interests should be developed and pursued (for example, time to recognize and respond to an outbreak, improved ability to characterize infectious disease agents, and expanded data sharing). Indicators used by other U.S. agencies and by international organizations should, of course, be considered for possible use by BTRP. To gain a better appreciation of trends reflected in indicators that are difficult to quantify, BTRP should support qualified local specialists who can undertake parallel efforts to measure the impacts of BTRP activities in their own countries.

Recommendation 3-10: BTRP should take into account possible local concerns about a large presence of DOD activities in the countries where it engages. Joint projects with other organizations playing important roles and an emphasis on responding to local initiatives will be helpful in this regard. Whenever possible, BTRP should partner with civilian organizations that have strong health and agriculture reputations in the developing countries, such as the World Health Organization, the Food and Agriculture Organization, the World Bank, the regional development banks, the U.S. Agency for International Development, and the Centers for Disease Control and Prevention (CDC).

RELEVANT ACTIVITIES OF OTHER ORGANIZATIONS IN DEVELOPING COUNTRIES

Many U.S. government departments and agencies, agencies of other governments, international organizations, international companies, and nongovernmental organizations are involved in activities related to biological threat reduction. DOD alone has more than 15 entities with relevant programs. At least six other U.S. departments and agencies have responsibility for significant international activities that can contribute to countering biological threats. BTRP can benefit from drawing on the capabilities, experiences, and activities of many of these organizations (see, for example, Box S-4).

BTRP currently interacts with about 35 organizations that have relevant program interests in the FSU. In developing countries beyond the FSU, the array of organizations with relevant programs will be much larger, with a stronger emphasis on international development and with less experience specific to biosecurity. Sharing experiences among organizations and identifying ways to

BOX S-4

Lessons Learned by CDC in Developing Countries

- Ensure the program is consistent with local priorities.
- Avoid taking personnel from other important local programs.
- Ensure local buy-in of activity.
- Ensure program compatibility and integration with existing local activities, structures, methods, and equipment.
 - Avoid high-technology solutions for low-technology environments and ensure availability of replacement equipment and parts.
 - Minimize reliance on foreign experts.
 - Design a system that is affordable and can be maintained locally.
 - Design a system that is capable of coping with unpredictable changes in the operating environment.
 - Have a monitoring and evaluation component.
 - Resolve implementation issues early.

SOURCE: CDC expert, presentation to the committee, July 2008.

develop complementary activities is increasingly important as the U.S. government, including DOD, expands international biosecurity activities. As BTRP launches programs beyond the FSU, coordination of activities in the field will be particularly important.

Recommendation 4-8: BTRP should station regional or country representatives in areas where new activities are initiated with responsibility for keeping abreast of related activities and for promoting synergies among BTRP activities and related interests of other organizations. Only through an on-the-ground presence will BTRP be able to stay abreast of the many activities and interests of organizations from around the globe that have programs that should interface with BTRP activities. In some cases, a BTRP representative might be based at an overseas DOD research laboratory. In other circumstances, it may be more appropriate for the representative to be stationed at the U.S. embassy in the country of interest or at an embassy in a region of interest.

POLICY AND PROGRAM COORDINATION AND INTEGRATION

Integration of biological nonproliferation activities supported by the U.S. government has for several years been on the agenda of the National Security Council (NSC), with the Department of State playing a leadership role in this

regard. The NSC and the Homeland Security Council lead a Policy Coordination Committee (PCC) for Biodefense with a panel on international bioengagement that brings together officials responsible for relevant aspects of homeland security and nonproliferation and some aspects of international development. Among the activities of the PCC is the development of government-wide frameworks for addressing biological threats in specific countries.

In the field, coordination is a critical component of integration, as noted above. Coordination is often dependent on the interests of the local U.S. ambassador. BTRP will have the challenge of ensuring that its activities are appropriately included in the embassy's Mission Strategic Plan and that U.S. government officials stationed abroad take advantage of BTRP's activities and capabilities. BTRP field representatives should be helpful in this regard.

An important step in setting the tone and framework for interagency coordination is to ensure that DOD is closely linked to the key U.S. government departments with internationally recognized expertise in relevant areas. The following recommendation is directed to this end.

Recommendation 5-3: The authors of the National Defense Authorization Act should include in the act a provision calling on DOD to utilize as appropriate the capabilities of other U.S. government departments and agencies, particularly the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA), to assist in the development and implementation of BTRP activities. To this end, the act should recognize the importance of transfers of BTRP's resources to these organizations as necessary and should call for BTRP to provide Congress within its annual reports information on the extent and effectiveness of such transfers. While BTRP has engaged other departments and agencies in its activities for many years, their participation is often ad hoc with uncertain duration. A legislative mandate for such involvement should help resolve uncertainties and enable BTRP to benefit more fully from international recognition of the scientific wherewithal of other participating departments. Of course, BTRP-supported activities should to the extent possible be integrated with activities supported financially by the other departments themselves. At the same time, BTRP should recognize that in some cases other agencies are better equipped to adequately address important biosecurity issues alone and should therefore not become involved in those issues.

THE WAY AHEAD

In short, the risk of bioterrorism is too great for BTRP not to be among the leading organizations internationally in addressing the threat outside the FSU. BTRP, in continuing consultation with partner governments, should emphasize a systems approach to address a range of pathogens—particularly those of day-to-day concern—that strengthens health and agricultural surveillance capabili-

ties, pathogen security, and research activities on a broad basis. BTRP needs to expand cooperation with U.S. and foreign government and nongovernment organizations with overlapping interests. DOD's planning and operational procedures should be streamlined. Sustainability must be at the top of its priority concerns. Strategic plans and more meaningful metrics developed with partner governments that respond to the overall interests of the governments need to guide the effort.

DOD should consider this report as more than a series of disconnected recommendations from which it can simply choose. Each recommendation addresses an important issue that needs to be considered in an integrated manner if BTRP is to find success in its effort to reduce the risks associated with the threat of bioterrorism. This report provides an overall framework and a starting point to finding the best approaches within the framework.

As the first step in developing an action plan, DOD should promptly identify initial target countries outside the FSU. The selection criteria for target countries are numerous but should include (1) the likelihood of significant risk reduction and (2) the near-term likelihood that successes can be sustained over the long term. In some cases, BTRP may be the appropriate lead organization for the U.S. effort, while in other cases, BTRP may play a supporting role in the national effort. Of course, BTRP must be welcomed in the countries of interest.

Whether reconstructing facilities, upgrading surveillance or research capabilities, or providing training and related services, BTRP's activities should be based on a clear vision of how they will improve biosecurity in the next 5 years. In some cases, a broad countrywide approach may be necessary to reduce vulnerabilities significantly. In other cases, a relatively minor contribution by BTRP may make a substantial difference in the biosecurity landscape of the country.

In conclusion, BTRP can make a significant contribution to raising awareness of the governments, specialists, and public in developing countries of the importance of a range of policies and programs for addressing biological threats. An effective mechanism for raising awareness is the launching of cooperative projects that demonstrate the impacts of practical approaches to addressing vulnerabilities while also enhancing economic development opportunities. The community of specialists in the field of biosecurity is small, and information about BTRP cooperative projects will spread quickly. Discrete, time-limited, and action-oriented projects rather than vague promises and endless discussions should continue to characterize BTRP's approaches. In time, BTRP activities, as part of an integrated U.S. government approach, should increase respect for U.S. humanitarian-oriented objectives while reducing biosecurity threats.

Introduction

The U.S. Congress included in the National Defense Authorization Act for Fiscal Year 2008 (P.L. 110-181, Title XIII, Section 1308) a provision calling for a study by the National Academy of Sciences (NAS) on “the prevention of proliferation of biological weapons.” This study, which is the topic of this report, was to identify areas for future cooperation with developing countries outside the former Soviet Union (FSU) within the framework of the Cooperative Threat Reduction (CTR) Program administered by the Department of Defense (DOD) in the specific area of prevention of proliferation of biological weapons. Such biology-oriented activities, whether carried out within the FSU or elsewhere, are currently referred to by DOD as the Biological Threat Reduction Program (BTRP).

During 2007, the National Research Council (NRC), acting on behalf of the NAS, conducted a related study of BTRP activities that had been carried out in cooperation with the states of the FSU, pursuant to the National Defense Authorization Act for Fiscal Year 2007 (P.L. 109-364, Title XIII, Section 1304). The NRC submitted the report of that study to DOD and to the Congress in the fall of 2007. The title of that report is *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*.¹ Against this background, the NRC welcomed the opportunity to undertake a second study of the potential role of BTRP in promoting U.S. interests in countries of security importance.

¹ National Research Council Committee on Prevention of Proliferation of Biological Weapons. 2007. *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=12005. This report is hereinafter referred to as the “October 2007 report.”

In March 2008, the NRC entered into a contract with the Defense Threat Reduction Agency (DTRA), acting on behalf of DOD, to carry out this study. This report sets forth the findings and recommendations of the Committee on the Prevention of Proliferation of Biological Weapons in States Beyond the Former Soviet Union, which was established by the NRC to undertake the study.²

Also included in the National Defense Authorization Act for Fiscal Year 2008 (Section 1306) was a provision calling for an NAS study of new initiatives for the CTR Program. In response, a separate report has been prepared by the NRC Committee on Strengthening and Expanding the Department of Defense Cooperative Threat Reduction Program and is scheduled to be released in March 2009.³ Since that report covers issues in the nuclear, chemical, biological, and missile fields, there is some overlap with this report. Nevertheless, each report stands on its own, and they are intended to be complementary.

DOD and the U.S Congress will be important audiences for this report. At the same time, BTRP has far-reaching implications for many governmental and nongovernmental organizations (NGOs) in the United States and abroad. Thus, the report should also be of wide interest to officials, health and agriculture practitioners, researchers, entrepreneurs, industrialists, foundation leaders, and policy analysts in several countries.

STATEMENT OF TASK

The four tasks to be addressed in the study as set forth in the legislation and in the subsequent contract between NAS and DTRA are as follows:

1. An assessment of the capabilities and capacity of governments of developing countries to control the containment and use of dual-use technologies of potential interest to terrorist organizations or individuals with hostile intentions.
2. An assessment of the approaches to cooperative threat reduction used by the states of the FSU that are of special relevance in preventing the proliferation of biological weapons in other areas of the world.⁴
3. A brief review of programs of the U.S. government and other governments, international organizations, foundations, and other private-sector enti-

² See Appendix L for biographical information on the committee members.

³ National Research Council Committee on Strengthening and Expanding the Department of Defense Cooperative Threat Reduction Program. 2009. *Global Security Engagement: A New Model for Cooperative Threat Reduction*. Washington, D.C.: The National Academies Press.

⁴ Congressional staff members have clarified for the committee that the intent of Congress was to limit "the approaches to cooperative threat reduction" to the approaches undertaken by the states of the FSU in cooperation with BTRP and not include approaches that may have been undertaken unilaterally by the states or through other international programs. This is the interpretation used in this report.

ties that may contribute to the prevention of the proliferation of biological weapons.

4. Recommendations on steps for integrating activities of the CTR Program relating to biological weapons proliferation prevention with activities of other departments and agencies of the United States, as appropriate, in states outside the former Soviet Union.

In addition, the contract provides the following guidance for the study:

- In response to a request by DOD, the study will have a special focus on activities in Asia and Africa.
- For the purposes of this study, “the prevention of proliferation of biological weapons programs” is defined by DOD as “those activities that could be carried out by DOD unilaterally or in cooperation with other U.S. government departments and agencies, contractors, nongovernmental organizations, and international organizations for the purpose of the prevention of proliferation of biological weapons-related materials, technologies, and expertise.”

Finally, DOD informed the NRC that the study should not address the situation in Iraq, which in DOD’s view has attracted sufficient attention through other DOD channels.

ELABORATION OF IMPORTANT CONCEPTS

Dual-Use Capabilities

The dual-use dilemma encompasses a wide range of biological capabilities that are intended for use in carrying out legitimate research, production, surveillance, therapeutic, and related activities. These capabilities include technical expertise of specialists who are trained or who have experience in addressing disease-related issues; methodologies that are used to characterize and manipulate biological systems; biological materials that are used for disease-related activities in laboratories, clinics, production facilities, and field investigations; and equipment that is essential for a wide range of biology-related activities. Unfortunately, many of these capabilities can be used for malevolent purposes.

Dual-use capabilities permeate a large portion of life sciences and biotechnology activities throughout the world, and the scope of dual-use activities continues to grow. Appreciation of this broad concept of dual use is essential in considering how to reduce the likelihood of proliferation of biology-related activities that could be used to cause harm. The recognition of the possibility of dual-use capabilities falling into the hands of hostile military forces, terrorist groups, or disgruntled individuals underlies many of the concerns set forth in the legislation calling for this study.

The National Science Advisory Board for Biosecurity (NSABB) has discussed dual-use research in considerable detail.⁵ The discussions of dual-use research by the NSABB have particular salience in a few developing countries with well-developed research capabilities. Most developing countries outside the FSU are not capable of conducting dual-use research designed to alter the properties of existing organisms through molecular technologies, but many of these countries conduct or could conduct applied research using organisms of concern for biological warfare or bioterrorism. Thus, NSABB reports provide useful guidance for addressing long-term research problems throughout the world. In this regard, NSABB has involved specialists from many developing countries in workshops and meetings that it has sponsored (see the organization's Web site at www.biosecurityboard.gov).

Biological Weapons and Bioterrorism

The legislation calls for the study to address proliferation of "biological weapons." For the purposes of this report, *biological weapons* include any biological material that could be deliberately misused to cause significant harm to humans, livestock, other agricultural resources, or environmental resources. This definition covers specific pathogens that could be disseminated in a wide variety of ways for harmful purposes.

The definition helps provide a conceptual umbrella for the activities of BTRP. It broadens the past focus by BTRP to include all agents that could be used for either biological warfare or biological terrorism. The distinction between biological warfare agents and biological terrorism agents is particularly important in considering expansion of BTRP beyond the FSU into countries with no history of involvement in preparation for biological warfare.

Specifically, preparation for biological warfare requires a large physical and human infrastructure. A significant quantity of a refined stabilized product that can be packaged, stored, and delivered is needed. The products are usually milled dry powders measuring 1 to 10 microns in particle size that remain suspended in air when released. Only a relatively small number of biological agents fit this profile, and few developing countries beyond the FSU have experience with such agents or the equipment required for production and release.

As to bioterrorism designed primarily to create widespread fear, a small amount of unrefined product may be sufficient to achieve the objective. For

⁵ See, for example, National Science Advisory Board for Biosecurity. 2007. Proposed Framework for the Oversight of Dual-Use Life Science Research: Strategies for Minimizing the Potential Misuse of Research Information. Bethesda, MD: U.S. Department of Health and Human Services. Available online at oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

this purpose, the agent may be easily accessible in nature and introduced into an unsuspecting community in a simple manner. Genetic manipulation, sophisticated technology, biohazard suites, or highly engineered delivery systems may not be needed. There may be no need to scale fences or pass armed guards to obtain the product, which could be abundant in nature and routinely encountered in areas where the associated disease is endemic. Trained microbiologists might easily acquire suitable organisms from the environment or from a rural health clinic or veterinary station to create a bioterrorism event.

A good example of an agent that requires little technology for use in bioterrorism is foot-and-mouth disease virus. This virus is endemic in many countries and could with limited technical capabilities be introduced into countries free of the virus. Large quantities of the virus could be produced in developing countries in a stable form by a simple procedure such as lyophilization (freeze drying) and then transported internationally to the United States or other Western countries.

The topic of pathogens of concern is addressed throughout the report.

Biosafety and Biosecurity

These terms are commonly used to describe a variety of activities related to the proliferation of biological weapons as discussed in the preceding paragraphs. However, they often have different meanings for different audiences.

For the purpose of this report, *biosafety* includes “the application of knowledge, techniques, and equipment to prevent personal, laboratory, or environmental exposure to potentially infectious agents or biohazards.”⁶ Biosafety procedures have been widely published, and they should conform to international standards, with an emphasis on facility containment practices to protect the worker.

In this report, *biosecurity* encompasses all direct or indirect measures that contribute significantly to (1) preventing inappropriate persons from gaining access to materials, equipment, or technology that could be used in producing biological weapons; or (2) detecting, characterizing, or responding to outbreaks of diseases that involve biological pathogens or toxins. It is an overarching concept that includes measures taken at the international, national, and local levels that reduce the likelihood that pathogens could be deliberately misused. It encompasses, but is much broader than, biosafety.

⁶ This definition is taken from the dictionary of medical terms available online at www.medterms.com/script/main/art.asp?articlekey=33817. Accessed November 26, 2008.

Biosurety

This term was developed within DOD during the 1990s. However, given the lack of familiarity of many potential readers of this report with the term, it is not used in this report.⁷

Roots of Terrorism

BTRP should, of course, consider the root causes of terrorism in the countries where it has engagement programs. Specifically, what motivates or induces people in the developing countries to resort to terrorism in general and perhaps trigger bioterrorism events in particular? Understanding terrorist motivations is important, both to provide insights on the political and economic environments and to help identify ways that BTRP activities can contribute to reducing the risks of bioterrorism. Credible analyses of the likelihood of bioterrorism must take into account the extent of the roots of terrorism in the specific countries of interest. However, such country-specific analyses are clearly beyond the scope of this report. A few comments on economic development challenges, which in some countries may relate to the roots of terrorism, are offered in this report, but broad-ranging assessments of the roots of terrorism are left to others.

Countries of Concern and Country Visits

U.S. and foreign specialists have identified in various publications and in presentations to the committee dozens of countries with biosecurity vulnerabilities. Some specialists believe that conditions in selected countries should be of immediate concern to the U.S. government. They also believe that many other countries should be of biosecurity concern in the longer term. Some countries with significant vulnerabilities are identified in Chapters 1 and 2.

However, the time and the resources for this study were limited. Thus, it was not possible to analyze in detail the biosecurity situations in individual countries. Also, the committee did not have access to classified information; and it had only a limited opportunity to obtain unpublished information from within the developing countries that would be needed for comprehensive analyses.

⁷ DTRA has characterized *biosurety* as follows: It includes (1) compliance with approved safety, environmental, occupational health, operational, and technical procedures; (2) physical security measures to preclude unauthorized access to or use of especially dangerous pathogens and protection of knowledge and intellectual property; (3) safe and secure acquisition, storage, handling, maintenance, transportation, inventory management, and disposal of especially dangerous pathogens; (4) emergency response to biological mishaps and incidents; and (5) personnel reliability. Thus, biosurety is intended to be a total concept that encompasses the practice of biosecurity at all levels, including biosafety. It also includes personnel reliability to ensure proper clearance and tracking of individuals who work with especially dangerous pathogens.

Two general limitations are included in the statement of task as to the countries that should be considered in the study. First, the countries of interest are “developing countries.” The list of developing countries prepared by the World Bank, which includes both middle- and low-income countries, has been used as guidance in identifying relevant countries.⁸ Second, the countries should be outside the FSU. The Baltic states of Estonia, Latvia, and Lithuania are among the currently independent countries that were at one time within the Soviet Union, even though there have long been diplomatic disagreements over whether those countries were legally incorporated into the FSU before its disintegration in 1991.

Two other practical considerations further limited the list of countries of interest. First, the situations in Afghanistan, Iraq, and other war-torn countries were too complicated to be addressed. Second, the internal and external political situations of countries that might be of interest in the long run ruled out some countries from consideration, recognizing that political acceptability is often difficult to predict. For example, Cuba, Iran, and Syria would not seem to be appropriate countries to consider for BTRP engagement in the near term. While the committee is concerned about the lack of adequate biosecurity conditions in North Korea, only limited information about conditions in that country is publicly available.⁹ If BTRP proceeds as recommended in this report, the list of countries of interest will undoubtedly change significantly over time.

As noted above, the committee did not attempt to carry out in-depth country studies. Rather, field visits by committee members provided limited sets of observations on examples of biosecurity issues that deserve particular attention. Also, reports of site visits by other U.S. specialists to facilities in countries at different stages of economic and technological development helped clarify conditions on the ground in a range of development and biosecurity settings.

In short, objectives of the field visits were limited. They were not intended to prioritize countries for BTRP consideration or to help jump-start BTRP activities in specific countries. Also, they were not intended to rule out countries as not being of high priority for BTRP.¹⁰ Rather, they were case studies to provide insights into important generic issues that must be addressed by the

⁸ A link to the list of countries and an explanation of the classification system is available online at go.worldbank.org/K2CKM78CC0. Accessed December 2, 2008.

⁹ Useful insights on conditions in North Korea were presented by Karl A. Western in “Infectious Diseases in the Democratic People’s Republic of Korea” at the National Institutes of Health, June 9, 2008. However, at present, DOD is barred by law from providing assistance to North Korea, although it can seek a Congressional waiver.

¹⁰ Country priorities are being addressed by an interagency committee assisted by private-sector specialists. See, for example, International Biological Threat Reduction Program, Sandia National Laboratories. 2009. Global Biological Threat Prioritization Pilot Study. Unclassified summary provided to the committee, January 12, 2009.

U.S. government in prioritizing countries for BTRP engagement and in developing BTRP engagement strategies and programs. They provided supporting material for the recommendations set forth in this report.

The field visits were limited in number and constrained in scope by the short time available for planning, obtaining clearances for, and carrying out the visits, as well as analyzing their results—a total of 4 months. Visits to four countries were arranged pursuant to the contract between NRC and DTRA: Morocco, Mexico, Malaysia, and the Democratic Republic of the Congo. These countries provided opportunities to observe a range of geographic and development settings and a variety of levels and types of U.S. and international involvement. The agendas for these four visits and summary reports are set forth in Appendix C. Also, brief consultations in Brazil, Colombia, and Thailand took advantage of itineraries arranged by individual committee members and financed through other channels. Observations during both sets of visits are reflected in appropriate places throughout the report.

Thus, the committee had a reasonably good appreciation of relevant security, economic, scientific, health, and agricultural situations in several countries of interest.

Legislative Authorities

With regard to legislative approaches, this report assumes that Congress will not appropriate funds for nonproliferation purposes directly to the Department of Health and Human Services (HHS), the Department of Agriculture (USDA), or the Environmental Protection Agency. Rather, funding for those organizations for nonproliferation purposes will continue to be provided from appropriations to the Department of State or DOD when those organizations consider such funding to be appropriate. However, the related report by the NRC Committee on Strengthening and Expanding the Department of Defense Cooperative Threat Reduction Program suggests that, alternatively, nonproliferation funds might be appropriated directly to HHS and USDA.

Thus, this report focuses on how DOD uses the funds for which it has responsibility. It does not address how some of these funds, in the first instance, might be better appropriated to other agencies. In either case, the recommendations in this report should provide useful suggestions as to the important roles of HHS and USDA, as well as DOD, in addressing proliferation challenges in developing countries outside the FSU.

Related to the foregoing discussion is an often-heard argument that other agencies could do the job of reducing biological threats in developing countries without the need for DOD involvement. The committee strongly believes that for many years DOD has demonstrated that it can bring unique skills and experiences to the field that are not readily available to other agencies in areas such as facility and personnel security, project management in difficult

environments, logistics, and training of a wide range of specialists. This topic is discussed throughout the report.

THE STRUCTURE OF THE REPORT

The report is presented in 6 chapters and 12 appendixes. Chapters 2 to 5 respond to the four tasks in the legislation calling for this study and present relevant recommendations. Chapter 6 consolidates the recommendations.

- Chapter 1 highlights the security context for potential BTRP activities in developing countries, including near-term concerns over containment of pathogens. Several issues are identified that should be addressed in initiating BTRP activities designed to help counter the proliferation of biological weapons.

- Chapter 2 addresses the capacities of developing countries to take advantage of achievements in the life sciences while containing potentially dangerous materials, expertise, and technologies. Capacity is directly linked to weaknesses of developing countries in effective biosecurity-related policies, adequate human resources, and appropriate physical infrastructures (see Task 1).

- Chapter 3 discusses some of the approaches used by BTRP in the FSU that seem appropriate for deployment in other countries. It points out significant differences between the biosecurity environments in the states of the FSU where biodefense activities were widespread during the Soviet era and the environments in other developing countries where biodefense activities have been very limited (see Task 2).

- Chapter 4 highlights activities in the life sciences supported by many international, governmental, and nongovernmental organizations in the developing countries that are important in considering an appropriate niche for BTRP. While a comprehensive inventory of such activities has not been undertaken, many of the most important activities are discussed, with pointers to other activities (see Task 3).

- Chapter 5 addresses the importance of coordination of U.S. government nonproliferation and related international efforts and the need to integrate these efforts internally and with activities of other governments, international organizations, and the private sector (see Task 4).

- Chapter 6 consolidates the recommendations that have been set forth and indicates priorities among these recommendations.

The appendixes provide references and other supporting documentation for the discussions in the report.

INFORMATION SOURCES

This report is based primarily on information that was available as of November 30, 2008. The committee members and the NRC staff reviewed many relevant reports prepared by officials and specialists from the developing countries, by U.S. and other international participants in biosecurity activities, and by other knowledgeable observers. A few key documents are cited in the text, footnotes, and appendixes of the report.

The October 2007 report provides a comprehensive overview of BTRP activities in the FSU. The information in that report was supplemented by updated information collected by NRC staff who attended the annual BTRP program review conference held in Garmisch, Germany, in April 2008. This conference involved officials and specialists that participate in BTRP in seven countries of the FSU. In addition, DOD and DTRA officials briefed the committee on their outlooks for future BTRP activities. Thus, the committee had significant insights as to the successes and challenges associated with BTRP in the FSU as a starting point for consideration of expansion of BTRP to other countries.

DTRA provided the committee with information concerning the international biology-related activities of several units of DOD, as discussed in Chapter 3. Important overview reports are DOD's *Global Emerging Infections, Surveillance and Response System*¹¹ [GEIS] and the Institute of Medicine's *Review of the DOD/GEIS Influenza Programs: Strengthening Global Surveillance and Response*.¹²

Also of special significance for this report has been a review of the international development literature. Significant reports have been prepared by development agencies and independent specialists concerning human resource development, health and agriculture programs, and physical infrastructure deficiencies in developing countries. Consultations with specialists associated with the World Bank, the private sector, and the NGO community helped fill gaps in the published literature.

Helpful briefings and associated documents were provided by the Department of State, the Department of Agriculture, and the Department of Health and Human Services (particularly the Centers for Disease Control and Prevention, the National Institute of Allergy and Infectious Diseases, and the Fogarty

¹¹ U.S. Department of Defense. 2007. DoD Global Emerging Infections Surveillance and Response System Annual Report Fiscal Year 2006. Silver Spring, MD: DOD. Available online at www.geis.fbp.osd.mil/GEIS/aboutGEIS/annualreports/GEIS_06_HR.pdf. Accessed December 2, 2008.

¹² Institute of Medicine Committee for the Assessment of DoD-GEIS Influenza Surveillance and Response Programs and Board on Global Health. 2007. *Review of the DoD-GEIS Influenza Programs: Strengthening Global Surveillance and Response*. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=11974. Accessed December 2, 2008.

International Center). The insights of the Department of State were especially important. This department has had the most active nonproliferation program of all U.S. government agencies directed explicitly to biosecurity in developing countries beyond the FSU.

Also of particular significance are the activities of the World Health Organization, the Food and Agriculture Organization, and the Animal Health Organization. Several committee members and staff have had extensive contacts with specialists of these organizations. Given these contacts and the ready availability of documents of the activities of the organizations, formal consultations in Europe or the United States were not pursued.¹³

As for previous activities of the National Academies, Appendix J identifies several relevant reports. In addition, the National Academies carried out international workshops on biosecurity and biosafety in Poland (November 2007), Uganda (February 2008), and Hungary (March 2008). These events involved specialists from more than 20 countries. Information developed at the workshops was available to the committee.

Finally, comments by knowledgeable specialists from around the world set forth in the boxes throughout the report present a limited sampling of views that are relevant to past activities of BTRP and its future activities beyond the FSU.

¹³ See, for example, World Health Organization. 2008. Guidance on Regulations for the Transport of Infectious Substances 2009-2010. Available online at www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10.pdf. See also World Health Organization. 2006. Biorisk Management: Laboratory Biosecurity Guidance. Available online at www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf.

Security Context for Geographical Expansion of the Biological Threat Reduction Program of the Department of Defense

The Department of Defense (DOD) has supported biological nonproliferation activities in seven countries of the former Soviet Union (FSU) during the past 12 years at a cost of about \$800 million within the framework of the Cooperative Threat Reduction Program (see Table 1-1). These activities, referred to as the Biological Threat Reduction Program (BTRP), are scheduled to continue in the FSU for at least 5 years. At present, the largest activity is establishment of the Threat Agent Detection and Response system. This system is devoted to upgrading capabilities of partner governments to detect, characterize, and respond to outbreaks of infectious diseases, and particularly diseases associated with especially dangerous pathogens. BTRP also assists partner governments in developing biosecurity policies and regulations at the national level and provides training and technical assistance at the facility level. Finally, it supports cooperative research programs.

DOD anticipates reaching an annual level of BTRP expenditures of about \$250 million during the next 5 years, including funding for activities in developing countries beyond the FSU.

With this experience as a starting point for understanding the role of BTRP, a brief discussion of relevant aspects of the security situation in developing countries outside the FSU is presented.

SUSTAINABLE SECURITY

A broadening of the traditional concept of *national security* to the longer term and more appropriate concept of *sustainable security* is presented in Box 1-1. Efforts to prevent and respond to the spread of infectious diseases, the theme of this report, cut across all three aspects of this expanded concept.

TABLE 1-1 BTRP Funding, by Country

	FY 1997-2008	FY 2009	Total
Azerbaijan	\$ 55,358,307	\$ 23,831,377	\$ 79,189,683
Armenia	\$ 1,723,385	\$ 6,695,680	\$ 8,419,065
Georgia	\$189,648,957	\$ 50,437,397	\$240,086,354
Kazakhstan	\$122,106,796	\$ 31,338,716	\$153,445,511
Russia	\$ 93,250,886	\$ 7,554,086	\$100,804,972
Ukraine	\$ 26,040,036	\$ 44,384,216	\$ 70,424,252
Uzbekistan	\$122,405,441	\$ 20,775,431	\$143,180,872
TOTAL	\$610,533,808	\$185,016,902	\$795,550,710

SOURCE: BTRP Program Manager, January 13, 2009.

NOTE: Figures shown have been rounded to the nearest dollar.

BOX 1-1 **Sustainable Security**

"Leading in this new world will require a fundamental shift from our outdated notion of national security to a more modern concept of sustainable security, that is, our security as defined by the contours of a world gone global and shaped by our common humanity. Sustainable security combines three approaches: national security, or the safety of the United States; human security, or the well being and safety of people; and collective security, or the shared interests of one world."

SOURCE: Smith, Gayle E. 2008. In *Search of Sustainable Security: Linking National Security, Human Security, and Collective Security to Protect America and Our World*. Washington, D.C.: Center for American Progress. Available online at www.americanprogress.org/issues/2008/06/pdf/sustainable_security1.pdf.

In the low-income countries and in many areas of the middle-income countries, the primary security issue for hundreds of millions of people is survival—enough food, adequate shelter, and tolerable levels of disease. Unemployment and underemployment are high in many areas of the world. Often impoverished populations must cope with wars as well as with insurgents, terrorists, and gangsters who ravage what little the populations have and frequently force poor people to move to unfamiliar surroundings. Neither the governments nor the general populations in these circumstances give priority to combating bioterrorism, which until now has not been a threat in their countries.

However, both the governments and the populations know that naturally occurring infectious diseases cause suffering and deaths. They can have

debilitating impacts on society. Thus, the governments give priority for using their meager budgets and the limited contributions of international donors to combating diseases that have an impact on the daily lives of the people, including in some countries, for example, HIV/AIDS, malaria, and tuberculosis. Few, if any, budget allocations remain to prepare for a seemingly abstract threat of bioterrorism.

Public health systems seldom function well in low-income countries where the ministries of health may not be considered “top-tier” ministries according to funding priorities. Ministries of agriculture also have serious funding shortfalls. Even in middle-income countries, public health services are usually well below the level of services of developed countries. Throughout the developing countries, databases (if they exist) concerning the presence, trends, and impacts of diseases are often incomplete and unverifiable. The capability to use data to improve public health practice is poorly developed. Also, data may be politically biased to help mask the inadequacies of governmental attention to health concerns of the people.

Governments may have little capability to diagnose and confirm suspected disease outbreaks, whether they be in humans or animals. Many diseases may not be reported. Treatment, even when quality drugs are available, is usually spotty at best. Food shortages, unreliable electricity, limited refrigeration, polluted water, and the absence of sanitation may all contribute to an unacceptably high disease burden.

As for human diseases, wealthy families sometimes travel abroad for health care. Laboratories may be equipped with modern instruments that will not be used in the near term because of a lack of trained technicians. Vaccines may become unusable because of storage problems, and immunizations may be sporadic and incomplete. Also, infections acquired in hospitals can be rampant.

Thus, it is not surprising that the capability of developing countries for addressing disease outbreaks initiated by terrorists are usually very weak, and in some countries essentially nonexistent. At the same time, promoting sustainable security that overcomes weaknesses that inhibit reliable reporting and treatment of diseases in distant lands is critical in advancing the far-ranging interests of the United States. We cannot afford to wait until an unusual disease burden becomes unacceptably high before we even know that a problem exists. (See Figure 1-1 concerning the communicable disease burdens in various areas of the world.)

THREAT OF BIOTERRORISM AND COUNTRIES OF CONCERN

The governments of the United States and other advanced countries increasingly view diseases that can lead not only to human suffering but also to political and economic destabilization as international security threats. In the age of expanding international travel and trade relations, biological pathogens

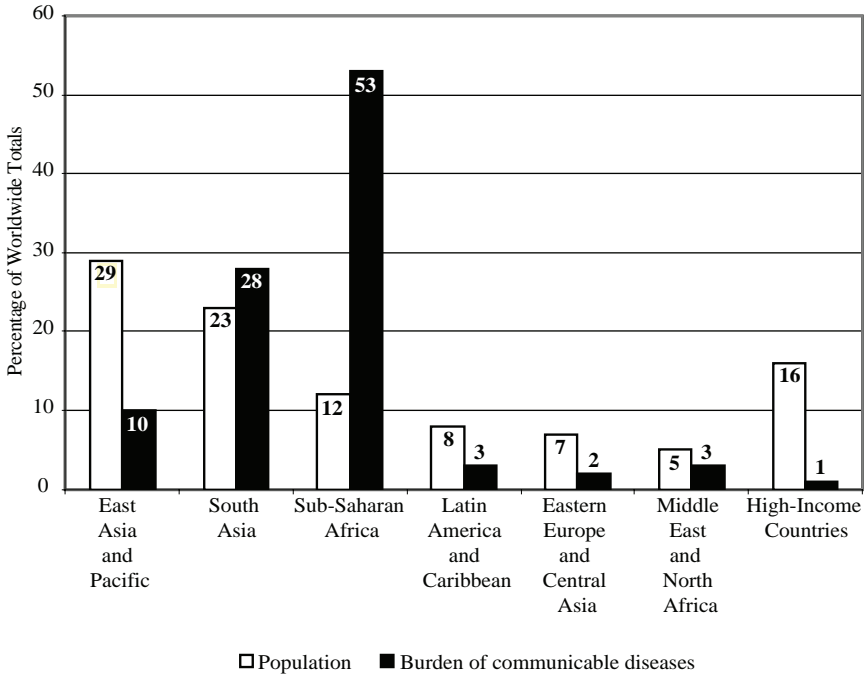


FIGURE 1-1 Worldwide distribution of global burden of communicable diseases.

SOURCE: The data presented in this figure were taken from the World Health Organization Web site on the global burden of disease, available online at www.who.int/healthinfo/global_burden_disease/en/index.html. Accessed January 29, 2009.

NOTE: The burden of communicable disease is a portion of the overall burden of disease. The overall burden of disease is assessed using the disability-adjusted life year, a time-based measure that combines years of life lost due to premature mortality and years of life lived in states of less than full health.

have become more mobile in reaching distant shores as infected travelers and contaminated food become unwanted byproducts of globalization. The day of the deliberately infected suicide terrorist riding in a crowded airplane through an international transportation system that is ill prepared to intercept the culprit may be close at hand. All the while, eliminating safe havens in developing countries where terrorists could plot their future attacks in distant lands or could attack local populations has become a mantra of security experts in Washington, D.C., and many other capitals.

Whether a dangerous infectious disease reaches the United States through a deliberate terrorist attack, through a sick passenger on international travel, or through the import of an animal for a zoo, the human suffering and the costs in

coping with such an event can be high. As to economic impact, the Department of State estimates, for example, that a deliberate foot-and-mouth disease outbreak at five Kansas stockyards could kill more than a million cattle, resulting in an economic loss of more than \$1 billion. Even if an incident were contained within a limited geographic area, the social and economic impact when alarms are sent across the nation could be significant.

The problems in combating bioterrorism in developing countries mirror the broader challenges of protecting global health and promoting international agricultural development. But special efforts are also needed to prevent, detect, respond to, and contain deliberately instigated outbreaks. On some occasions, intelligence services may play an important role in providing early warning about the plans of terrorists. But we cannot simply rely on the success of such efforts as bioterrorism enters the tool chests of dangerous groups and individuals.

Box 1-2 summarizes the threat of bioterrorism as viewed by an important international official with responsibilities for uncovering terrorist networks.

Box 1-3 presents a similar view that has been held by the Department of State for several years.

As to naturally occurring biological threats, Box 1-4 highlights the presence of especially dangerous pathogens in sub-Saharan Africa. Similar types of concerns are increasingly voiced on other continents as well.

On a broader scale, reports from the World Health Organization, as exemplified in Box 1-5, are equally disturbing.

The foregoing observations underscore the importance of containing pathogens of many types while having robust detection and response systems.

BOX 1-2

Availability of Dangerous Pathogens

"There are many ways for terrorists to obtain deadly pathogens. They can buy or steal them from universities, research labs, pharmaceutical companies, military stockpiles, or commercial supply houses; acquire them from 'friendly' states or sympathizers; buy them on the black market; or produce the agents on their own. It is also becoming ever more possible for them to produce the pathogens as the volume and sophistication of the necessary information become increasingly accessible through publications, the internet, and other sources."

SOURCE: Robert K. Noble, Secretary General, Interpol. P. xvii In Kellman, B. 2007. *Bioviolence: Preventing Biological Terror and Crime*. New York: Cambridge University Press.

BOX 1-3 Threat of Global Bioterrorism

"The threat of global bioterrorism is increasing. The gradual lowering of the technical and financial barriers to purchase the materials, technologies, and expertise to develop biological weapons is linked to the worldwide growth in biotechnology; and nonstate actors and terrorist groups are now capable of obtaining and maliciously disseminating infectious disease agents. At the same time there has been a rise in highly organized and well financed transnational terrorist groups that have shown an interest in bioterrorism.... Although many nations have recently taken steps to improve their ability to detect and respond domestically to a bioterrorist incident, few programs are designed to prevent terrorists from acquiring, developing, and disseminating the technology and materials to produce biological weapons."

SOURCE: Department of State presentation of 2006 estimate to the committee, May 22, 2008.

BOX 1-4 Spread of Especially Dangerous Pathogens in Sub-Saharan Africa

- Ebola has been present in Sudan and the Republic of the Congo since 1976.
- Marburg has been present in Kenya, Uganda, and Angola since 1980.
- Yellow fever and dengue now exist in Kenya, Sudan, and Somalia.
- Rift Valley fever reappeared in Kenya, Somalia, and Tanzania in 1997 and in 2006.
- West Nile disease is present in Africa.

SOURCE: Virologist, Central Veterinary Laboratory, Tanzania, presentation in Washington, D.C., July 2008.

The following incidents underscore that the threat of bioterrorism is at the doorsteps of the world:

- Anthrax letters were disseminated in the United States in 2001.
- The 11th volume of al Qaeda's *Encyclopedia of Jihad* is devoted to

BOX 1-5
2007 World Health Organization Report

"Infectious diseases are not only spreading faster, they appear to be emerging more quickly than ever before. Since the 1970s, newly emerging diseases have been identified at the unprecedented rate of one or more per year. There are now nearly 40 diseases that were unknown a generation ago. In addition, during the last five years, WHO has verified more than 1100 epidemic events worldwide."

SOURCE: www.who.int/whr/2007/overview/en/index1.html. Accessed November 29, 2008.

chemical and biological weapons.¹ Also, plans for bioterrorism were set forth in documents recovered from al Qaeda training camps in 2001.²

- An attempted theft targeted on the pathogen collection at the central reference laboratory for animal health in Indonesia in May 2007 was thwarted by security systems installed by the U.S. government.³

The infrastructure required to support a biological terrorism attack is strikingly smaller than the facilities and personnel resources that were developed to support biological warfare capabilities during the Cold War. Indeed, several years ago the U.S. Department of Health and Human Services demonstrated that it is possible to obtain through the Internet all of the needed components for a laboratory capable of dangerous genetic manipulation.⁴

The infrastructure required to counter bioterrorism should be broadly based—from import controls, biosafety programs, and security of pathogen collections to detection, diagnostic, response, and treatment capabilities. The current focus of security experts is on compact attack scenarios and on defensive strategies that take advantage of existing networks for addressing human and agriculture diseases. Broad and numerous defensive countermeasures are an important theme throughout this report.

¹ Kellman, B. 2007. P. 55 in *Bioviolence: Preventing Biological Terror and Crime*. New York: Cambridge University Press.

² National Research Council Committee on Prevention of Proliferation of Biological Weapons. 2007. P. 15 in *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*. Washington, D.C.: The National Academies Press.

³ *Ibid.* For additional views on the threat of bioterrorism, see Hoffman, Bruce. 2006. Pp. 274-280 in *Inside Terrorism*. New York: Columbia University Press.

⁴ Centers for Disease Control and Prevention (CDC) specialist briefing to the committee, October 6, 2008.

BOX 1-6 Al Qaeda Networks

"Al Qaeda (AQ) and associated networks remained the greatest terrorist threat to the United States and its partners in 2007. . . . AQ and its affiliates seek to exploit local grievances for their own local and global purposes. They pursue their own goals, often at large personal cost to the local population. These networks are adaptive, quickly evolving new methods in response to countermeasures. AQ utilizes terrorism, as well as subversion, propaganda, and open warfare; it seeks weapons of mass destruction in order to inflict the maximum possible damage on anyone who stands in its way, including other Muslims, and/or elders, women, and children."

SOURCE: U.S. Department of State. 2008. *Country Reports on Terrorism, Trends in 2007*, p. 7.

Many biological pathogens are of near-term concern. The anthrax letters have illustrated the simplicity of disseminating a deadly agent, while the spread of avian influenza has highlighted the ease with which a virus can circulate through large regions of the globe. As to other possible schemes of terrorists, botulinum toxin is lethal if ingested through contaminated food products, with the safety of milk supplies of special concern. There are no vaccines for many livestock diseases, which could spread rapidly if introduced into feed lots in developing countries as well as in the industrialized countries. Introducing diseases onto vulnerable crops seems relatively easy to execute and particularly dangerous in countries where high concentrations of monocultures with limited genetic diversity are susceptible to the spread of contagious plant diseases.⁵

At the top of the list of terrorism concerns of the Department of State are the activities of al Qaeda and related organizations, as indicated in Box 1-6. As al Qaeda continues to spawn cells that operate with considerable independence in several countries, the capabilities and intent to do harm internationally of such offshoot organizations spread accordingly. While some terrorist groups continue to look to al Qaeda leadership and expertise for guidance, others may be developing their own capabilities in the biological area as well as in the more traditional bullets-and-bombs area.

The Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism has stated that it is "more likely than not that a

⁵ According to an Agency for International Development (USAID) briefing to the committee on July 24, 2008, USAID reports that wheat rust UG 99 spread from Uganda and Kenya in 1998 to Ethiopia in 2003 to Yemen and Sudan in 2006 and to Iran in 2008, with the possibility of spreading further into Saudi Arabia, Egypt, India, and Afghanistan in the near future—and without the involvement of bioterrorists.

weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013.” Furthermore, focusing specifically on bioterrorism, “the Commission further believes that terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon. The Commission believes that the U.S. government needs to move more aggressively to limit the proliferation of biological weapons and reduce the prospect of a bioterror attack.”⁶

There is a growing list of countries where biosecurity vulnerabilities and the presence of dissident groups come together. Among the countries beyond the FSU that have been mentioned by U.S. experts at meetings of the committee as high on their biological threat indexes are the following: Indonesia, Pakistan, the Philippines, Malaysia, Thailand, Libya, China, Taiwan, Vietnam, India, Sri Lanka, Mongolia, Nigeria, Kenya, Democratic Republic of the Congo (DRC), South Africa, and Mexico. Many other developing countries also have vulnerabilities that could be exploited by bioterrorists.⁷

A variety of specialists who are familiar with biosecurity-related conditions in developing countries have expressed the view to the committee that many developing countries are highly vulnerable. As discussed in the introduction of this report, the committee has not attempted to prioritize the countries where the international community or BTRP should focus attention. Governments of all developing countries should be encouraged to balance the risks associated with possible bioterrorism-related activities now and in the future with the many other types of health, security, and economic challenges they face. Such balancing should help them decide how to use their limited resources to improve the well-being of their populations and whether to seek international assistance in the area of biosecurity. Upon request, U.S. and other experts should be able to assist governments of developing countries in clarifying the costs and benefits of steps to reduce the likelihood of bioterrorism attacks and to limit the consequences of such attacks should they occur.

Biosecurity experts sometimes compare the large international and national programs devoted to countering proliferation of nuclear weapons with the smaller programs to counter proliferation of biological weapons. They argue that biological risks are just as great, or even greater, and deserve comparable attention. One specialist has offered the analysis set forth in Table 1-2 to support this position.

⁶ Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism. 2008. P. xv in *World at Risk: The Report of the Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism*. New York: Vintage Books.

⁷ The committee is unaware of publicly available, U.S. government-wide criteria for ranking countries of concern, although the Department of State, CDC, and other organizations are developing their own models in this regard. See, for example, International Biological Threat Reduction Program, Sandia National Laboratories. 2009. *Global Biological Threat Prioritization Pilot Study*. Unclassified summary provided to the committee, January 12, 2009.

TABLE 1-2 Characteristics of Fissile Materials and Pathogens

Fissile Materials	Biological Pathogens
Do not exist in nature	Generally found in nature
Nonliving, synthetic	Living, replicative
Difficult and costly to produce	Easy and cheap to produce
Not diverse: plutonium and highly enriched uranium are the only fissile materials used in nuclear weapons	Highly diverse: more than 20 pathogens are suitable for biological warfare
Can be inventoried and tracked in a quantitative manner	Because pathogens reproduce, inventory control is unreliable
Can be detected at a distance from the emission of ionizing radiation	Cannot be detected at a distance with available technologies
Weapons-grade material are stored at a limited number of military nuclear sites	Pathogens are present in many types of facilities and at multiple locations within a facility
Few nonmilitary applications (such as research reactors, thermoelectric generators, and production of radioisotopes)	Many legitimate applications in biomedical research and the pharmaceutical and biotechnology industries

SOURCE: Tucker, J. B. 2003. Preventing the misuse of pathogens: the need for global biosecurity standards. *Arms Control Today* 33(June):3-10. Available online at www.armscontrol.org/act/2003_06/tucker_june03.

Clearly, containing the threat of biological weapons deserves a high level of attention by the international community. The United States has the experience, skills, and technologies to address the threat as well as being a potential target of embittered individuals or groups of vengeful extremists with newly acquired biological capabilities.

At the same time, overall capabilities to capitalize economically on the revolution in the life sciences or even to use more traditional achievements of biology laboratories in the more than 130 developing countries are highly variable. For example, Brazil is in a class by itself in pressing forward with biotechnology in Latin America. Singapore is leaving its neighbors in its scientific wake in Asia. Turkey and Egypt are ahead of many of their neighbors in the Middle East. South Africa is far ahead in promoting modern biotechnology in Africa.

Also, within an individual developing country, conditions to contain biological assets are usually uneven. For example, in some countries a central modern biotechnology facility stands apart from more rudimentary facilities located in areas distant from this central facility. In Pakistan, both the research productivity and the level of effective security at the country's dozens of bioscience and biotechnology facilities vary considerably.

Finally, the DRC and the Republic of the Congo are endemic with some of the deadliest microbial agents (for example, Ebola, monkeypox, plague, and

anthrax, among others). Yet none of the three national laboratories are capable of characterizing such pathogens.

THE GLOBAL SPREAD OF BIOTECHNOLOGY

Rapid scientific advances in the life sciences and in biotechnology and the increasing global dissemination of research results will continue to make important contributions to improving global health and international agriculture for the foreseeable future. Medical researchers are using ever more sophisticated techniques to manipulate microorganisms in their efforts to combat infectious diseases through more effective vaccines and drugs and through improved diagnostic methods. Agricultural scientists are also using newly developed approaches to create inexpensive scientific platforms for developing important animal vaccines and antibodies. At the same time, public health and veterinary applications are not the only results of the revolution in life sciences as new advances are increasingly realized in the search for improved crop productivity, industrial enzymes, and environmental remediation methods (see Box 1-7).

There is also a dark side to such impressive accomplishments, including the possible acquisition of dangerous microbes and viruses by groups that plan to use them as bioterrorism agents. As research laboratories and biotechnology firms increase in number and size throughout the world to address human and agricultural diseases, new pathogens that can cause human catastrophes may be uncovered. In particular, genetic engineering and related technologies may create more virulent pathogens that resist current methods of preventing diseases through vaccines and drugs.

Most advanced bioscience research, development, and production activities will be concentrated in the industrialized countries for the near future. To a limited degree, foreign pharmaceutical companies and other multinational firms are also investing in biotechnology in a few developing countries. In these countries, government officials and local scientists are hoping not to fall still farther behind the more prosperous countries on the economic and scientific development scales.

BOX 1-7

Rapid Advance of Biotechnology

"Starting in 2002, it took 2 years for a team to synthesize the polio virus. In 2005, it took 2 weeks for a team to synthesize a virus of comparable length."

SOURCE: International Council for the Life Sciences, briefing to the committee, July 24, 2008.

An important concern is the possibility that a firm in an advanced country with weak controls on exports of biological materials might simply sell dangerous genetic materials to firms in developing countries where skilled scientists could assemble fragments into particularly potent pathogens. Such scenarios are perhaps being considered by groups with hostile intentions. These scenarios send a warning that strengthening the control of international commerce in biotechnology products is essential.

Meanwhile, the number of biology specialists from the developing countries who are being trained in modern laboratories in the more advanced countries is on the rise. A few of the most talented are returning to their home countries. Too often, however, they may find only unacceptably low salaries and inadequate facilities for continuing their scientific endeavors in poverty-stricken countries. The future of this underutilized talent pool should be of concern.

A recent report recommended the five approaches set forth below in bold print to help guide the U.S. government's efforts to promote responsible use of biological assets in the United States.⁸ The recommendations have relevance in developing countries as well. It would be useful to elaborate them as necessary for implementation at the international level. The brief discussion of the following approaches is a first step in this direction.

- **Policies and practices should, to the maximum extent possible, promote the free and open exchange of information in the life sciences.** Transparency that accompanies exchanges of information can help provide international confidence that the intent of individuals and groups engaged in biological activities is to use biological assets for appropriate, and not for malevolent, purposes. However, security measures to contain scientific advances with dual-use implications may prevent international exchanges of some information and thereby inhibit scientific advances while raising suspicion as to why information is being withheld. Nevertheless, exchange of information to the extent possible is still a desirable policy.

- **A broader perspective of the number and types of pathogens that pose potential dangers should be adopted as to the biological threat spectrum.** As discussed in Chapter 3, BTRP, along with other U.S. government nonproliferation programs, uses a core list of a limited number of especially dangerous pathogens in its efforts to combat bioterrorism in distant countries. But bioterrorism could involve a much wider range of pathogens beyond this list. Also, partner governments in developing countries are most interested in engagement when cooperative activities focus on the pathogens that are causing day-to-day problems for human and agricultural health even though these pathogens may

⁸ Institute of Medicine Board on Global Health. 2006. *Globalization, Biosecurity, and the Future of the Life Sciences*. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=11567. Accessed December 2, 2008.

not be well suited as bioterrorism agents. In response, BTRP has demonstrated flexibility in adding avian influenza, swine flu, cholera, and other diseases of day-to-day concern to its list of target diseases. Continued expansion of the list will be very important in the developing countries beyond the FSU, where bioterrorism concerns often take a very distant backseat to demands to address common illnesses. Indeed, in some settings, the pathogen-specific approach should give way to a more generic approach to strengthen surveillance and research systems that address a range of pathogens.

- **The scientific and technical expertise within and across the security community should be strengthened.** The security community in most developing countries is not scientifically equipped to adequately assess the risks associated with pathogens or to effectively enforce appropriate biosecurity regulations even if they are in place. Too often in everyday practice local officials may not recognize significant risks. On the other hand, they may overestimate risks and discourage research or production practices that are not of serious security concern simply because they do not have the expertise to make nuanced judgments concerning risks.

- **A common culture of awareness and a shared sense of responsibility within the global community of life science specialists should be adopted and promoted.** Unfortunately, many officials and scientists in developing countries may not fully appreciate the importance of appropriate laboratory measures or do not have the time or resources to devote to measures that help ensure appropriate security arrangements. Interactions with counterparts in the more advanced countries who routinely implement biosecurity procedures, and particularly biosafety measures, can help them assess the extent of the problems in their countries and identify appropriate measures to respond to both near-term and long-term biological threats.

- **The public health infrastructure and existing response and recovery capabilities should be strengthened.** In developing countries, public health services are usually weak, and many years and considerable investments may be needed to upgrade such capabilities to a level of international acceptability. An effective public health system is an essential step in developing the capability to combat bioterrorism.

The growing access to highly sophisticated tools that could be used to construct biological weapons is expanding the character of the biological threat. In this regard, the National Science Advisory Board for Biosecurity has recommended that careful consideration be given to knowledge, products, or technologies that could pose threats on many fronts (see Box 1-8).

While not of immediate likelihood in most developing countries, major scientific advances in biotechnology are important in the long term. Of special importance are India and China, which have made considerable progress toward establishing research- and innovation-based biotechnology sectors.

BOX 1-8 Dual-Use Threat Criteria

Research products (including techniques and technologies) that have the potential to inflict harm or damage to public health or economies may include the following elements or characteristics:

- Enhance the harmful consequences of a biological agent or toxin
- Disrupt immunity or the effectiveness of an immunization without clinical and agricultural justification
 - Confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies
 - Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin
 - Alter the host range or tropism of a biological agent or toxin
 - Enhance the susceptibility of a host population
 - Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent

SOURCE: NSABB Draft Guidance Documents, July 2006, p. 4. Available online at [oba.od.nih.gov/biosecurity/PDF/NSABB_Draft_Guidance_Documents_27Sep06_\(12_11_2006\).pdf](http://oba.od.nih.gov/biosecurity/PDF/NSABB_Draft_Guidance_Documents_27Sep06_(12_11_2006).pdf). Accessed November 29, 2008.

Each of these countries has several vaccines and drugs on the market. While the efficacy and safety of such products produced in developing countries are of concern, this topic was beyond the scope of this study.⁹

In short, specialists involved in biotechnology activities should be aware of the potential security implications as well as the business opportunities that are accompanying the rapid advances in the life sciences.¹⁰

⁹ Frew, S. E., H. E. Kettler, and P. A. Singer. 2008. The Indian and Chinese health biotechnology industries: Potential champions of global health. *Health Affairs* 27(4):1029-1041.

¹⁰ For an overview of biotechnology interests in developing countries, see United Nations Conference on Trade and Development, Division on Investment Technology and Enterprise Development. 2002. *Key Issues in Biotechnology*. New York and Geneva: United Nations. Available online at www.unctad.org/en/docs/poitetebd10.en.pdf. Accessed November 30, 2008.

CONVERGENCE OF CHEMISTRY AND BIOLOGY

Biologists and chemists have long recognized the overlap between their disciplines. Now, advances in the life sciences and biotechnology are resulting in a considerably expanded overlap. This is due to several types of advances. Genome mapping and synthetic biology have facilitated increased understanding of biological systems. Automation of the synthesis and screening of chemical compounds has enabled laboratories to assess many new structures with an enhanced understanding of the characteristics of chemicals of biological origin. Also, the increased ability to observe chemical action at the cellular level brings the two disciplines closer together, as does the application of nanotechnology to deliver pharmaceuticals to specific cells.

Consequently, the overlapping measures to control the proliferation of biological and chemical weapons are increasingly recognized in the international arena. In the past, implementation activities pursuant to the chemical and biological arms control agreements have consistently been kept separate since biological issues are more difficult to address than chemical issues. This difficulty is particularly acute with regard to verification of international agreements. Maintaining this separation will be increasingly difficult with advances in research and production activities.

In short, cooperative programs designed to control only dangerous chemical agents or only dangerous biological agents will continue to be important. But sharp separation of these two approaches may not be the most effective approach in reducing the risks of terrorism resulting from advances in chemistry and biology.¹¹

Is the expanding overlap of chemistry and biology of significance in developing countries? In many settings, probably not. But the overlap may have important ramifications when countries are seeking to expand their research capabilities in major ways. The governments of these countries will most likely have a single unit that is responsible for compliance with both chemical and biological obligations. At the same time, they may lack technically qualified staff to adequately monitor activities, particularly in the intersecting areas of biology and chemistry.

INTERNATIONAL BIOSECURITY AGREEMENTS, GUIDELINES, AND CODES OF CONDUCT

Several international agreements and other international documents are designed to prevent the deliberate or accidental spreading of biological agents of concern. Several of these agreements and documents are highlighted below.

¹¹ Trapp, R. 2008. Advances in science and technology and the Chemical Weapons Convention. *Arms Control Today* 38(March):18-22. Available online at www.armscontrol.org/act/2008_03/Trapp. Accessed November 30, 2008.

The Biological Weapons Convention (BWC), which entered into force in 1972, was an international nonproliferation landmark. It outlawed the development and production of biological weapons. It also required destruction of existing stocks of such weapons. The language of the BWC prohibits the following activities by states parties to the BWC:

... in any circumstances to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes. ...¹²

Difficulties have frequently arisen at international meetings and in other settings in interpreting “peaceful purposes,” a concept that is linked to intent. Also, problems in elaborating the mechanisms for ensuring compliance with the BWC have been insurmountable. Nevertheless, the BWC, which has more than 160 states parties as of February 2009, has set at least a low bar for preventing malevolent use of biology by governments.¹³

In a more general sense, in 2004 the UN Security Council adopted a nonproliferation resolution (Resolution 1540) calling for all states to refrain from supporting by any means nonstate actors that attempt to acquire, use, or transfer nuclear, chemical, or biological weapons and their delivery systems. Of special interest is the following section of the resolution:

... the Council decided that all States would establish domestic controls to prevent the proliferation of such weapons [of mass destruction] and means of delivery, in particular for terrorist purposes, including by establishing appropriate controls over related materials, and adopt legislative measures in that respect. The Council called on all States to promote dialogues and cooperation on non-proliferation in addressing the threat posed by proliferation of nuclear, chemical, and biological weapons and their delivery systems. Further to counter that threat, it called upon all States according to their national legislation and consistent with international law to cooperate in preventing illicit trafficking in such weapons, means of delivery, and related materials.¹⁴

Another major international achievement has been development of international guidelines that are designed to limit the proliferation of pathogens and of critical equipment needed for the production of some classes of biological agents. Within the informal setting of the Australia Group, more than 40 of the world’s leading industrial countries have developed these guidelines. Of

¹² Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Article I. 1972. Available online at www.opbw.org/convention/documents/btwctext.pdf. Accessed November 30, 2008.

¹³ The complete list of participants and nonsignatories may be found online at [www.unog.ch/80256EE600585943/\(httpPages\)/7BE6CBBEA0477B52C12571860035FD5C?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/7BE6CBBEA0477B52C12571860035FD5C?OpenDocument). Accessed November 27, 2008.

¹⁴ United Nations Security Council Resolution 1540. 2004. Press Release SC/8076. Available online at www.un.org/News/Press/docs/2004/sc8076.doc.htm. Accessed November 26, 2008.

course, many of the items on the control list have dual-use capabilities, and the impact of the implementation of the guidelines on legitimate trade activities is a constant concern.

A third development of special relevance to this report is the promulgation of the World Health Organization (WHO) 2005 International Health Regulations. The full document may be found on the WHO Web site at www.who.int/csr/ibr/en. A summary is included in this report as Appendix H. These widely accepted regulations provide a framework for responsibly addressing and reporting the growing spread of human diseases, whatever their source. In this regard, the WHO has reported more than 1,100 disease outbreaks during the past 7 years.

Also of importance is the Cartagena Protocol, with more than 150 parties (the full text of the protocol may be found online at www.cbd.int/biosafety/protocol.asp). It is intended to protect biological resources from the potential risks posed by living modified organisms resulting from modern biotechnology. The protocol has encouraged many developing countries to introduce biosafety laws and regulations. The United States and a handful of other major countries are not signatories to this agreement, which they believe unnecessarily constrains development of important new agricultural products. As indicated in Box 1-9, developing countries may have serious implementation problems.

Other international actions that warrant mention are the World Trade Organization Phytosanitary Standards and the Codex Alimentarius Standards, which help prevent the spread of contaminants in international trade; the International Plant Protection Convention, which helps control exports and imports that might spread pests (available online at www.ippc.int/IPP/En/default.jsp); and the Declaration of Helsinki on the Conduct of Clinical Research (available online at www.bioscience.org/guides/decthels.htm).

As international concerns about biosecurity grow, many organizations have also become active in developing codes of conduct and other statements of

BOX 1-9 Implementing the Cartagena Protocol

"Developing countries face particular challenges with the Cartagena Protocol because their capacity to implement, monitor, and enforce biosafety laws remains weak. They also need to address the issues in the Protocol that are left to national discretion, and they must balance their rights and obligations under the Protocol with their commitments under the World Trade Organization."

SOURCE: Senior Pakistani official, presentation in Washington, D.C., July 2008.

BOX 1-10 **Selected Codes of Conduct^a**

- UNESCO Declaration of Science and the Use of Scientific Knowledge, adopted by the World Conference on Science, July 12, 1999
- International Committee of the Red Cross, Preventing Hostile Use of the Life Sciences: From Ethics and Law to Best Practice, November 11, 2004
- American Society for Microbiology, Code of Ethics 2005
- American Medical Association, Guidelines to Prevent Malevolent Use of Biomedical Research, June 2004
- Council for Responsible Genetics, Campaign for the Peaceful Development of the Biological Sciences
- InterAcademy Panel on International Issues, Statement on Biosecurity, December 1, 2005
- International Union of Microbiological Scientists, Code of Ethics against Misuse of Scientific Knowledge, Research, and Resources, April 28, 2006
- Global BioBusiness, Code of Conduct for Life Sciences Professionals, University of Southern California Global Business Initiative
- National Science Advisory Board for Biosecurity, Life Scientists: Core Responsibilities Regarding Dual Use Research of Concern, July 2006 draft

^a The Codes Archive of the Organization for Economic Cooperation and Development lists other codes online at www.biosecuritycodes.org/codes_archive.htm. Accessed November 26, 2008.

SOURCE: Adapted from Kellman, B. 2007. *Bioviolence: Preventing Biological Terror and Crime*. New York: Cambridge University Press, p. 141.

principles for consideration by governments and nongovernmental groups. Box 1-10 identifies several codes of conduct and related types of international pronouncements.

DOD'S INVOLVEMENT IN DEVELOPING COUNTRIES

In 1997, in accordance with a decision of President Clinton, DOD expanded its role in addressing threats to the United States and to other nations posed by infectious diseases that were emerging or reemerging throughout the world.¹⁵ Requirements for demonstrating direct linkages between proposed DOD health-related activities abroad and the health of U.S. armed forces personnel deployed abroad were to be relaxed. This expanded international

¹⁵ Presidential Decision Directive NSTC-7. 1996.

mandate for DOD in the medical field was soon buttressed by a National Intelligence Estimate (NIE) in 2001 that stated the following:

Emerging infectious diseases are a global security issue because they have the capacity to harm U.S. interests abroad through destabilizing key institutions, obstructing trade and human migration, slowing or reversing economic growth, fomenting social unrest, and complicating U.S. response to refugee situations by increasing the demand for humanitarian intervention and through their association with biological terrorism and warfare.¹⁶

DOD has underscored the validity of this NIE by pointing to the international significance of the quick emergence of severe acute respiratory syndrome in 2003 and avian influenza in 2005.¹⁷ From DOD's perspective, infectious diseases are a national security issue, and DOD must respond to the threat that they pose. Other U.S. government departments also consider such outbreaks as national security issues.

Against this background, DOD continues to strengthen its overseas public health capabilities, pointing, for example, to successes in improving diagnostic capabilities for malaria, dengue, and respiratory diseases. In recent years, DOD has carried out medical activities in more than 60 developing countries, relying heavily on its 5 overseas laboratories as well as other resources temporarily deployed abroad.¹⁸ In short, DOD has a well-developed medical system within the U.S. government with a mission of health surveillance through the monitoring of infectious disease outbreaks using modern laboratory methods for detection coupled with standard epidemiological surveillance methods.¹⁹

This growing activity by DOD, directed in large measure to disease surveillance and response, reflects DOD's view of the significance of this national security issue. An important part of the DOD activity is development of new drugs and vaccines for use against malaria, dengue, diarrheal diseases, meningitis, and adenovirus. This interpretation of "national security" is only one of several factors that need to be taken into account as to whether DOD should become involved in specific country situations.

Appendix E describes the missions and highlights particularly relevant activities of 15 DOD entities that have activities in developing countries outside the FSU.

BTRP has in large measure operated independently from many of the other health-related programs supported by DOD. There have been important exceptions; and now BTRP is increasingly engaging several other DOD organizations, particularly Walter Reed Army Institute of Research, the U.S.

¹⁶ U.S. Department of Defense. 2007. P. 3 in DoD Global Emerging Infections Surveillance and Response System Annual Report Fiscal Year 2006. Silver Spring, MD: DOD.

¹⁷ DOD. Global Emerging Infections.

¹⁸ *Ibid.*, p. 68.

¹⁹ *Ibid.*, p. 5.

Army Medical Research Institute of Infectious Diseases, and a DOD overseas laboratory, the U.S. Naval Medical Research Unit 3 (NAMRU-3), in its activities in the FSU. Still, the arrangements have been largely ad hoc and often are not well integrated, as discussed in Chapter 3.

AN EXPANDED PROGRAM TO ENHANCE BIOSECURITY

Recommendation 1-1: DOD should, within the U.S. government's evolving global biological engagement strategy, promptly expand BTRP into selected developing countries beyond the FSU.

As noted previously, potent ingredients for bioterrorism attacks are becoming more available to vengeful parties in developing countries. The skills required to launch such attacks are not difficult to buy, borrow, or develop. BTRP is the largest biological nonproliferation program in the world. The United States and the broader global community can benefit from an expansion of BTRP to protect their assets. The expansion should be on a sufficient scale to significantly reduce the threat of bioterrorism.

However, a geographical expansion of BTRP should be undertaken within an interagency context—both to ensure complementary approaches of different U.S. government agencies and to facilitate BTRP's drawing on appropriate expertise across the government. At present, the secretary of state must concur with any expansion of BTRP activities; and this requirement helps ensure that BTRP activities will be launched within a government-wide context. At the same time, the agencies should recognize the importance of BTRP's assets and encourage BTRP to expand its activities.

Also of importance is recognition by BTRP, and indeed throughout the U.S. government, that there is considerable overlap between strengthening health and agriculture disease surveillance systems that are already in various stages of development in developing countries and enhancing biosecurity capabilities of the countries. (See Chapter 5 for additional discussion of interagency coordination.)

A reasonable target is for BTRP to begin biological engagement in at least 10 countries outside the FSU during the next 5 years. Ten countries is a reasonable number given the seriousness of the global threat, the complexities of effective engagement, and the limited resources that are likely to be available to BTRP. This is a more ambitious objective than current DOD plans that call for new engagements with only three countries within or outside the FSU during the next 5 years. Engagement in three countries is an inadequate response to a widespread global threat. DOD estimates that the total cost of engaging three countries would be about \$180 million and has preliminarily earmarked such funding in its long-term planning process. The basis for such an estimate depends on a multiplicity of factors related to the levels of engagement, which

in turn depend on the countries of interest. Nevertheless, the estimate provides one perspective of the costs of expanding into the developing countries.

The levels of engagement should be appropriate to country-specific threats, to local capabilities for effective use of enhanced capabilities, and to interests of counterpart countries in such engagement. At the same time, BTRP should not divert resources that BTRP needs to complete activities in the FSU for its new efforts. This financial challenge requires careful analyses of where and how BTRP can achieve the greatest impact in risk reduction within the context of commitments of both local and international commitments to biosecurity.

Recommendation 1-2: BTRP’s initial engagement activities in any developing country outside the FSU should be planned to last for up to 5 years, with consideration given to extending engagement activities for another 5 years depending on initial successes in reducing biological threats and the future importance of continued engagement.

To implement this recommendation in a responsible manner, BTRP will have to launch programs promptly and implement them without the delays that too often have characterized activities in some countries of the FSU largely because of DOD’s reluctance, despite the potential threats, to make BTRP activities a priority. (See Table 1-3 for the long timelines in the countries of the FSU.) Also, BTRP needs to emphasize the importance of *sustainable* biosecurity programs and the necessity for host governments to promptly attract multiple international partners to the long-term task of enhancing local capabilities. A similar challenge has been encountered within the President’s Emergency Program for AIDS Relief, and BTRP should review relevant steps taken in this program. There are too many countries with severe biosecurity vulnerabilities for BTRP to remain in any country for a long period in order to address sec-

TABLE 1-3 Duration of BTRP Engagement in Countries of the FSU

Country	Duration of Engagement
Armenia	2008-? (end date not yet set)
Azerbaijan	2005-2013
Georgia	2002-2015
Kazakhstan	2003-2016
Russia	1997-2009
Ukraine	2005-2013
Uzbekistan	2003-2016

SOURCE: Biological Threat Reduction Program, October 2008.

ondary problems. However, within a constrained timetable BTRP can not only complete important upgrade activities but can also help jump-start additional activities and be a catalyst for action for complementary and sustained activities by others, and particularly by the host countries themselves.

The remainder of this report addresses how enhanced biosecurity capabilities in developing countries can help prevent groups or individuals with hostile intentions from obtaining and dispersing harmful biological agents. It describes conditions in a variety of countries and provides a menu of activities that could be undertaken by BTRP. It also presents lessons learned by several organizations that are engaged in preventing bioterrorism.

The report will show that BTRP is in a good position to help counteract nefarious schemes of individuals who live in or have access to developing countries and who are determined to wreak havoc with infectious diseases, whether for ideological or personal motives. At the same time, BTRP must ensure that its activities do not inadvertently contribute to bioterrorism concerns. Training specialists, collecting pathogens in centralized facilities with uncertain long-term security, and transporting pathogens by insecure means all have the potential to offer new targets for terrorists.

Capacities of Developing Countries to Counter Biological Threats

The capacities of the more than 130 low- and middle-income countries to counter existing and potential biological threats vary greatly, although most countries have severe weaknesses in this regard. Box 2-1 provides an important overview of systemic weaknesses across the developing countries.

This chapter highlights four critical aspects of a country's capacity to address effectively the proliferation of biological weapons within, into, or out of the country. They should be of special interest to the Biological Threat Reduction Program (BTRP) and are as follows: (1) the availability of trained human resources in many relevant fields; (2) an appropriate policy framework for addressing a variety of cross-cutting biology-related development and security issues; (3) an adequate physical infrastructure and supporting services for carrying out activities to prevent, detect, characterize, and respond to disease outbreaks; and (4) the government's commitment, through implementation of appropriate policies, budgetary allocations, or both, to enhancing biosecurity in ways that take advantage of and reinforce global biosecurity efforts. Several BTRP actions are recommended in these areas, taking into account BTRP's experience in the former Soviet Union (FSU), but recognizing the need to adjust programmatic approaches to the situation in each country of interest.

TYPES OF BIOLOGICAL THREATS

As discussed in Chapter 1, naturally occurring biological pathogens are of far greater concern to developing countries than seemingly abstract threats of bioterrorism. For decades, common diseases have spread across large portions of the world such as HIV/AIDS, malaria, cholera, hepatitis, and foot-and-mouth disease. Also, disease syndromes such as respiratory illness are commonplace. Other diseases of concern may be unique to specific regions.

BOX 2-1
**Systemic Weaknesses in Addressing the
Risk of Disease Threats**

Most developing countries have limited ability to

- monitor disease patterns,
- identify new organisms,
- investigate outbreaks and routes of transmission,
- stockpile and mobilize commodities,
- rapidly respond with trained staff,
- educate the public on prevention and care seeking,
- regulate unsafe animal rearing, transport, and selling, and
- coordinate routine and emergency operations among health, animal, and other sectors.

SOURCE: U.S. Agency for International Development briefing to the committee, November 3, 2008.

Some diseases emerge in one region and are then transported by different mechanisms to other regions hundreds or even thousands of miles away. Avian influenza is an example. At the same time, other disease agents have been confined to local areas as the result of national and international disease control efforts.

Several infectious diseases that are present in developing countries and are of concern to the U.S. government are set forth in various lists of dangerous pathogens. BTRP in particular has a list of diseases, syndromes, and agents of concern (see Box 2-2). U.S. interagency working groups and other agencies also have their own lists for determining research and surveillance priorities.

The focus of this report is on malevolent actions of disenfranchised groups or individuals that deliberately divert dangerous biological substances to destructive causes. The capabilities and approaches of such adversaries vary, depending on their technical skills and on the political, economic, and security environments where they operate. The perpetrators may change their approaches or their target countries over relatively short periods of time, perhaps periods of several years. The threats are usually country-specific and require country-specific responses that should be both flexible and sustainable. Of course, well-developed epidemiological and surveillance programs, together with proven laboratory diagnostic techniques, are broadly applicable in addressing many types of disease burdens and in identifying unusual outbreaks.

An important aspect of the capacity of developing countries to address

BOX 2-2
**Diseases, Syndromes, and Agents of Priority Concern to
BTRP in the Former Soviet Union**

- Diseases: high priority for plague, anthrax, brucellosis, tularemia, Crimean-Congo hemorrhagic fever (CCHF), tick-borne encephalitis, foot-and-mouth disease, rinderpest, classical swine fever, African swine fever, Newcastle disease, glanders, poxviruses, avian influenza
- Syndromes: high priority for fevers of unknown origin requiring hospitalization, flu-like symptoms requiring hospitalization
- Other: entire Select Agent list except plant pathogens

SOURCE: BTRP, November 2008.

biological threats is the expanding activities of biotechnology firms in some countries. As they increase their activities, local capabilities to understand disease characteristics and countermeasures should also increase. At the same time, however, there may be fears that the dual-use assets of emerging biotechnology firms, including the expertise of their employees, could be diverted by irresponsible parties for inappropriate purposes. Also of concern is the possibility of unintentional incidents. For example, research by local biotechnology firms or governments intended to address chronic food shortages by exploring genetically modified crops could inadvertently damage traditional crops on nearby fields, could create disease viruses with unknown properties, or could break down disease resistance in livestock or humans. As noted in Chapter 1, in Pakistan the government is greatly concerned about this aspect as agricultural research activities intensify.¹

Also as discussed in Chapter 1, reducing and countering the threats of naturally occurring diseases to human health and agriculture have long been an objective of many organizations, including foreign assistance agencies. But the potential problems of bioterrorism are widespread and have not been adequately addressed. Greater efforts by both individual governments and international development organizations are needed to upgrade the capacity of developing countries to counter all types of biological threats.

Against this background, this chapter considers common vulnerabilities of developing countries to infectious diseases. These vulnerabilities have been present for decades to some degree within almost all countries. Now, with

¹ Senior Pakistani official, presentation in Washington, D.C., July 2008.

greater capabilities in the biological sciences of vengeful groups and individuals, actions to reduce vulnerabilities deserve more attention.

Biosecurity weaknesses vary in scope and intensity in countries at different stages of development, in different geographical settings, and within different political and economic environments. These countries range from the more advanced middle-income countries such as Malaysia, which has a growing biotechnology sector and is increasing its readiness to counter at least some of the common biological threats, to countries near the bottom of the development scale such as the Democratic Republic of the Congo, where the government has little capability to counter bioterrorism that might take root in the country or to deal with endemic diseases.

Tanzania is an example of a developing country with a long history of unresolved problems that contribute to vulnerabilities to diseases. These problems include the government's preoccupation with other issues, such as hunger and education, conflicts between the government and international donors over funding priorities and acceptable time lines for discernible impacts of projects on development problems, rudimentary survey and surveillance capabilities, inadequate laboratory equipment, need for trained and motivated personnel, and weak supporting services. At the same time, the government is increasingly aware of steps that should be taken to combat diseases.²

Countrywide risk assessments or prioritization of vulnerabilities in specific country settings are not presented in this report. Such ambitious efforts, while critically important, were beyond the scope of the study. However, this chapter identifies types of biosecurity weaknesses that should be taken into account in establishing a framework for BTRP's efforts to carry out risk assessments, to set priorities for countering disease outbreaks, and to determine needed biosecurity upgrades.

Recommendation 2-1: BTRP should continue to emphasize to partner governments the importance of their strengthening on a broad basis the infrastructures necessary to address human, animal, and plant diseases and the underlying scientific capabilities of the countries as essential foundations for addressing threats of bioterrorism.

Health and agriculture disease surveillance systems and associated research facilities are obviously important. The security services, facility design and construction entities, and electric and water utilities play significant roles. Well-functioning transportation systems and communication networks are needed. As discussed below, of critical importance are the education, training, and

² Yonglolo, M. G. 2008. Sustainable global capacity of surveillance and response to emerging diseases of zoonotic origin. Presentation in Washington, D.C., July.

employment infrastructures that can increase the number and quality of personnel engaged in biological activities.

The following sections address three critical aspects of the necessary infrastructure:

1. Human resources
2. Policy framework
3. Physical infrastructure, including facilities, support services, and data systems

HUMAN RESOURCES

The deficiencies in the availability of skilled human resources in all developing countries have for many decades been a major international development concern of the United States and other industrialized countries, as well as the developing countries themselves. From research scientists and medical doctors to security guards and maintenance personnel, the types of technical personnel who are needed for an effective biosecurity regime are in short supply. Short-term training programs supported by external parties to enhance specialized skills directly or indirectly related to biosecurity are commonplace in almost every developing country. But they are limited and are seldom adequate in quality of instruction or in the number of graduates to provide a solid basis for reducing pervasive deficiencies in skilled work forces.

Many well-educated and adequately trained specialists in biology-related fields have difficulty finding rewarding employment in their home countries. In some developing countries, for example, foreign organizations have donated state-of-the-art laboratory equipment that is idle because of a lack of funds for supplies and maintenance or lack of technical expertise. Frustrated by inadequate salaries, poor working conditions, or both, many specialists simply abandon their scientific careers for positions in banking, commerce, or other more lucrative endeavors. They often turn for employment to foreign entities operating in their countries, which pay higher salaries and provide more comfortable working conditions than local organizations for specialists, particularly those with international experience. Others leave the country with the intention of returning but find the attractions abroad addictive. In short, at the top of the list of impediments in promoting international development or in enhancing biosecurity are the shortages of adequate human resources with the requisite skills.

Examples of the different situations in different countries are Pakistan, Indonesia, and the Philippines. Despite a massive brain drain, Pakistan nevertheless has a substantial cadre of well-trained scientists available to work on both biological research challenges and biosafety issues. In Indonesia the situation is bleaker, with only a limited number of specialists, who have been trained

primarily in Australia. Still of greater concern is the situation in the Philippines, given the inadequacies of the outdated educational system and its failure to keep pace with developments in neighboring countries.³

The same security personnel frequently assume responsibility for both biosecurity and biosafety. Few formal educational programs exist in these fields, although biosecurity seems to be of growing interest. For example, a leading Moroccan university has established an educational program in the field of biosecurity.⁴ Specialized training programs will probably be important in many countries for the foreseeable future. Biosafety associations at the regional and national levels, such as the African Biosafety Association, are increasingly being formed and provide good training venues. Regional organizations have also become interested in sponsoring training workshops and special courses to help upgrade skills in these areas. On a broader but related basis, in the FSU, BTRP has provided training in laboratory management, design of laboratory systems, associated maintenance, and project management.

Some level of advanced scientific skill is needed by every country as an underpinning for biosecurity-related programs across a range of development sectors. Designing and managing laboratory systems to detect and respond to outbreaks of diseases, for example, are obviously dependent on scientific capabilities. As countries begin to undertake research efforts that are intended to contribute to improved health, agriculture, or environmental system capabilities, a steady influx of well-prepared young specialists is essential for sustainability. However, the necessary educational capabilities to prepare such scientific cadres are not well developed in most countries that are likely to be of interest to BTRP.

For scientists working in developing countries, continuing communication with an international network of colleagues is important. The network could include U.S. government laboratories and local government facilities. Also, sustained university-to-university relationships can be of special importance. Such contact enables local scientists to use the products of international science and to have a sense of belonging to the broader international community. Support for attendance at international meetings, encouragement of publications in internationally recognized journals, and development of joint projects are desirable goals. BTRP and its U.S. partner organizations have considerable experience in supporting such activities.

³ According to the United Nations Educational, Scientific and Cultural Organization (UNESCO) Institute of Statistics, the total number of research and development personnel in these countries was as follows, as of the date in parentheses: Indonesia 52,000 (2001); Pakistan 102,000 (2005); the Philippines 13,500 (2003). These data were taken from the institute's Web site, stats.uis.unesco.org. Accessed December 31, 2008. For purposes of comparison, such personnel represented approximately 0.02 percent of Indonesia's population, 0.06 percent of Pakistan's population, and 0.015 percent of the Philippines' population, compared with 2007 World Bank population figures.

⁴ Information provided by a Moroccan government official, November 2008.

An often neglected aspect of biosecurity is the need for a strong cadre of engineers and technicians who design and maintain equipment, facilities, transportation and communication networks, and electrical and water systems that provide the backbone for many activities. Unfortunately, this physical infrastructure is in fragile condition in almost every developing country. Some of the malfunctioning of existing systems can be attributed to weak engineering skills within the countries. This problem should be recognized in considering future systems that require high-technology skills to maintain and operate.

Well-trained specialists usually command substantial salaries in engineering-related fields, resulting in competition for the limited pool of specialists. The number of young specialists trained is woefully inadequate in most countries of interest. Establishment of engineering universities has not been a strong aspect of development assistance activities, although there are exceptions, such as establishment of the Indian Institutes of Technology and the Asian Institute of Technology. BTRP cannot be expected to take on the burden of expanding educational opportunities for engineers. But BTRP can provide financial incentives such as fellowships to encourage students who have studied abroad or trained locally to seek engineering careers and then to work to strengthen the physical infrastructures that provide the underpinnings for biosecurity improvements.

Recommendation 2-2: BTRP should give special attention to strengthening the human resource base to address biosecurity challenges.

Biosafety training may be an appropriate entry point for sustained engagement if there is local interest. Training in technical subjects such as epidemiology, laboratory analytical techniques, use of geographic information systems and global positioning systems, equipment maintenance and repair, and field-sampling methodologies should also be considered. In addition, biological ethics and research management are important topics. BTRP has initiated activities in all of these areas in the FSU.

But even more fundamentally, BTRP's contributions to upgrading important components of the partner nation's educational system may be necessary to help achieve an acceptable level of biosecurity capabilities. To help ensure sustainability, training of the trainers and education of the educators should be considered from the outset. International and regional initiatives, including short-term visits to the United States and to regional centers of excellence by developing-country specialists, may offer opportunities for joint external efforts in many aspects of education and training while enhancing the viability of international networks of institutions of specialists.

POLICY FRAMEWORK

Many developing countries have well-developed policy frameworks for programs in the health and agriculture sectors that encompass activities directly related to biosecurity. The international development banks, UN agencies, and U.S. and other bilateral donors have for decades played active roles in the development of such policies. Often a broad policy framework that surrounds and drives a specific program has been a precondition for reaching international agreement on a relevant loan by an external organization (for example, the World Bank) to finance the program.

A variety of economic, industrial, environmental, and other policies overlap with biosecurity concerns. They include, for example, intellectual property rights that may affect support of research activities, export control limitations that relate to international exchanges of pathogen strains, and trade policies that affect the tax aspects of needed equipment for facilities.

It is unlikely that biosecurity will command a special policy framework involving a range of legislative actions, national regulations, and ministry directives, as biosecurity cuts across many traditional development fields. Rather, it is more likely that the framework for biosecurity-related activities will have components in a variety of policies established for other purposes (see Box 2-3, for example). Strong policy support for biosecurity programs is important, particularly if funding is to be directed to upgrading facilities and human resources that include substantial investments. Of course, the policy framework must be consistent with the goals of BTRP.

A critical issue is the effective implementation of existing policies. Of special concern is *sustainable* implementation of program commitments if long-term external financing for projects is not available. In any event, a good policy framework is an important starting point for considering major external investments in biosecurity.

BOX 2-3

Agriculture Policy as a Component of Biosecurity

“Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyze and manage risks in the sectors of food security, animal life and health, and plant life and health, including associated environmental risk.”

SOURCE: Deputy Director General, Department of Agriculture, Malaysia, Asia-Pacific Economic Cooperation workshop, October 13, 2008.

Recommendation 2-3: From the outset of engagement with a specific country, BTRP should give attention to encouraging the country to improve its policy framework that affects upgrading of biosecurity capabilities and related activities.

PHYSICAL INFRASTRUCTURE: FACILITIES, SUPPORT SERVICES, AND DATA SYSTEMS

In most developing countries, some or all facilities that handle pathogens should be upgraded, and in some cases, new facilities should be constructed, in order to address both biosafety and broader biosecurity concerns. In some countries, such as Pakistan, there are dozens of significant facilities. In other countries, such as Bolivia, there is only a handful. Often several facilities are well secured but others are not (for example, in Colombia).

In addition to the security aspects of facilities, there are issues regarding the capabilities of these facilities to contribute effectively to the national effort in controlling diseases and in conducting research. The laboratories may be searching for new tools for use in the agricultural, health, and environmental sectors. They may be laboratories for training university students. They may be diagnostic or health service centers. Whatever their functions, it is important for BTRP to work with counterpart ministries to ascertain whether they should be upgraded, reconfigured, or even closed because of the risks associated with security inadequacies.

In the FSU, BTRP correctly focused on establishing near-term security of pathogen collections. This concern is equally important in many developing countries. These collections may be distributed throughout the country for use in veterinary laboratories and health clinics. They may be housed in universities that have relevant courses and research. Professors concerned about theft of their research materials may even keep them in private basements or other places that they consider to be safe from theft.

As underscored in the preceding section, supporting services are often unreliable. Electricity failures can affect both scientific endeavors and security procedures. Water and sewage problems can disrupt work. Communication failures may prevent reporting of outbreak data and receiving of relevant information to investigate outbreaks. Heating and cooling problems can render facilities inoperable, and scientific equipment breakdowns are rampant in developing countries.

The foregoing concerns lead to two recommendations.

Recommendation 2-4: BTRP should draw on its extensive experience in providing and upgrading facilities and equipment in the FSU to improve the functioning of important facilities in the developing countries, including both scientific and security aspects.

Recommendation 2-5: An early step in BTRP engagement efforts with specific countries should be to jointly identify and characterize pathogen collections—both collections established under the auspices of the government and informal collections under the purview of individuals or groups of scientists. The security aspects of these collections, and particularly the capacity of the government to ensure compliance with internationally acceptable biosafety regulations on a long-term basis, should be given high priority.

Effective data systems are an essential component of the infrastructure required to control the spread of diseases. Unfortunately, in most developing countries, these systems are very rudimentary in design and operation. Common problems include the following:

- Some diseases are not reported, and the data that are available on reported diseases are incomplete.
- Available data are unverifiable, and the data may be politically biased.
- Detection, diagnosis, and confirmation of suspected outbreaks are impossible to carry out.
- Sources of diseases (tourists, business travelers, migrant laborers, neighboring countries, indigenous reservoirs) are unknown.

The objective of BTRP's Threat Agent Detection and Response (TADR) Program is to address precisely these questions. It is still in the early stages of development, but some aspects may be helpful in the developing countries, as discussed in Chapter 3.

Additional systems that deserve mention are the systems to protect water and food supplies from bioterrorist attacks. While this has not been an area of responsibility for BTRP in the past, the unprotected character as well as the generally poor sanitation aspects of these systems should be taken into account. Also, deliberately infecting the components of the systems with biological agents may not be difficult. It is unlikely that in the near future developing countries will take aggressive measures to replace water and food delivery systems that have been in place for many decades. However, a few precautionary upgrade steps (for example, licensing of operators of facilities and surveillance of critical points in the distribution systems) should be easy to implement. Simply raising awareness about these steps to counter the threat of bioterrorism is important.

COMMITMENT TO BIOSECURITY BY DEVELOPING COUNTRIES

The commitment of a developing-country government to adopting and maintaining biosecurity standards is reflected in actions or lack of actions in all of the above areas: the involvement of skilled personnel in disease-related

programs, the policy framework within which these personnel work, and the infrastructure and support systems that are available to enable the specialists to address important problems. Frequently, external parties play important roles in supporting this commitment. However, too often the government does not recognize the importance of controlling diseases beyond limiting the immediate adverse impacts of diseases on the population and on agricultural resources. Of course, addressing these impacts is essential and is an important aspect of a long-term biosecurity program.

Raising awareness of local government officials, specialists, and the public regarding the seriousness of biological threats in the future is important if cooperative threat reduction programs are to succeed. An effective mechanism for raising awareness is the launching without delay of cooperative projects that highlight existing vulnerabilities and demonstrate by example practical approaches to correcting deficiencies both in security and in productivity of facilities. The communities of specialists in biosecurity, systems management, and scientific research are small in most developing countries. Thus, word about cooperative projects will spread quickly. Promptly launched cooperative projects that team national and international partners rather than vague promises and discussions will help win support of other governments for achieving a variety of U.S. objectives in the economic and political spheres, including economic development and counterterrorism objectives.

Applicability of Biological Threat Reduction Approaches in the Former Soviet Union to Other Developing Countries

Since 1998, the Biological Threat Reduction Program (BTRP) has developed into a broadly based international program operating in seven countries of the former Soviet Union (FSU). As previously discussed, its overall objective is to reduce the likelihood of proliferation of materials, equipment, technologies, and expertise that could be used in the development or construction of biological weapons. This objective includes reducing the risk of bioterrorism. In 2008, BTRP received funding to explore the expansion of its activities to developing countries outside the FSU. This report, and particularly this chapter, is directed to such an expansion.

In the FSU, BTRP has used a wide range of approaches spanning the security, scientific, public health, and agriculture fields, which have been designed to help prevent the proliferation of biological weapons. The budget for BTRP's activities through Fiscal Year (FY) 2009 has been almost \$800 million. The budget for FY 2009 is about \$185 million. Ten million dollars from FY 2008 funds and a comparable amount from FY 2009 funds are to be directed to activities in developing countries beyond the FSU.

Budget projections of the Department of Defense (DOD) show growth of BTRP to about \$250 million annually by FY 2014. Expecting gradual expansion of activities beyond the FSU, DOD has estimated that about \$180 million of the total BTRP budget through 2014 will be used to expand the program to other countries, primarily outside the FSU. Thus, according to these projections, the major geographic focus of BTRP will continue to be selected states of the FSU for the foreseeable future.

In FY 2008, BTRP's funds were devoted primarily to three categories of activities: (1) biosecurity and biosafety, (2) threat agent detection and response (TADR), and (3) cooperative biological research (CBR). The first and second categories included many construction projects to establish and renovate diag-

nostic facilities, a variety of training programs, and efforts to enhance laboratory and field investigation capabilities in order to improve surveillance capabilities. These activities will probably continue to command most of the available funds for the foreseeable future. CBR funds have supported both researchers in the FSU and U.S. collaborators. The funds have also been used to purchase equipment when needed by FSU participants for specific research projects and to upgrade laboratories in the FSU.

Until FY 2008, funds were also devoted to activities in a previously existing category of dismantlement and conversion of facilities. These efforts had included redirection of three facilities in the FSU that produced pathogens and other materials that could be used for biological warfare activities. BTRP has completed its activities in this category.

The future of BTRP within the FSU was considered in the October 2007 report.¹ This report draws on the October 2007 report in discussing future BTRP activities while recognizing the many differences between operating in the FSU and in other regions.

THE NEED FOR A SUSTAINED COMMITMENT TO NONPROLIFERATION

As discussed in Chapter 1, the likelihood of bioterrorism attacks in developing countries outside the FSU is growing in unpredictable directions. Countering bioterrorism is highly complicated, requiring a wide-ranging defensive infrastructure. Many scenarios could be carried out exploiting the vulnerabilities found in almost every developing country.

As emphasized in Chapter 1, tens of millions of dollars will be required for BTRP to have a significant impact on limiting proliferation of dangerous biological assets within, into, or out of even a handful of developing countries beyond the FSU. The problem is widespread, and activities to reduce some of the most important vulnerabilities are expensive. Few developing countries have major resources of their own to devote to countering the potential of bioterrorism.

As will be discussed in Chapter 4, substantial international development assistance resources are being devoted to strengthening the capabilities of developing countries to control health and agriculture diseases. Of course, such activities will help in the prevention of and response to threats of bioterrorism. But in the FSU, BTRP—together with programs of several other U.S.

¹ National Research Council Committee on Prevention of Proliferation of Biological Weapons. 2007. *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=12005. In the current report this report is referred to as the “October 2007 report.”

departments—has more directly addressed vulnerabilities of bioterrorism concern. Such a focus should be one of the essential aspects of nonproliferation approaches in other countries as well.

The U.S. commitment to biological nonproliferation activities focused on the developing countries outside the FSU during the next 5 years will be determined in significant measure by the size of BTRP's budgetary commitment and the success of its activities. Given the magnitude of the threat, BTRP's commitment for activities beyond the FSU should reach a robust level of prevention and response. At the same time, the planning and implementation of such activities should take into account issues raised throughout this report.

BTRP has had considerable success in working with the governments of the states of the FSU to upgrade many aspects of biosecurity. Still, with the possible exception of Russia, none of the countries is well prepared to sustain on its own successful approaches that have been financed by BTRP. Therefore, adopting approaches to ensure sustainability of activities initiated with the support of BTRP should be a high priority both within the FSU and in other countries as well.

THE UNIQUE ENVIRONMENT WITHIN THE FSU

The predecessor program to BTRP, the Biological Weapons Proliferation Prevention Program, was initiated by DOD in 1998 at a time of heightened international concern over the possibility that biological weapons-related activities would be undertaken in the FSU. It was believed that such illegitimate activities could be undertaken by the Russian government or by individuals previously involved in the Soviet weapons program who might develop connections to criminal or terrorist organizations. The legacy of a robust Soviet biological weapons program loomed large, and the U.S. government considered that greater transparency at previously closed biological facilities in the FSU was a national security imperative. At the same time, the states of the FSU were in a downward economic spiral. This decline raised additional international concerns over the possibility that impoverished scientists would try to earn money through the unauthorized sale of biological assets that together with their expertise could lead to dangerous consequences.

DOD's initial efforts quickly focused on containment of those assets of greatest immediate concern to U.S. biosecurity specialists. Prompt attention was given to consolidating and strengthening security of pathogen collections. Redirection to peaceful purposes of research activities at former defense-related facilities and of individual weapon scientists was a priority. Also, monitoring the use of the results of research carried out in the FSU that could be deliberately or inadvertently diverted to inappropriate uses rather than internationally acceptable applications became a related priority, although this task was difficult to

carry out. Each type of redirection activity was to promote transparency as an important contribution to prevention of proliferation of biological weapons.

The facilities of primary concern to the U.S. government included biological research and production centers that had histories of handling significant quantities of dangerous pathogens, which had been of interest to Soviet military authorities. These facilities were accustomed to extensive security procedures, including high fences and close screening of personnel. However, with the economic decline, security budgets were being reduced, and atrophy of effective security measures was apparent even within some of the most heavily guarded facilities. In short, the need for urgent action to prevent biological pathogens from falling into the hands of unauthorized personnel was widely recognized; and BTRP focused its efforts on obvious vulnerabilities, particularly at facilities where pathogens had been produced or handled under military contracts.

At the same time, the U.S. government recognized new opportunities to engage highly talented former defense-oriented scientists in the FSU in research of considerable interest to the United States—research for biodefense purposes and for applications in improving public health, combating agricultural diseases, and advancing fundamental science. BTRP became the largest U.S. government program that supported such researchers in the FSU, where the pools of well-trained and experienced specialists with previous orientations toward defense activities were large, although their equipment was rapidly aging, facilities needed improved maintenance, and salaries had dipped to low levels. Also, the intake of young talent to pursue civilian-oriented activities at research and production facilities had nearly halted because of the severe budget decline. In short, many members of a large pool of underemployed scientists were searching for opportunities to increase their incomes with declining personal concern over how their talents would be used.

No developing country outside the FSU has found itself in a comparable position involving (1) previous governmental leadership in developing biological weapons, (2) large and highly skilled pools of specialists with dual-use capabilities, and (3) a sudden shift from a stable, centrally planned economy to economic chaos as the transformation to market economies began. While South Africa established and then dismantled a biological weapons capability and may have residual capabilities of concern, it is an exception among developing countries.² When BTRP began its activities and even today, the conditions in the FSU were and continue to be different from the environments encountered in developing countries outside the FSU. Tables 3-1 and 3-2 present striking differences in the characteristics of developing countries within and outside the FSU that are relevant to biosecurity. For example, the differences in literacy rates and availability of trained physicians are particularly great.

² Purkitt, H., and S. Burgess. 2005. *South Africa's Weapons of Mass Destruction*. Bloomington, IN: Indiana University Press.

TABLE 3-1 Biosecurity-related Development Characteristics of Selected FSU Countries

	Armenia	Azerbaijan	Georgia	Kazakhstan	Ukraine	Uzbekistan
Population in millions, 2007 ^a	3,001	8,571	4,396	15,481	46,383	26,868
Gross national income per capita (U.S. \$), 2007 ^a	2,640	2,550	2,120	5,060	2,550	730
Annual gross domestic product (GDP) growth (percent), 2007 ^a	14	19	12	8	7	10
Life expectancy at birth, 2006 ^b	69	64	70	64	67	68
Adult literacy rate (percent of population age 15+), 2007 ^a	n/a	99.38	99.00	99.62	99.69	99.30
Total expenditure on health as percent of GDP, 2005 ^c	5.40	3.90	8.60	3.90	7.00	5.00
Improved water source (percent of population with access), 2006 ^b	98	78	99	96	97	88
Improved sanitation facilities (percent of urban population with access), 2006 ^b	91	80	93	97	93	96
Physicians per 10,000 population, 2000-2006 ^b	37	36	47	39	31	27
Persons employed in research and development, 2006 ^c	n/a	10,195	11,997	11,910	85,211	n/a
Gross tertiary enrollment rate, 2006 ^{c,d}	n/a	14.81	38.20	51.18	72.78	9.80
Computers per 1,000 people, 2005 ^c	n/a	20	50	n/a	50	30
Internet users per 1,000 people, 2007 ^a	n/a	120	80	120	220	40
Exports of goods and services as percent of GDP, 2006 ^b	n/a	72.50	45.30	50.60	48.20	38.40

^aThe World Bank Group World Development Indicators; www.worldbank.org. Accessed January 12, 2009.

^bWorld Health Statistics 2008; www.who.int/whosis/ubostat/EN_WHS08_Full.pdf. Accessed January 12, 2009.

^cThe World Bank Knowledge for Development (K4D) Custom Scorecard; info.worldbank.org/etools/kam2/KAM_page3.asp?default=1. Accessed January 12, 2009.

^dThe ratio of total enrollment, regardless of age, to the population of the age group that officially corresponds to the level of education indicated.

TABLE 3-2 Biosecurity-related Development Characteristics of Selected Countries Outside the FSU

	Democratic Republic of Congo	Malaysia	Mexico	Morocco	Pakistan	South Africa
Population in millions, 2007 ^a	62.399	26,550	105,281	30,861	162,389	47,588
Gross national income per capita (U.S. \$), 2007 ^a	140	6,540	8,340	2,250	870	5,760
Annual gross domestic product growth (percent), 2007 ^a	6	6	3	2	6	5
Life expectancy at birth, 2006 ^b	47	72	74	72	63	51
Adult literacy rate (percent of population age 15+), 2007 ^a	n/a	91.90	92.43	55.58	54.89	88.00
Total expenditure on health as percentage of GDP, 2005 ^c	4.20	4.20	6.40	5.30	2.10	8.70
Improved water source (percent of population with access), 2006 ^b	46	99	95	83	90	93
Improved sanitation facilities (percent of urban population with access), 2006 ^b	31	94	81	72	58	59
Physicians per 10,000 population, 2000-2006 ^b	1	7	20	5	8	8
Persons employed in research and development, 2006 ^c	n/a	12,669	33,484	n/a	12,689	17,915
Gross tertiary enrollment rate, 2006 ^{c,d}	n/a	28.58	26.08	11.83	4.52	15.41
Computers per 1,000 people, 2005 ^c	n/a	220	140	20	10	80
Internet users per 1,000 people, 2007 ^a	n/a	560	220	240	110	80
Exports of goods and services as percent of GDP, 2006 ^b	n/a	117.10	31.90	37.80	15.50	29.10

^aThe World Bank Group World Development Indicators; www.worldbank.org, Accessed January 12, 2009.

^bWorld Health Statistics 2008; www.who.int/whosis/whostat/EN_WHS08_Full.pdf, Accessed January 12, 2009.

^cThe World Bank Knowledge for Development (K4D) Custom Scorecard; info.worldbank.org/etools/kam2/kam_page3.asp?default=1, Accessed January 12, 2009.

^dThe ratio of total enrollment, regardless of age, to the population of the age group that officially corresponds to the level of education indicated.

At the same time, there are common characteristics when comparing opportunities for BTRP to achieve its objectives in the FSU with opportunities in other developing countries. Identified below are commonalities that deserve careful attention in this regard. In some cases, minor adjustments of BTRP approaches used in the FSU might be appropriate for deployment outside the FSU. In other cases, major modifications of these approaches are in order. In still other cases, BTRP's approaches may not be appropriate; and in some instances, BTRP may not be welcomed by other governments that are concerned about an expanded U.S. military presence—in such situations, BTRP probably should remain on the sidelines for the near future.

In any event, the achievements of BTRP to date provide a starting point for considering transportability of BTRP approaches developed in the FSU to other countries. The overall outcome of BTRP's activities in any country should be a reduction in the risk from bioterrorism. Two important aspects of risk reduction are (1) a reduction in the likelihood that pathogens that are present in the country or introduced into the country will be diverted for nefarious purposes within the country or elsewhere, and (2) an enhanced capacity to detect and characterize outbreaks causing excessive levels of morbidity and mortality. As discussed in Chapter 2, to achieve these outcomes, steps are needed in almost every developing country to strengthen (1) the human resource base; (2) the policy framework, including enforcement of an appropriate regulatory approach; (3) the existing physical infrastructure for carrying out activities involving pathogens; and (4) the government's commitment to nonproliferation. Discussed below are some of BTRP's activities to these ends in the FSU.

BTRP OBJECTIVES AND RESULTS

BTRP's available funds are currently focused primarily on achieving four principal objectives in the FSU, as follows:

1. Prevent the sale, theft, diversion, or unintended proliferation of bio-weapons-related materials, equipment, technology, and expertise through better control of access to biological pathogens and through greater transparency of research, surveillance, and related activities.
2. Consolidate especially dangerous pathogens into safe, secure repositories at central reference laboratories (CRLs) and establish effective monitoring systems for ensuring appropriate use of these pathogens.
3. Improve capabilities to detect, diagnose, and report bioterrorism attacks and potential biological pandemics through enhanced surveillance and improved investigations of disease outbreaks.

4. Catalyze strategic research partnerships involving U.S. scientists from the public and private sectors.³

Several positive changes in five countries of the FSU where BTRP has been most active (Russia, Georgia, Kazakhstan, Uzbekistan, and Azerbaijan) were identified in the October 2007 report. Changes observed in that report that seem to be desired outcomes of BTRP programs that might be carried out in other areas of the world include the following:

- Transparency at important facilities with dual-use capabilities that had not been open to foreign specialists on a regular basis
- Sharing of local databases involving pathogens with international collaborators
- Improved biosecurity and biosafety programs at research and surveillance institutions, particularly with regard to consolidation and physical protection of pathogen strains
- Development of national regulations and related training programs concerning the safety and security of biological materials and good laboratory practices that meet international standards
- Construction and equipping of modern research, public health, and agricultural facilities where disease-related activities of interest to both local and international specialists are carried out
- Adoption by local institutions with responsibilities for controlling diseases of U.S.-style approaches to facility and project management, to fiscal accountability, and to inventory control
- Attraction and retention of highly talented young specialists to upgraded local facilities carrying out research and providing services in the fields of public health and agriculture
- Capabilities of local specialists to use effectively modern diagnostic and research equipment
- Enhanced disease surveillance and response capabilities that become an integral part of the national effort
- Participation in scientific conferences and training programs abroad by local specialists interested in infectious diseases who had not previously traveled abroad
- Publication by local scientists in peer-reviewed international journals of their disease-related research findings that demonstrate their capabilities to participate effectively in international scientific activities
- Enhanced quality of local research projects and technology transfer activities that build on the experience and expertise of participation in international collaboration

³ BTRP presentation to the committee, July 2008.

At times, BTRP investments in the FSU have led to continuing international linkages among specialists based on friendships and common professional interests. These personal contacts help build mutual respect and trust necessary for successfully addressing technical issues with dual-use implications. They also provide important insights as to present and future scientific aspirations and intentions of foreign colleagues and their institutions in areas of national security interest.

Finally, intergovernmental cooperation in the biological sciences and biotechnology, exemplified by BTRP activities, offers important opportunities for political and scientific leaders from the United States and partner countries to discuss common security, public health, agricultural, and scientific interests. Together they have new opportunities to develop complementary approaches for combating the threat of global terrorism. They should quickly recognize the overlaps between immediate security concerns and long-term international development priorities.

APPROACHES TO EMPHASIZE IN OTHER DEVELOPING COUNTRIES

A central theme of the October 2007 report was the importance of transforming BTRP from a Washington-directed program of foreign assistance to a genuinely collaborative program of sustained partnerships with governments that contribute substantially to the program. Of course, the governments of many poor countries are accustomed to assuming that any foreign funds coming into the country are foreign aid and that they should appear grateful. But if they can be convinced through both words and actions that BTRP wants them to be true partners in every step of developing and implementing cooperative programs, the path to success of BTRP will be wide and the likelihood of sustainability will be increased.

Recommendation 3-1: As BTRP moves beyond the FSU, the theme of partnerships with counterpart organizations in host countries should be a guiding principle.

Multifaceted Approach

In recent years, BTRP has increasingly recognized the importance and benefits of a multifaceted approach to international engagement as an essential aspect for achieving overlapping biosecurity, public health, and agriculture objectives. Developing countries outside the FSU have little history of deliberate misuse of biological assets for weapons or for bioterrorism purposes. Some of their leaders are skeptical as to the benefit of diverting woefully inadequate national resources from well-established economic development priorities to

BOX 3-1

Strengthening Health Systems

“Strengthening health systems may sound abstract and less important than specific disease control technologies. However, without health system strengthening, there will be no results.”

SOURCE: World Bank. 2007. Healthy Development: The World Bank Strategy for Health, Nutrition, and Population Results, p. 5. Available online at siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1154048816360/HNPStrategyFINALApril302007.pdf. Accessed November 30, 2008.

programs for preventing bioweapons proliferation. Therefore, a multifaceted approach that addresses their development priorities as well as the priorities of the international security community, and particularly BTRP priorities, has much more appeal than a narrow biosecurity agenda of activities. Very simply, they will have an incentive to embrace foreign investments if the systems that are established support their own health and agriculture priorities, both in the near term and in the long term.

As previously noted, the BTRP approach has included not only enhancement of facility security but also jointly developed disease surveillance activities, collaborative research projects, implementation of biosafety procedures, and development of human resources. The near-term payoffs from investments in research and surveillance are difficult to measure. But in the longer term, they strengthen scientific capabilities and can be significant activities to help detect misuse of pathogens and to respond promptly to incidents resulting from misuse. As a primary example of responding to multiple biological threats, strengthening the entire health system is essential, as indicated in Box 3-1, although programs other than BTRP must carry most of the burden in this regard.

The wide variety of recommendations throughout the reports of the World Bank reflects the importance of a multifaceted approach to upgrading biosecurity capabilities. This approach is underscored in Recommendation 2-1 of Chapter 2 (page 50).

Country Assessments and Strategic Plans

During the past several years, BTRP has developed “Science Plans” to document and clarify its approach in countries in the FSU where it has programs. An elaboration of this general concept is applicable to other countries where BTRP plans to invest its resources.

Initially, BTRP focused in large measure on targets-of-opportunity. For example, if an important facility was not well secured and upgrades were of immediate interest to a partner government, BTRP would invest in physical upgrades. If an important research group had demonstrated a capability to obtain interesting research results, BTRP would support the researchers. If virulent pathogen strains were being used, BTRP would support biosafety training.

This approach provided good entry points into different countries while addressing significant problems. In the long run, however, it might have been more effective to launch activities within the framework of more comprehensive nationwide analyses.

Recommendation 3-2: BTRP should develop in cooperation with each partner government a Strategic Plan that describes the security situation and particularly vulnerabilities relevant to biological assets in the country, disease burdens and trends, local capabilities to detect and respond to outbreaks, and plans for cooperative threat reduction activities within the context of national plans and capabilities of both countries.

Development of country-specific Strategic Plans should begin during the process of BTRP's selection of countries for engagement. The first step should be multidisciplinary countrywide assessments carried out jointly with partner governments, particularly with the ministries of health and agriculture. Also, ministries of science and education should be involved, given their portfolios of direct relevance to BTRP interests. Of course, achieving coordination of these fragmented interests will not be easy. In many developing countries, such ministries are often so weak that they have difficulties with their own responsibilities, let alone with interfacing with other ministries. While mutual acceptance of these assessments will probably require resolution of controversial issues, they nevertheless should be prepared without delay—that is, in months, not in years, which has too often been the case in addressing nationwide issues in the FSU. The plans should be regularly updated.

The Strategic Plans should have several characteristics that have not always been embraced by BTRP in the FSU, including the following:

- A Strategic Plan should be jointly developed with organizations designated by the partner government.
- A Strategic Plan should be consistent with U.S. government-wide biosecurity and related objectives in the country. The plan should, of course, reflect host-country priorities while being consistent with BTRP's interests and capabilities.
- A Needs Assessment (see Box 3-2) that is jointly developed should be an important component of the plan. It should analyze current and potential

BOX 3-2 Needs Assessment

"In public health, an initial 'needs assessment' in a target population is critically important. It gives an estimate of the burden of disease or need, it describes gaps in services or responses, it provides a basis for setting priorities for interventions, it provides a baseline for estimates of program progress or success, and it begins the partnership and local ownership and helps build sustainability by breaking down barriers among disciplines and among local government agencies."

SOURCE: American health policy analyst commenting on the importance of country-specific needs assessments as important missing components of the TADR program, July 2007.

disease-related problems, including disease burdens throughout the country, the significance of these burdens, and current and recommended approaches to responding to the diseases.

- The plan should address the four common weaknesses in developing countries discussed in Chapter 2: human resources, policy frameworks, physical infrastructures, and host-government commitments to biosecurity.

- The plan should describe anticipated activities by BTRP while emphasizing steps to ensure sustainability of activities initiated under the auspices of BTRP.

- It should take into account relevant activities of other external parties as well as local activities.

- Emphasis should be given to engagement of both leading specialists and promising young specialists in the host country.

- The planned activities should be attractive to potential U.S. collaborators with appropriate skills and experience.

- The plan should include BTRP's time-limited exit strategy. Also, the plan should provide for early exit by BTRP should political or other developments negate the value of continued BTRP involvement in the country.

Both the World Bank and the United Nations Conference on Trade and Development (UNCTAD) are preparing a series of Science, Technology and Innovation Policy (STIP) reviews. These STIP reviews address many (albeit, not all) of the broader science and technology policy issues addressed in this report. The main government counterpart for these reports is typically a ministry of science or education. It may not be too difficult to incorporate many BTRP issues and concerns into ongoing STIP reviews, especially if this is seen as part of a broader U.S. government initiative focused on such high-priority

items as capacity building in the agricultural and health sciences, laboratory upgrades, student scholarships, cooperative research programs, and faculty improvement programs at local universities. Such cooperation with the World Bank and UNCTAD would probably add considerable credibility to BTRP's approach.

Pathogens of Interest

Initially, BTRP focused on a limited number of especially dangerous pathogens that were considered as likely agents for bioweapons, for example, biological agents linked to anthrax, smallpox, plague, Ebola, Marburg, and tularemia. While BTRP quickly found a common understanding of the basis for this emphasis within the formerly weapons-related facilities in Russia, these pathogens were of limited interest to the Ministry of Health in Russia and to many ministries in the other states of the FSU. There were too many other diseases of more immediate health and agriculture concern. Therefore, receptivity among many important officials and scientists of the FSU to such a short list of especially dangerous pathogens was not high. Also, many host-government officials were focused on preventable diseases of priority interest to the World Health Organization, ranging from polio to HIV/AIDS to tuberculosis.

At the same time, the economic situation throughout the FSU was critical. Most local officials succumbed to the attraction of external funds, however targeted, to help offset economic hardships. But as economic conditions improved, external funding became less of a dominant factor in promoting the program, at least in the oil-rich countries of Russia, Azerbaijan, and Kazakhstan.

It is unlikely that many countries outside the FSU will be attracted by a short list of especially dangerous pathogens or by even the entire Select Agent List of 72 pathogens. Indeed, in the United States and other industrialized countries, the Select Agent List is too limited as a focal point in establishing priorities, as has been demonstrated with the emergence of severe acute respiratory syndrome. Again, the partner governments may be attracted by external funding for currently underpaid scientists, regardless of the agents to be targeted. But such a rationale does not bode well for sustainability after BTRP departs the scene. In short, BTRP should focus on building capacity that will be helpful in addressing many diseases.

To its credit, BTRP has gradually expanded its list of diseases and agents of interest in the FSU. First, it focused on certain syndromes, such as illness requiring hospitalization, as indicators of the presence of diseases of concern, as well as on a list of especially dangerous pathogens. The syndrome approach enabled local officials and scientists responsible for surveillance activities to address many pathogens of interest. Second, BTRP has added a few diseases of global concern to the BTRP core portfolio, including avian influenza, swine fever, and cholera. Local interest in these diseases has been high in some areas

of the FSU. (See Box 2-2 for the list of diseases and pathogens that are currently considered by BTRP to be of priority interest.)

Recommendation 3-3: As BTRP considers engagement in developing countries outside the FSU with little or no history of biological warfare or bioterrorism activities, BTRP should continue to expand its list of pathogens of interest to include pathogens of high-priority local interest.

Other DOD programs have projects devoted to HIV/AIDS and to malaria and other tropical diseases that are threatening populations. While BTRP is not equipped to address these diseases, it can partner with other entities that have the needed expertise. The inclusion of such diseases in BTRP's portfolio, recognizing that the more traditional biological weapons agents must still receive appropriate priority, is important. In short, poor countries cannot afford both a separate surveillance system for pathogens of bioterrorism concern and a surveillance system for other disease agents. They are already well attuned to the International Health Regulations, and they should build on, and not compete with, these regulations, which help identify the many pathogens of interest.

Facility Upgrades and Integrating Contractors

The upgrading of research, surveillance, and related facilities has been at the center of BTRP's activities in the FSU. BTRP has relied almost entirely on U.S. integrating contractors to design and implement the upgrades. The contractors employ local subcontractors and local personnel for most of the required labor. Much of the construction material has been imported, sometimes without adequate consideration of local supplies that are available. However, now BTRP is relying more heavily on locally purchased materials and approaches that reduce long-term maintenance challenges when BTRP is no longer on the scene. This approach bodes well for sustainability.

In general, committee members have observed that the quality of facilities built or upgraded by BTRP contractors is usually state of the art. Modern construction makes a favorable impression on both local government officials and researchers who had become accustomed to working in rundown facilities. However, there has also been negative reaction to the expensive made-in-America approach. The U.S. contractors have often been criticized by local counterparts for using funds for imported materials and services that should have gone to local construction organizations and for not being sensitive to local priorities when working out details. On occasion, the practices of contractors are not appropriate and lead to criticism, as indicated in Box 3-3.

But, the need for facility upgrades that are sustainable in countries within the FSU is extensive, and responding to that need has been complicated, as indicated in Box 3-4. Conditions in developing countries beyond the FSU prob-

BOX 3-3

Criticisms of BTRP's Integrating Contractors

"Many problems have resulted from BTRP reliance on intermediary contractors who control budgets and do not inform institutes of details of budgets. Also, there is a lack of flexibility in budget practices of contractors, with all funds committed at the beginning of projects even if projects need to change. Perishable items (e.g., growth mediums and enzymes) are purchased so far in advance that they are out of date and unusable when they are needed."

SOURCE: Georgian senior scientist, April 2007.

"Some hardware ordered by the American contractor fails to meet our specifications. For example, freezer plugs don't fit our power outlets, vortex devices have no plugs, and the centrifuge does not match Eppendorf tubes."

SOURCE: Kazakhstani manager of BTRP project, April 2007.

BOX 3-4

Upgrading Facilities in the FSU

"We are not just dropping projects into well-equipped institutes that have staffs that are trained in modern techniques, that have biosafety programs up to U.S. standards, and that have animal-use protocols that would pass in the United States. We have to start with none of these and set them all up. This is an engagement program that supports institutes that have struggled through years of very poor funding. Their infrastructures are in terrible shape, and we try to modernize them. A large portion of the costs on the U.S. side is ensuring that such modernization takes place—training people correctly and designing facilities to meet U.S. standards. When the institutes are up to U.S. standards, the costs to the U.S. side will drop significantly."

SOURCE: U.S. scientific adviser to BTRP, May 2007.

ably will often be worse than conditions in the FSU. BTRP has clearly learned important lessons from its early experiences with contractors in the FSU. With individual integrating contractors now receiving hundreds of million of dollars, the pressure has increased within DOD for these contractors to perform well, although BTRP does not have the personnel to work with them as often as is desirable.

BOX 3-5

Problems Encountered by BTRP Contractors

- Undercapitalized and inexperienced local subcontractors
- Poor workmanship of local subcontractors, which requires reworking
- Complex permitting requirements
- Legal requirements to meet the letter and intent of local regulations
- Political developments that impact on desires of local governments to cooperate
- Constant concerns over long-term maintenance and sustainability
- Local disinterest in maintaining stringent timetables

SOURCE: Bechtel program manager, presentation to the committee, October 8, 2008.

Finally, the on-the-ground experience of contractors in overcoming obstacles in the FSU, such as those set forth in Box 3-5, will be important in Asia, Africa, and elsewhere. The contractors are accustomed to working in challenging environments, repeatedly emphasizing the importance of pursuing systems approaches, selecting and coaching local subcontractors, navigating local and regional procurement systems, and dealing with local employment regulations. While the contractors will continue to be targets for criticism of delays and other shortcomings in implementation, BTRP could not perform without them.

Recommendation 3-4: Projects requiring renovation and construction activities should be an important aspect of BTRP activities in countries outside the FSU.

To the extent possible, BTRP contractors should involve appropriate local institutions in all aspects of design and construction activities while of course continuing to provide quality control and accounting oversight. The long-term payoff from placing increased responsibility for renovation and construction projects in local hands should be substantial even though delays may be encountered.

In summary, BTRP has considerable relevant experience and well-qualified on-call contractors for physical upgrading of research, surveillance, and containment facilities. Such facilities are generally in poor condition throughout the developing countries. However, host country ministries should be fully engaged in the selection of the facilities for upgrading and in the technical approaches that are used. They should help ensure that facility specifications and laboratory

practices are consistent with local regulatory requirements, as well as with internationally acceptable approaches.

At the same time, the World Bank, the African Development Bank, and the Asian Development Bank, among others, frequently finance laboratory upgrades as part of their ongoing agriculture, health, and science development programs. Some of these ongoing activities may be relevant for BTRP. However, it is difficult to say for certain because BTRP standards or expectations for laboratory upgrades are not clear. The U.S. government could publish standards for reference laboratories and central instrumentation centers and have BTRP work actively with these multilateral development banks on laboratory upgrade programs.

Cooperative Research

Initially, BTRP-supported research was designed to redirect defense-oriented scientists to peaceful endeavors, to open doors and increase transparency in previously closed FSU laboratories, and to generate data directly related to BTRP's program interests. The research projects have usually been developed by FSU researchers, often in cooperation with U.S. counterparts, in fields designated as important by BTRP. The scientific integrity of the projects has been ensured by peer review in the United States, as well as by field visits to the FSU laboratories by U.S. specialists.

BTRP has devoted only a relatively small portion of its resources to support CBR in the FSU. Nevertheless, the results have been quite good, particularly in Russia, given the number of favorably received reviews of research results presented at international meetings. This success was partly due to parallel expenditures by BTRP for upgrading key research facilities so that they could carry out credible research of international interest.⁴

BTRP has recently encountered strong Russian government resistance to continuation of CBR. There clearly is a mismatch between CBR's nearly exclusive focus on bioterrorism-related pathogens in Russia and the interest of the Ministry of Health and Social Services in projects directly relevant to diseases affecting the population on a daily basis and requiring the ministry's attention. Also, political concerns about an appropriate DOD role are undoubtedly a factor in the ministry's reluctance to engage with BTRP.

In other states of the FSU, CBR commands strong support at both the government and the facility levels. A trend in the CBR program has been the

⁴ Appendix F of the October 2007 report lists the research projects supported by BTRP from 1999 to 2007. They ranged in size from \$108,000 to \$1.5 million, with a total of \$21.3 million transferred to the FSU institutions where the research was conducted. The support for CBR has increased substantially in FY 2008 (\$19 million) and FY 2009 (\$24 million). The budgets include costs of refurbishing laboratories when necessary. Travel support and occasionally stipends have also been provided for American collaborators.

closer coupling of CBR projects with the development of the TADR system. In earlier times, these two activities were carried out on separate tracks. Now CBR projects are increasingly justified as contributing in both the short term and the longer term to improved disease surveillance and response. Such coupling may also be appropriate in countries outside the FSU that are upgrading surveillance and response capabilities.

All recent CBR projects have involved U.S. collaborators from DOD's research organizations. Most have also included one or more additional U.S. collaborators from other government or academic research organizations. Reciprocal visits have been the norm. Consequently, many U.S. scientists now have a vested interest in research carried out in the FSU.

Projects in fundamental research that provide underpinnings for long-term surveillance activities, in addition to those with prompt applications of results, are of increasing interest to CBR. This interest is particularly high in several countries in Central Asia and the Caucasus. A sharper focus on fundamental research should attract additional leading experts from home and abroad to the program. In this regard, CBR currently lists the following research areas of particular interest:

- Genomics: detection and phylogenetic relationships of smallpox and hemorrhagic fevers
- Diagnostics: development of collection, detection, and identification technologies
- Immunology: identification of antigens and adjuvant development
- Disease surveillance: development of methods for pathogenic strain characterization and related epidemiological studies
- Therapeutics: manipulation and development of antivirals, antibodies, and bacteriophages

For many developing countries outside the FSU, such topics seem quite advanced and perhaps out of reach. Yet limited efforts on a highly selective basis could be useful in introducing particularly talented researchers to international trends. They could also contribute in the longer term to improved understanding of country-specific strains and related scientific uncertainties that are not being addressed by the international scientific community.

Some governments of developing countries outside the FSU should be enthusiastic about participating in the CBR program if the administrative arrangements are consistent with the approaches already used in their countries in working with international development agencies and other supporters of science. Also, the five overseas DOD research laboratories have extensive experience in reaching out to local research communities and seem well positioned to serve as an important link in BTRP's research engagement with other countries. Occasionally, there are frictions between the laboratories and local

officials (for example, in Indonesia), but these are the exceptions. The U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture also have scientific contacts around the globe and should be able to provide insights as to opportunities and problems in mounting efforts in low- and middle-income countries.

Of course, the needs of each country differ, and programs will have to be customized to fit the needs. Some countries have poor physical infrastructures, and significant research will first require laboratory upgrades. Almost all countries will need a substantial training component—for example, on research management, proposal preparation, and laboratory quality control—linked to research activities.

Effective research cooperation usually requires long-term commitments—perhaps 8 to 10 years to firmly establish research groups in poverty-stricken countries. Since BTRP should not remain indefinitely in any country, new mechanisms for sustaining particularly promising research projects over the long term should be considered. For example, in addition to country-specific activities, BTRP should consider establishing regional or global research grant programs to assure continued support of researchers who were nurtured through country-specific BTRP programs and who have important international contacts. A good example of the importance of U.S.-sponsored research in a country with very weak capabilities is a current project supported by the U.S. Army Medical Research Institute of Infectious Diseases in the Democratic Republic of the Congo. This project is aimed at identifying and characterizing very dangerous pathogens. It underscores the importance of BTRP relying on specialists from other organizations to lead important research activities in highly specialized areas. American academics as well as government researchers can play critical roles in such BTRP-supported research projects.

The World Bank has developed research and development improvement programs in a wide range of countries—for example, Kazakhstan, Chile, Brazil, Nigeria, and Uganda. These programs go beyond health and agriculture. Nevertheless, there may be important lessons of experience that could be gleaned from these programs and potential opportunities to link them to BTRP research interests. Such opportunities should be explored in countries of interest to BTRP where the World Bank is active.

Recommendation 3-5: BTRP should support cooperative biological research in countries where it engages, even if local research capabilities are limited.

In summary, cooperative research involving significant local and U.S. scientists from government and academia can be important for several reasons, and BTRP should continue to reach out to the U.S. academic community through the integrating contractors and directly when appropriate. It can enhance transparency of approaches to biological threat reduction and build trust in BTRP's

intentions. In time, regional networks of BTRP-supported researchers may offer particularly important approaches to building sustainable international research relationships as well as providing results of near-term interest to the international scientific community.

PROBLEMS ENCOUNTERED BY BTRP

BTRP has identified the problems set forth in Box 3-6 as being major challenges that have been encountered in the FSU. These same challenges are likely to be encountered in developing countries beyond the FSU.

Over the years, BTRP has encountered other problems in establishing programs in the FSU. Several deserve special attention, as discussed below. They will undoubtedly arise as BTRP reaches out beyond the FSU. In addition to BTRP experience in the FSU, the experience of other U.S. and international organizations in addressing related issues should be helpful to BTRP.

Bilateral Agreements, Executive Agents, and Appropriate Partners

In the FSU, BTRP has signed formal agreements with ministries and other government organizations as the basis for undertaking programs. Also, BTRP has required that each host government designate an executive agent. This executive agent serves on behalf of the government in approving specific actions in the development and implementation of cooperative activities.

However, this approach has not been acceptable to Russia, largely because of the reluctance of the Ministry of Health and Social Services to enter into an agreement with DOD, which is not its natural partner. Therefore, BTRP has

BOX 3-6 Challenges Encountered by BTRP

- Introduction of new technologies, methods, and practices creates training and sustainability challenges.
- It is difficult to reach all levels of the health systems, particularly in rural areas.
- Important diseases remain unaddressed.
- Cultural and social change is necessary for systems to work.
- Unempowered executive agents and ministries may be responsible for program activities.

SOURCE: BTRP program manager, July 2008.

operated in Russia within the framework of the international agreement that established the International Science and Technology Center in Moscow. This center provides facilitative services for BTRP and other foreign organizations interested in supporting science and technology projects in Russia and several other countries of the FSU.

While Russia is of course unique in many respects, other countries of interest that are outside the FSU may also be hesitant to enter into the types of intergovernmental arrangements to which BTRP has become accustomed. Limited levels of engagement may not require new intergovernmental agreements or may be implemented under existing bilateral military-to-military or science and technology agreements. Also, developing formal agreements may be very time consuming and raise politically difficult issues, whereas less formal arrangements may facilitate prompt beginnings of important engagement activities.

Of course, in some cases, agreements and executive agents may be necessary, particularly if large construction projects are to be undertaken. But in other countries, insistence on such formal arrangements may pose unnecessary obstacles.

In some low- and middle-income countries, the ministries of defense provide significant health services for civilian populations and are responsible for responding to emergency situations. They may be the only ministries with adequate logistical capabilities to reach elements of the population, such as in some rural areas of Africa. Sometimes, the surgeon general of the country is a military general. Under such circumstances, it may be possible for BTRP to establish an important bond with the ministry of defense. At the same time, BTRP should ensure that the ministries of health, agriculture, science, and education are involved, either formally or informally, and are comfortable with military-to-military arrangements. Engaging the civilian as well as the military authorities in initial discussions of BTRP engagement is a critical step to this end. The local U.S. embassy can often be helpful in assessing options.

Recommendation 3-6: In moving beyond the FSU, BTRP should be flexible in the types of formal commitments it requires of partner governments as a basis for cooperation.

Human Resources

As discussed in Chapter 2, few developing countries have adequately trained human resources in the biosciences and biotechnology to participate effectively in a robust BTRP-supported scientific engagement program. Often, many of the best specialists have emigrated, taken employment with foreign entities operating in their countries, or changed careers to fields with greater near-term remuneration. As interest in the biosciences and biotechnology continues to expand, the existing and projected human resource base will become

even more stretched. Therefore, a large percentage of BTRP's engagement efforts probably should be devoted to training young specialists and then providing incentives for them to find key scientific positions in local institutions, as discussed in Chapter 2.

BTRP has encountered human resource-related problems in the FSU. Several training programs devoted to career reorientation have been undertaken with considerable success. However, the human resource issue is different in the FSU because at the time BTRP launched its efforts there was a large pool of underemployed scientists who, after relatively brief training programs, were able to operate effectively in modern laboratories and at other facilities. Of course, there is now great concern over how to replace this older cadre of specialists as they retire, but there has been time for transition. Also, the primary and secondary school systems in the FSU, despite a decrease in quality in recent years, are still much stronger than systems in almost all developing countries outside the FSU. As recommended in Chapter 2, BTRP should be prepared to support a variety of education programs and related training programs in the countries of interest for an extended period of time.

To the extent that future training programs can incorporate experience from the already developed programs in the FSU, these new programs should help expand and strengthen the global biosecurity network.

BTRP's Chain of Command

BTRP's projects in the FSU have often been delayed throughout the DOD chain of command that has been established for guiding the process, coupled with stringent DOD guidelines for executing projects. In 2004, at least 27 months were required by DOD from the development of the concept for a research project to the signing of the contract with the appropriate institution in the FSU to initiate the project. Fortunately, in most cases, this time line has been substantially reduced, but it is still too long.

For all BTRP activities, the overarching policy is approved by senior policy officials within DOD, who then instruct the Cooperative Threat Reduction (CTR) Program policy office as to appropriate approaches. That office in turn tasks the Defense Threat Reduction Agency (DTRA) to implement specific activities. DTRA has several levels of responsible officials, and they must in turn fill in details of the tasks that are being assigned. BTRP then normally turns the tasks over to integrating contractors, which typically employ subcontractors. Finally, the tasks reach the specialists who are responsible for on-the-ground activities. Turnover among these specialists is often frequent, on occasion resulting in misunderstandings and failures to recognize precedents that could be helpful.

The lengthy separation between the DOD policy officials who initially

design the tasks and the implementers has caused difficult program situations. Instructions are sometimes delayed or must be revisited because of changes on the ground. In dealing with countries outside the FSU that have only a handful of interlocutors who are experienced with foreign providers of goods and services, BTRP should be more adept in reacting promptly with more flexibility in embracing good project ideas. Otherwise, excessive correspondence concerning BTRP may remain for months in in-boxes of a few overworked local officials who are the only empowered decision makers.

Given likely sensitivities concerning DOD programs in some developing countries, misunderstandings and false expectations should be avoided to the fullest extent possible. While DOD has well-established management procedures for drawing on contractors as implementers of programs, the procedures developed for BTRP have been unnecessarily complex and too Washington-centric. DOD should of course ensure that requirements are satisfied, but nevertheless DOD needs to reduce the number of intermediaries between approvers of plans and implementers of projects.

Recommendation 3-7: DOD should streamline its chain of command for implementing BTRP and simplify the operational process within DOD to enhance efficiency, reduce misunderstandings, and increase transparency in U.S. intentions toward the host governments.

Given the many demands on senior DOD officials with responsibilities for BTRP, a strengthening of their staff capabilities devoted to BTRP would be particularly helpful in this regard.

Visa Challenges

Obtaining visas for travel by U.S. and foreign officials and specialists has been and will continue to be a problem in promoting meaningful engagement activities. Usually the reason for visa problems is late application for the visa. Of course, there are at times also denials for security and political reasons. The visa issue deserves attention from the outset of BTRP's involvement in additional countries, but there must be a two-way street. Influencing U.S. visa decisions as well as partner-country decisions on visas for U.S. travelers on a case-by-case basis will not be easy.

Recommendation 3-8: BTRP should give priority to adequate advanced planning in order to ease visa problems for travel between the United States and partner countries in both directions.

Metrics and Evaluation

Comprehensive metrics to evaluate the success of BTRP activities are in the early stage of development. In the past, BTRP has focused on collecting output data, for example, the number of facilities that have received security upgrades, the number of trainees in various aspects of biosecurity, the number of former weapon scientists involved in redirection efforts, the number of sustainable peaceful jobs created, the number of collaborative research products that reach the markets, and the number of joint publications in internationally recognized journals. But the metrics have not gone to the essence of the program, namely, “To what extent has the likelihood of containing outbreaks of endemic and emerging diseases and of the related terrorism aspects been increased?”⁵

BTRP is working toward having indicators of “outcomes” of the program as well as indicators of “outputs.” This effort responds to long-standing instructions from the Office of Management and Budget to address both types of results. Now that BTRP has become the largest component of DOD’s CTR Program, increasing attention is focused on the results it is achieving.

As an interim step, BTRP is expanding its reporting to Congress from one indicator of accomplishments to four indicators. The original indicator is the number of diagnostic laboratories that are built and equipped. The three new indicators are the number of cooperative biological research projects that have been completed, the number of pathogen repositories that are secured, and the number of disease surveillance networks that have become electronically operational.

BTRP is also developing more-specific metrics for meeting program objectives and requirements. For example, an objective could be improvements in biosafety, and a metric could be positive changes in the biosafety policy of the government. An objective could be improved data sharing, and a metric could be the number of recipients of certain types of data. In this effort, BTRP should consider the work of the World Health Organization, which uses timeliness and completeness of data reporting in its metrics, and others. Box 3-7 presents an evaluation framework being developed by BTRP. It should be expanded to address other major items, such as human resources, national policies, and physical infrastructure, taking into account related efforts through DOD’s Global Emerging Infections Surveillance and Response System and other organizations, such as the Department of State, the Department of Homeland Security, and CDC.⁶ Overall, the measurement effort should be strongly encour-

⁵ For related observations on metrics, see National Research Council Committee on Prevention of Proliferation of Biological Weapons. 2007. P. 62 in *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=12005.

⁶ See, for example, the discussion of the efforts of the Department of Homeland Security to develop models for assessing the risk (threat, vulnerability, consequences) of bioterrorism set forth

BOX 3-7
BTRP Draft Framework for Development of Metrics

- Biological safety/security and laboratory practices are sustainable and consistent with internationally accepted best practices.
- U.S. select agents are consolidated and secured.
- Partner nations demonstrate sustained and transparent capability for surveillance, detection, reporting, and response to bioterrorism events and suspected disease outbreaks.
 - Scientists working with U.S. select agents are engaged in peaceful, transparent, and sustainable activities.
 - Biological weapon infrastructure, equipment, and material are eliminated.

SOURCE: BTRP, November 2008.

aged within BTRP. The International Health Regulations may also provide approaches that BTRP should consider adopting (see Appendix H).

In a related effort, BTRP is conducting a field evaluation of the effectiveness of TADR in Georgia. The purpose is to provide guidance on fine-tuning TADR. This evaluation includes demonstrating whether and how TADR recognizes extremely dangerous pathogens, promptly initiates communications from the primary health care or livestock service provider who reports an outbreak to the national level, and effectively executes other important aspects of TADR. Thus, the evaluation is to assess the effectiveness of protocols for epidemiological response and for sample collection and transportation. Finally, it addresses laboratory confirmation procedures at the regional and national levels.

Inferring BTRP's impact on a nation's security from such evaluations, however, is the most difficult task. Such a task involves understanding the security situation when BTRP entered the scene (the baseline) and the unique contributions of BTRP to reducing biological threats. One approach is for BTRP to support continuing assessments of BTRP impacts by both a group of specialists within BTRP in Washington and a counterpart group of local specialists in the host country focused on risk reduction. They could develop either common or competing methodologies and then compare results of their assessments. Their different insights as to how BTRP can most effectively enhance security on a broad basis in the country would be of considerable interest.

in National Research Council Committee on Methodological Improvements to the Department of Homeland Security's Biological Risk Analysis. 2008. Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=12206.

In short, as BTRP expands into other countries, this concern with BTRP impacts on reducing the threat of bioterrorism deserves greater emphasis. Evaluation efforts should begin from the outset of BTRP involvement in a country, because after projects are completed, it will be too late to examine reliable indicators of risk reduction as a result of the projects. At the same time, the current midcourse review of the effectiveness of the TADR system in Georgia is a step in the right direction, even though the assumption that TADR is an appropriate approach is not being challenged by the external evaluators—a shortcoming that should be corrected in the future.

Recommendation 3-9: BTRP should continue to develop improved metrics that will help guide evaluations of the impacts of BTRP and provide information for setting priorities for activities designed to reduce proliferation of biological weapons as well as related risks from naturally occurring contagious disease agents.

SPECIAL CHALLENGES

Political Aspects of a DOD-BTRP Presence in Developing Countries

The United States is often criticized as seeking military domination throughout the world. Nevertheless, BTRP has been welcomed as a useful and necessary program in many countries of the FSU. Local interest in BTRP activities has been driven in large measure by financial benefits and also in some countries by a local desire to have strong U.S. support of newly independent governments to help balance the nearby Russian military presence with roots into the past. This latter type of political-military incentive to welcome BTRP is not present in many parts of the developing world.

Indeed, there is a major issue of whether BTRP should help develop public health and agriculture roles in countries that are not accustomed to a highly visible U.S. military presence and have no history with biological weapons. At the same time, DOD's record in responding to natural disasters, in conducting research on tropical diseases, and in engaging in military-to-military contacts with dozens of developing countries is impressive.

The issue is not whether BTRP should be engaged outside the FSU. For the reasons set forth in Chapter 1, it should be. The issue is how BTRP should be engaged. The following suggestions are offered in this regard:

- BTRP should have a deliberate but realistic timetable when initiating engagement activities. It should recognize the importance of having the local authorities understand the benefits that will be derived over time from the program and thereby buying into the program, keeping in mind that developing-country governments are inundated with offers of foreign assistance from

much larger donors, such as the international development banks. Similarly, BTRP should be realistic in developing timetables for carrying out projects. The partner governments and local specialists will undoubtedly have to go through a lengthy education period concerning BTRP objectives and approaches. But excessive BTRP control over activities in the name of efficiency could degrade the likelihood of sustainability. In short, prompt delivery of promised goods and services should be balanced with assurances that they will be used effectively in a manner consistent with host-country long-term interests.

- Whenever possible, BTRP should partner with civilian organizations that have strong health and agriculture reputations in the developing countries, such as the World Health Organization, the Food and Agriculture Organization, the World Bank, the regional development banks, the U.S. Agency for International Development, and CDC.

- With the exception of BTRP activities in war-torn countries where U.S. military forces are omnipresent, such as Iraq and Afghanistan, BTRP should have a relatively modest presence in the countries of interest. This means that BTRP should have the clear objective of not only undertaking specific projects but also catalyzing international interest in complementing BTRP activities with activities of other organizations.

- Finally, BTRP should not hesitate to change plans to engage in a country when the government clearly indicates a lack of interest in such engagement.⁷

Recommendation 3-10: BTRP should take into account possible local concerns about a large presence of DOD activities in the countries where it engages. Joint projects with other organizations playing important roles and an emphasis on responding to local initiatives will be helpful in this regard.

Threat Assessment and Response

DOD has indicated a strong interest in extending the TADR system that is being developed and deployed in the FSU to countries around the world. The system is to improve biosecurity, and it has been described by BTRP as having the following characteristics:

⁷ The plan of Africa Command (AFRICOM) to locate its headquarters in Africa is of interest. The plan was poorly received by most African governments, which were not widely consulted in advance of the announcement of the plan. Civic groups across the continent opposed what they viewed as a permanent U.S. military presence in Africa targeted on Africa's natural resources. See Smith, G. E. 2008. In search of sustainable security: linking national security, human security, and collective security to protect America and our world. Washington, D.C.: Center for American Progress. Available online at www.americanprogress.org/issues/2008/06/pdf/sustainable_security1.pdf. At the same time, AFRICOM has a staff of 16 medical personnel under the command's surgeon. They are focused on the health of military personnel, but its leadership has expressed interest to committee staff in assisting with BTRP, which has not been on AFRICOM's agenda.

- Nationwide surveillance system
- Close to real-time detection, reporting, and response
- Integrated reporting of human health and veterinary health, including vectors
 - Tracking of diagnostic tests, results, and stored specimens
 - Electronic integrated diseases surveillance system
 - Diagnostic laboratory system
 - Standard and molecular methods that minimize culture volumes
 - U.S. biosafety level 2 (BSL-2), except for central reference laboratory (BSL-3)

The key TADR components include the following:

- Central reference laboratory (BSL-3 capabilities), where human and veterinary facilities are combined and a national response team is headquartered (see below)
 - BSL-2 diagnostic and detection laboratories at existing human and veterinary laboratories for disease surveillance and epidemiological analysis, case investigations involving sample transport capabilities, and disease detection and diagnostics by molecular and classic methods
 - Region-level support stations for disease surveillance and epidemiological analysis, case investigations, and disease reporting by veterinarians and epidemiologists

Some aspects of this system are obviously important for many developing countries. But there may be competing systems in various stages of development in different countries. Therefore, some components of the TADR system may be appropriate for some countries, and other components, for other countries.

In addition to questions as to TADR's compatibility with other surveillance systems in various stages of development, several concerns about the system were expressed in the October 2007 report and have not yet been fully addressed by BTRP.

- How will the TADR network be sustained after BTRP completes its participation in development and operation of the network? This means there must be substantial buy-in from a wide range of local officials and specialists with access to financial resources.
- The focus of TADR should be broadened from a limited number of disease agents, classes of agents, and syndromes of interest to DOD for proliferation purposes to a broader range of agents that are of greater interest from human health and agriculture perspectives. It makes little sense to have differ-

ent systems for different disease agents in the same country, as noted earlier in this chapter.

- Automatic transmission through the TADR information systems of all data that are collected by physicians, laboratory specialists, and other participants in the program will result in false alarms. Raw data are most useful at the national and regional levels, where such data influence budget allocations. Local specialists should be trained to screen the data before they are entered into the international component of the system to reduce the false alarm rate. BTRP's haste to immediately have all of the data in the United States should be tempered with reality of the likely significance, analysis, and use of the data.

- Data recipients in the United States that are BTRP partners should be prepared to accept and analyze the data as an important component of their overall missions. In the absence of such interest, a long-term program to send all raw data to the United States makes little sense.

Recommendation 3-11: The design and operation of the TADR system should be carefully reviewed by a well-qualified, independent organization that has not been directly involved in the design or establishment of the system before BTRP advocates transportability of the components of the system to other countries beyond the FSU.

This review should emphasize the risk-reduction potential of TADR, including its ability to strengthen local response to disease outbreaks and indications that TADR is achieving this goal.

Central Reference Laboratories

A special concern is the plan of BTRP to construct within the TADR system central reference laboratories with BSL-3 capabilities in one or more countries of the FSU (at a cost of up to \$90 million each, plus operational costs of \$5-10 million annually) or in some cases BSL-2 laboratories. Preliminary DOD plans call for such facilities in other countries as well. CRLs are to serve as national centers for research and surveillance systems and will include consolidated repositories for dangerous pathogen strains.⁸ The unanswered questions include the following:

⁸ There is considerable interest in some developing countries in BSL-3 and even BSL-4 laboratories. At the same time, there are uncertainties as to current safety designations of some of the high-containment laboratories by specialists from the developing countries. According to fragmentary information available to the committee, there is one BSL-4 laboratory operating in South Africa and two BSL-4 laboratories operating in India. As for BSL-3 laboratories, there are three in Malaysia, three in Mexico, two in Bangladesh, seven in Indonesia, five in Thailand, and 16 in India. (This information was compiled from committee field visits and from a presentation by Dr. Nicoletta Previsani on WHO's [World Health Organization] Biosafety and Laboratory Biosecurity delivered

- Will there be enough demand for use of the facilities to justify the expense of constructing, maintaining, and operating them?
- Is there enough local talent to adequately staff the facilities without diverting specialists from equally important assignments in other institutions?
- Will there be adequate safeguards to ensure that if the host government undergoes significant political changes that lead to an estrangement with the United States that the facilities will not be used for nefarious purposes?
- Would it be more appropriate to construct regional rather than national facilities, given the uncertain demand for their usage, the human resource issues, the expense, and the need for international assurance that they will not be misused over the long term?

Recommendation 3-12: Before BTRP begins planning construction of CRLs outside the FSU, it should resolve issues concerning the need, location, operations, and international transparency in the long term regarding the facilities to which it has committed in the FSU.

Advanced Technologies

Most developing countries are not prepared to adopt advanced technologies such as computer-based, automated disease surveillance systems. Also, unfamiliar high-technology approaches that could be beyond the reach of local specialists might be viewed as a form of U.S. technological imperialism. This does not mean that advanced technologies should not be deployed in developing countries when the circumstances are appropriate. But traditional ways of addressing disease problems should be given careful consideration. When appropriate, the latter should be incorporated into technologically upgraded approaches.

Recommendation 3-13: BTRP should refrain from advocating high-technology approaches that may be inappropriate in low-technology environments.

CONCLUSION

In summary, the risk of bioterrorism being rooted in developing countries is too great for BTRP not to be among the leaders in addressing the threat on a broad basis. Since the late 1990s, BTRP has had unique experiences in working with states of the FSU that are at various levels of development. Much of this

at the Biological Weapons Convention Meeting of Experts at Geneva, Switzerland, August 18-22, 2008, and available online at www.bwpp.org/2008MX/documents/PresentationWHO20080819.pdf.) A more complete survey would undoubtedly indicate the presence of many more BSL-3 laboratories throughout the developing countries.

experience seems to be readily transferable to developing countries beyond the FSU. Such experience should be brought to bear in a variety of development settings as an important component of overall U.S. efforts to reduce the likelihood of bioterrorism throughout the world. At the same time, BTRP should recognize that other international or local organizations themselves may be better positioned, better equipped, or both to upgrade specific biosecurity weaknesses that deserve prompt attention. Also, BTRP should ensure that its activities are carried out within the framework of the overall U.S. government approach to biological threat reduction, including the selection of countries and problems within countries that need attention.

Several of the recommendations in this chapter are designed to broaden the approach of BTRP from a narrow focus on specific pathogens, and indeed only on agents that cause human and animal diseases, to the broader science and technology agendas of developing countries, including science and technology policies, higher education, and improvement of research. Casting this wider net should reveal an array of opportunities both for BTRP and for the broader U.S. and international communities to make meaningful contributions to enhancing biosecurity in developing countries.

BTRP should not become involved in all situations that need prompt attention, and particularly those that are a more logical focus of attention of other organizations that also have access to necessary resources. BTRP may be able to address such situations faster, more comprehensively, and with more expertise than other organizations, but the biosecurity problems are so numerous throughout the world that BTRP should not hesitate to let other interested organizations take the lead when possible.

Biosecurity-Related Activities of Other Organizations

Many external organizations have a wide variety of biosecurity programs already under way in developing countries outside the former Soviet Union (FSU). This chapter and appendixes E, F, G, and H describe many of the programs that are directly relevant to the interests of the Biological Threat Reduction Program (BTRP).

These organizations are primarily departments and agencies of the governments of developed countries, and particularly the United States; international organizations; and other public- and private-sector entities based in developed countries that operate in developing countries. Biosecurity has been a major thrust of the international activities of only a few of these organizations, however. Most of the organizations provide developing countries outside the FSU with economic development assistance, opportunities for cooperation in the biological sciences, or both.

Many programs that are not designed as biosecurity programs should nevertheless contribute to reducing the risks from proliferation of materials, equipment, technologies, or expertise that could be used for bioterrorism purposes. In particular, some organizations provide important financial or technical support or both in strengthening local security, agricultural, health, educational, and scientific systems. As noted throughout this report, these systems can contribute to the efforts to counter bioterrorism. Of course, the nonbiosecurity programs will continue to focus on their primary missions, but many are increasingly taking into account the biosecurity dimensions of their activities as the global interest in this issue rapidly grows.

Some of the U.S. entities are within the Department of Defense (DOD) complex. Others in the United States and abroad have pursued broad international development agendas for decades. Some of these and other more recent entrants into the field of international development are sharply focused on

addressing global health or international agricultural problems. In summary, the entities of interest for this report may be included within the following categories of organizations:

- Current contractors and other partners of BTRP
- Health-related components of DOD
- Other U.S. government departments and agencies
- International organizations
- Ministries of foreign affairs, foreign assistance agencies, and development banks
- Industrial and professional associations, foundations, and nongovernmental organizations

The organizations that are considered in this report are only a sampling of the entities with programs relevant to BTRP's interests. However, they are among the organizations with the largest programs related to biosecurity. Other national and international entities—probably numbering in the many dozens—have smaller programs of interest. Both large and small programs provide the international framework within which BTRP will be operating as it expands geographically.

Collectively, the activities of these organizations offer many opportunities for BTRP to obtain up-to-date information on conditions in the countries of interest. They have experience in pursuing approaches that have been effective in specific countries. They also have encountered pitfalls in operating abroad. In some cases, they are well positioned to partner with organizations with similar or complementary interests in planning and carrying out a variety of approaches. The feasibility and desirability of such partnerships should be of special interest to BTRP.

ORGANIZATIONS THAT DIRECTLY SUPPORT BTRP ACTIVITIES

BTRP provides funds to an extensive array of support organizations for activities in the FSU. BTRP also cooperates with many others with related interests. Some of these BTRP partners are included both in the list of stakeholders in Appendix D and in Appendixes E and F, where they are recognized as also having their own programs independent of BTRP financial support.

The organizations that work for BTRP include, primarily, integrating contractors, which were discussed in Chapter 3. Their contracts are usually 5 years in duration. Collectively, the contracts currently provide for a level of support exceeding \$1.5 billion over 5 years, thereby enabling BTRP to use these contractual arrangements quickly to provide a broad spectrum of services. Each integrating contractor has several subcontractors on its team, with universities, nonprofit organizations, and for-profit companies involved.

BTRP makes smaller awards for other more specialized contracts and interagency agreements. These contractors and interagency partners provide unique expertise and experience that require individualized arrangements. A few universities and nongovernmental organizations are involved in such arrangements.

While BTRP has positions for only 22 government employees, more than 1,200 people are currently working on BTRP activities as employees of contractors or participating through interagency arrangements, with BTRP providing the necessary funds. These support organizations bring considerable experience and scientific credibility to BTRP. Several U.S. contractors have employees stationed in one or more of the FSU countries where BTRP is active. But BTRP staff will surely require enlargement as BTRP addresses new challenges outside the FSU. Particular attention should be given to new employees with experience working in international development and others who are trained to address a broad range of common diseases.

Examples of U.S. government organizations that received funding from BTRP in Fiscal Year (FY) 2008 for support activities include the following:

- U.S. Army Medical Research Institute for Infectious Diseases: \$2 million
- Walter Reed Army Institute of Research: \$2 million
- Armed Forces Institute of Pathology: \$1.2 million
- Centers for Disease Control and Prevention (CDC): \$7.3 million

Each of these four organizations also has related program interests outside the FSU and has its own limited funding to support such programs. In countries where they have more experience than DOD/DTRA (Defense Threat Reduction Agency), larger allocations of BTRP funds to such partners may be in order.

Presented below are comments on the activities of several important organizations with relevant activities of their own in developing countries outside the FSU. They are the Department of State, selected entities of DOD, the U.S. Agency for International Development (USAID), CDC, the World Bank, and several private-sector organizations. Against this background, together with the supplemental information provided in the appendixes, several recommendations concerning BTRP relationships with other organizations are set forth.

Department of State

The biological nonproliferation activities of the Department of State are of special importance for two reasons. First, the department has the most extensive activities of any organization worldwide designed explicitly to address biosecurity threats in developing countries outside the FSU. It has pioneered working

with developing countries in this field and has significant budgetary resources to this end, with about \$25 million focused on developing countries outside the FSU during FY 2008 and a comparable amount set aside for FY 2009. Second, the department has a lead role in the interagency process in Washington, which is designed to coordinate government-wide approaches to biosecurity in the developing countries. This responsibility is also discussed in Chapter 5. Thus, it has both experience and a mandate that are of considerable importance as BTRP begins to expand into developing countries beyond the FSU.

Geographically, engagement efforts are focused on areas where the department considers that there is the greatest biological risk, with substantial efforts under way in South and Southeast Asia, particularly Pakistan, Indonesia, and the Philippines, as well as in the Middle East. These regions will probably continue to be of high priority in FY 2009. The program is expanding regionally to cover areas in Africa and Latin America, as well as continuing efforts in Eurasia. The department has established field offices in Manila, Jakarta, and Islamabad, with a regional training hub planned for Thailand.

Global assistance is directed in the following areas:

- Strengthening laboratory biosafety and biosecurity, including best practices, standard operating procedures, personnel reliability programs, and enhanced physical security measures
 - Ensuring safe, secure, and sustainable laboratory buildings, education, planning, management, and operations
 - Enhancing molecular diagnostics and disease surveillance networks
 - Fostering collaborative research projects in priority areas to engage scientists and promote sustainable implementation
 - Advancing host-nation commitments to the International Health Regulations (IHR), particularly as they pertain to best practices, laboratory capacity development, and areas surrounding laboratory biosafety and biosecurity
 - Promoting global cooperation on biosecurity standards, regulations, and legislation

The legislative basis for the Department of State's activities is set forth in Box 4-1.

As an example of the Department of State's approach, Box 4-2 describes activities in Brazil.

Recommendation 4-1: DOD should continue to be an active participant in the interagency nonproliferation process by responding whenever possible to requests of the Department of State and the National Security Council to deploy BTRP assets in countries beyond the FSU and by taking the initiative to advocate deployments that can effectively enhance the overall national effort.

BOX 4-1
**Biosecurity Engagement Program of the
Department of State**

“The Secretary of State shall establish a program to combat bioterrorism worldwide by providing training, equipment, and financial and technical (including legal) assistance in such areas as biosecurity, biosafety, pathogen surveillance, and timely response to outbreaks of infectious disease, and by providing increased opportunity for scientists who possess expertise that could make a material contribution to the development, manufacture, or use of biological weapons to engage in remunerative careers that promote public health and safety.”

SOURCE: Chapter 9, Part II, Foreign Assistance Act of 1961, as amended by the Security Assistance Act of 2008, Section 584A, Global Pathogen Security Program.

BOX 4-2
Department of State’s Approach in Brazil

- Work through U.S. embassy and ministries to promote transparency
- Support Brazil as a regional leader on biosecurity through threat reduction collaboration
 - Organize biosafety and biosecurity workshops
 - Encourage university participation in awareness-raising meetings
 - Support the Brazilian Biosafety Association
 - Enhance bilateral relations through the U.S.-Brazil Joint Commission on Science and Technology

SOURCE: Department of State, November 2008.

Department of Defense

Appendix E identifies many of the components of DOD that have programs with biosecurity dimensions in the developing countries beyond the FSU. In recent years, relevant DOD activities in addition to BTRP have involved specialists from more than 100 developing countries and are continuing to expand. Activities have included foreign participants in training programs and international scientific meetings in the United States. Also, many U.S. specialists have participated in on-the-ground activities in various countries.

For decades, more than a dozen medically oriented units of DOD have

been involved in health-related activities in developing countries. Usually these efforts have been aimed at ensuring the protection of U.S. military forces stationed abroad. At the same time, some activities contribute to capacity building in developing countries directly and indirectly.

DOD's Global Emerging Infections Surveillance and Response System (GEIS), involving several DOD entities, is particularly relevant to BTRP's interests. The specific focus areas of GEIS include respiratory diseases, especially influenza; gastroenteritis syndromes; febrile illness syndromes, especially dengue and malaria; antimicrobial resistance; and sexually transmitted infections. In addition, four broadly based surveillance areas span all emerging infectious diseases of concern: mortality surveillance, electronic data capture for surveillance, syndromic surveillance, and modeling.

Five overseas research laboratories are important components of DOD's medical system. About one-fourth of their budgets are for disease surveillance and response. Most of the remainder of their budgets supports research. Examples of their activities are as follows:

- U.S. Naval Medical Research Unit 3 (NAMRU-3), which is located in Cairo but also has regional responsibilities, has become the World Health Organization (WHO) influenza reference laboratory for the eastern Mediterranean region and is working in many countries in the Middle East and Central Asia.
- At the U.S. Naval Medical Research Unit 2 (NAMRU-2) in Jakarta and the Naval Medical Research Center Detachment in Lima, an Early Warning Outbreak Recognition System has expanded, facilitating regional networks to provide outbreak recognition.
- The Armed Forces Research Institute of Medical Sciences in Bangkok has a satellite laboratory in Nepal, which detected and provided advance notice of influenza virus genetic changes that later emerged globally, allowing better vaccine strain selection worldwide.
- The U.S. Army Medical Research Unit in Kenya has strengthened its program to become one of the few laboratories in Africa that can provide reliable disease data from sub-Saharan Africa.

The activities of the GEIS system are discussed in detail in a recent report of the Institute of Medicine.¹ Two particularly relevant recommendations of that report are set forth in Box 4-3.

As pointed out in Chapter 3, BTRP must exert care as to how it expands

¹ Institute of Medicine Committee for the Assessment of DoD-GEIS Influenza Surveillance and Response Programs and Board on Global Health. 2007. Review of the DoD-GEIS Influenza Programs: Strengthening Global Surveillance and Response. Washington, D.C.: The National Academies Press. Available online at www.nap.edu/catalog.php?record_id=11974. Accessed December 2, 2008.

BOX 4-3

DOD Health-Related Activities

DOD Coordination with Other Organizations

“DOD-GEIS should further strengthen its coordination and collaboration on pandemic influenza and other emerging infectious diseases with all U.S. partners, both domestically and in its overseas operations. These partners include HHS [U.S. Department of Health and Human Services], CDC, the National Institutes of Health, FDA [U.S. Food and Drug Administration], USDA [U.S. Department of Agriculture], the Department of State, the U.S. Agency for International Development, the Department of Homeland Security, and other relevant U.S. government efforts.”

Expanding Mission of DOD’s Overseas Laboratories

“DOD should issue a directive reaffirming that these traditionally research-oriented laboratories, particularly overseas, have a public health mission with respect to the host country and region; the directive should also provide strategic direction on the balance of military medicine-related research and public health activities.”

SOURCE: Institute of Medicine Committee for the Assessment of DoD-GEIS Influenza Surveillance and Response Programs and Board on Global Health. 2007. Review of the DoD-GEIS Influenza Programs: Strengthening Global Surveillance and Response. Washington, D.C.: The National Academies Press. Pp. 222 and 209, respectively.

into developing countries outside the FSU. As indicated in Box 4-4, DOD specialists who are working abroad are sometimes skeptical about being aligned with BTRP.

Other senior DOD officials consider such attitudes a legacy of the past, when turf and budget concerns were high. They argue that now budgets are much greater and the realities of bioterrorism have become clearer. In their view, discomfort within DOD with BTRP activities is rapidly being replaced with determination to gain acceptance of BTRP by governments of distant countries.

During discussions with committee members, senior officials and biosecurity specialists in several countries of Asia, Africa, and Latin America expressed the view that cooperation with BTRP based on mutual interests and benefits would be welcomed. These foreign colleagues did not anticipate reluctance on the part of their governments in this regard. They noted that their countries have cooperated with DOD in a variety of areas and that continuation of such cooperation could be arranged without difficulty. While this was a very small sampling, the convergence of opinions that were solicited seems important.

BOX 4-4**Skepticism over Role of BTRP in Developing Countries**

"Our laboratory commanders and staff take great pains to distance themselves from the counter-bioterrorism programs of DOD, as even the perception of such an agenda on the part of our host national sponsors could compromise our ability to gain their support for collaborative projects to combat such important public health threats as pandemic influenza."

SOURCE: Senior official, Naval Medical Research Center, September 2008.

With care and sensitivity when designing programs, and with the backing of DOD's leadership, BTRP should be able to overcome hesitancy within other DOD units to support an expansion of BTRP. Transfers of BTRP funds to DOD's overseas laboratories for participation in BTRP programs may be appropriate at times and could well influence internal enthusiasm for an expanded BTRP presence. Such transfers could be particularly important in countries where sensitivities to an expanded DOD presence may be high, but where the overseas laboratories have already established positive relationships.

Also, care is needed to prevent confusion in the field about the role of BTRP's contractors and that of the DOD laboratories, as well as other BTRP partners. Mistakes in this regard could affect access to local institutions that have been traditional partners with U.S. organizations at precisely the time when there may be unprecedented opportunities for BTRP and its U.S. contractors and grantees to strengthen relations with important local institutions and specialists.

Recommendation 4-2: BTRP should work closely with other DOD entities that are involved in activities that support biosecurity in developing countries, drawing on the familiarity of these entities with conditions on the ground and their sensitivity to important issues in dealing with local leaders of government organizations and facilities in the countries of interest.

U.S. Agency for International Development

USAID has extensive and unique experience in the life sciences, albeit not explicitly directed to biosecurity, in carrying out programs in developing countries. It should be an important partner of BTRP in activities beyond the FSU. The relationship between USAID and BTRP has not been strong in the

FSU. Indeed, on occasion there have been important conflicts in approaches: for example, lack of coordination of software to be used for disease surveillance and analysis systems.

Three central offices of USAID, as well as USAID's missions abroad, have significant activities relevant to BTRP's interests. Several programs of the central offices are as follows:

1. **Bureau of Global Health:** USAID is responsible for managing a health budget of more than \$5 billion for FY 2009. A large percentage of the budget is to support the President's HIV/AIDS and malaria initiatives. Other USAID health programs are directed to avian influenza, tuberculosis, neglected tropical diseases, child survival and maternal health, and water supply and sanitation. Crosscutting all of these activities are efforts to strengthen health systems on a broad basis. USAID has identified the following key problems in controlling diseases:

- Helping countries meet the requirements of the IHR
- Integrating laboratories and other existing infrastructure into surveillance systems
 - Expanding human capacity in the field of epidemiology and creating rapid response teams
 - Resolving health system problems, such as laboratory strengthening, through performance-oriented initiatives with planned outcomes

Many of USAID's interests overlap BTRP's interests, and USAID's formidable experience in global health should be an asset that is utilized more fully by BTRP.

2. **Office of Agriculture:** Much of USAID's interest in biotechnology is focused on food-related issues and opportunities to increase agricultural productivity. USAID believes that biotechnology can play an important role in solving critical food shortages in several countries. Of course, such solutions will not come easily, but over time the likelihood of still greater contributions from biotechnology than in past decades seems high. In this regard, controlling agricultural diseases has been an area of interest for decades. BTRP's focus on human and animal diseases and interest in the increased application of biotechnology, when coupled with USAID's extensive agriculture experience, should be helpful in encouraging broad approaches by BTRP and other agencies that are addressing disease challenges in the agricultural sector.

3. **Global Development Alliance:** This cooperative effort between USAID and U.S. private-sector organizations to jointly finance and carry out activities of mutual interest has repeatedly been hailed by the U.S. government as a suc-

cessful new model for international development. Hundreds of American firms and nongovernmental organizations (NGOs) have been involved, although there are few, if any, examples of biology-oriented projects that would be of immediate interest to BTRP. Nevertheless, the program should provide lessons learned as to how BTRP might expand its efforts to harness the relevant strengths of the international private sector in developing countries.²

Recommendation 4-3: BTRP should strengthen its relationships with USAID in Washington and in the field. One or more jointly funded projects would be an effective step in this regard.

Centers for Disease Control and Prevention

BTRP has for years recognized the importance of benefiting from the achievements of CDC's worldwide network for disease surveillance and response. As indicated in Box 4-5, experienced practitioners in strengthening disease surveillance activities in the developing countries recognize the potential for development of complementary approaches of CDC and BTRP.

BOX 4-5 Joint CDC-BTRP Activities

"CDC overseas facilities are often weak and understaffed. If BTRP partners with CDC, both could benefit."

SOURCE: Senior medical adviser, The World Bank, September 2008.

CDC has a unique history of linking domestic and global public health research and practices to improve health outcomes in resource-constrained settings. Today, CDC has more than 200 employees in more than 50 countries throughout the world, in addition to its activities in the United States. Moreover, CDC employs and trains local staff from each of its platform countries and is an important partner in worldwide efforts to build public health capacity. CDC's global health work supports the newly revised IHR through a connected network of growing partners within the U.S. government, WHO, and other multinational organizations and governments.

² Details on the program are available online at www.usaid.gov/our_work/global_partnerships/gda/.

CDC has scientific experts and programs in influenza, HIV/AIDS, tuberculosis, malaria, polio, food safety and foodborne disease, environmental health, zoonoses, laboratory testing and safety, quarantine migration, strategic communication, and information technology. Driving CDC's global health efforts is the ability to utilize its assets effectively and link these capabilities to the larger pool of global health resources in each of WHO's six regions.

In 2004, CDC began the Global Disease Detection Program (GDD) to develop and strengthen global health capacity for identifying and responding to emerging infections and bioterrorist threats around the world. Today, GDD Regional Centers are located in Kenya, Thailand, Guatemala, China, Egypt, and Kazakhstan. Programs and resources in these countries are linked to headquarters and interconnected to respond to disease outbreaks anywhere in the world. The scientists who work in these programs are a valuable U.S. source of expertise in infectious disease detection and control (ranging from leadership in the control of common infectious syndromes such as pneumonia, to cutting-edge laboratory detection of rare viruses such as Ebola and severe acute respiratory syndrome coronavirus). In nonemergency settings, CDC works with country partners to build public health capacity in disease detection and response interventions that help to strengthen systems that will be used in times of crisis. In response to major international emergencies or large-scale disease outbreaks, CDC typically functions as a member of the Global Outbreak Alert and Response Network, which is coordinated by WHO.

Finally, CDC's global reputation in strengthening public health systems cooperatively with ministries of health and WHO is a product of the Field Epidemiology Training Program (FETP). Operating in 29 countries, FETP has more than 1,000 graduates, many of whom hold leadership positions within ministries of health in their own countries.

Box 4-6 sets forth important lessons learned by CDC.

Other U.S. Government Organizations

For the past few years, the nonproliferation group of U.S. government organizations has included the Department of State, DOD, HHS, USDA, the Department of Energy, and the Environmental Protection Agency (EPA). The nonproliferation funding for HHS, USDA, and EPA has flowed through the Department of State, although the available funds to support their activities declined significantly to less than \$3 million during FY 2008. As previously noted, BTRP also funds activities involving components of HHS, particularly CDC. In addition, USDA, with important lessons to share from its involvement in nonproliferation programs in the FSU (see Box 4-7), has become a recipient of BTRP funds. Somewhat belatedly, the Department of Homeland Security is now also being included in the nonproliferation policy and program discussions, as further discussed in Chapter 5.

BOX 4-6

Lessons Learned by CDC

- Ensure the program is consistent with local priorities.
- Avoid taking personnel from other important local programs.
- Ensure local buy-in of activity.
- Ensure program compatibility and integration with existing local activities, structures, methods, and equipment.
 - Avoid high-technology solutions for low-technology environments and ensure availability of replacement equipment and parts.
 - Minimize reliance on foreign experts.
 - Design a system that is affordable and can be maintained locally.
 - Design a system that is capable of coping with unpredictable changes in the operating environment.
 - Have a monitoring and evaluation component.
 - Resolve implementation issues early.

SOURCE: CDC expert, presentation to the committee, July 2008.

Each of the nonproliferation-oriented departments and agencies has supported other activities of relevance to biosecurity in developing countries, either through their core budgets or through interagency arrangements. For example, the National Institutes of Health, and particularly the National Institute of Allergy and Infectious Diseases, have been major funders of cooperative research projects on disease issues in Africa, Asia, and elsewhere. USDA has interagency arrangements with USAID in many fields related to agricultural biosecurity. Also, the Animal and Plant Health Inspection Service and the Foreign Agricultural Service of USDA are important organizations keeping abreast of developments abroad in the agricultural field.

BTRP's expanding relationships with CDC, USDA, and other agencies will be of increasing importance as BTRP attempts to expand into developing countries, where government suspicions about U.S. military interests abound. Such BTRP partners can both contribute to the technical basis for BTRP programs and help build international confidence in the positive objectives of BTRP. In some cases, they may be more appropriate than BTRP to be the lead agency in the country of interest to BTRP.

World Bank

The World Bank and the other international development banks have for decades financed major health and agricultural programs that intersect with

BOX 4-7**USDA's Project Selection and Project Evaluation Criteria****Selection Criteria**

- Project that will advance the missions of both the Department of State and the Agriculture Research Service
- Project that is truly interactive
- High probability of success and sustainability through publications and products
 - Committed principal investigators—in the United States and in the partner country—who are effective and willing to make exchange visits
 - Adequate facilities abroad (including compliance with animal welfare requirements)

Evaluation of Effectiveness

- Number of exchange visits
- Number of scientists involved
- Hours of training provided
- Monetary value of equipment provided
- Patents filed
- Publications and international conference presentations

SOURCE: Adapted from a presentation to the committee by an Agricultural Research Service official, July 24, 2008.^a

^a References to weapons scientists have not been included, since they are relevant only in very special cases outside the FSU.

the biosecurity interests of BTRP. Disease prevention and control are considerations in many bank programs designed to improve health care or increase agricultural production. Also, because of the size and impact of major bank loans, a representative of one of the banks who is located in the field, such as the World Bank country director, often becomes a de facto coordinator for the international community interested in health or agriculture system improvements in the developing country of interest, working as cochair with a local official of a consultative committee.

An important aspect of the activities of the banks is the attention given to early comprehensive analyses of the local situation in the specific field of interest. These analyses provide important background for lending decisions and should be of interest to BTRP. Also, many loans give emphasis to training of local specialists who are to be involved in implementing the loan. Unfortunately,

despite the obviously important role of the banks, BTRP has had few interactions with the development banks to date.

As of 2008, the World Bank annually commits \$1-2.5 billion in new loans in the field of health and disperses amounts in the same range from existing loans. The other banks in the aggregate commit and disperse a comparable amount. Until recently, the World Bank had emphasized loans targeted on specific diseases. However, the bank is currently transitioning to a new emphasis on strengthening the entire health system, often in partnership with the United Nations International Children's Fund and WHO, which have stronger scientific capabilities. In the agricultural area, the activities of the banks include large agricultural loans, although diseases are much less of a focus area.

Given the sizes of the portfolios of disease-related activities of the international development banks in Asia, Africa, Latin America, and Europe, as well as the World Bank, these organizations should be of special interest to BTRP. In some cases, such an international development bank might be an appropriate lead organization in a country of interest to BTRP.

International Organizations

The roles of WHO, the Food and Agricultural Organization, and the World Organization for Animal Health are of particular relevance to BTRP.³ The interests and capabilities of these organizations are sometimes taken into account in the design and implementation of BTRP projects. For example, BTRP is giving considerable attention to the local responses to the International Health Regulations of 2005, which provide an international standard for health-related activities. These regulations, which are in the early stage of implementation, require the signatories to

... develop, strengthen, and maintain core national public health capacities at the primary, intermediary, and national levels in order to detect, assess, notify, and report events [that may constitute a public health emergency of international concern] and to respond promptly and effectively to public health risks and emergencies.

Recommendation 4-4: BTRP should adopt progress toward the host country's effective implementation of the International Health Regulations, including actions concerning public health emergencies, as an important measurement of success in countries where it mounts major efforts. (See the related discussion of metrics in Chapter 3.)

Also of interest are the global funds (for example, the Global Fund to

³ Key documents include the WHO Constitution of 1948; World Health Assembly Resolution 55.16 (2002); International Health Regulations, Resolution 58.3 (2005); and World Health Assembly Resolution 58.29 (2005).

Fight AIDS, Tuberculosis and Malaria), trust funds, and other special funds set up under the umbrella of WHO. They are increasingly used as channels for assistance to counter pervasive disease problems.

Of growing importance are the expanding interests of regional organizations in biosecurity. Broadly based regional health organizations such as the Pan American Health Organization are beginning to embrace biosecurity as an important issue. The Asia-Pacific Economic Cooperation organization and other political groups also convene meetings and provide guidance concerning bioterrorism. Specialized regional organizations provide venues for discussions and training in selected areas of biosecurity, such as the African Biosafety Association. Undoubtedly, additional governmental and nongovernmental regional organizations will become more active participants in this field in the months and years ahead.

Recommendation 4-5: BTRP should give greater attention to the biosecurity roles of the international development banks and of international and regional organizations. In coordination with the Department of State and USAID, BTRP should regularly consult with these organizations concerning the further development of BTRP activities.

The Private Sector

Many foundations, professional and trade associations, and other nongovernmental organizations have programs directed to global health and international agriculture. However, with several exceptions, to date their programs have had relatively little direct impact on biosecurity concerns in developing countries. Their significance will undoubtedly increase in the future; however, a few of the larger foundations with international programs in these fields are well positioned to have more focused impacts on biosecurity concerns in the near term. They include the Gates Foundation, the Rockefeller Foundation, the Wellcome Trust, and Google.org.

Google.org, a newcomer to international development, has already committed \$30 million in grants to identify hot spots where diseases may emerge, to detect new pathogens and outbreaks earlier, and to respond quickly to prevent local threats from becoming global crises. More specifically, its projects are intended to

- enhance the use of automated systems for effective disease surveillance;
- improve pathogen discovery and understanding of those classes of viruses that pose the greatest threat; and

- strengthen efforts to bring molecular sequencing capacity closer to hot spot countries.⁴

The Sloan Foundation has also embraced biosecurity as a priority issue. The foundation provides grants in this field to a variety of organizations ranging from universities to international organizations such as Interpol and WHO. While the grants are modest—totaling about \$2.5 million annually—they nevertheless have been helpful in introducing a broad range of important government officials and scientists to the field of biosecurity.

About 20 major research-based biopharmaceutical companies headquartered primarily in the developed countries have established the Global Health Progress initiative to address health care challenges in the developing countries. They emphasize networks of partnerships with governments, citizen groups, and other organizations. The program reports more than 70 organizations involved in these partnerships. The initiative emphasizes the following activities:

- Strengthening health care systems
- Donating and discounting medicines
- Developing and delivering innovative diagnostics
- Providing health care assistance during emergencies and disasters
- Conducting research and development on new medicines
- Developing new policy ideas and solutions

Global Health Progress has recently published a special report on the activities of its members in developing countries, which is available online at www.globalhealthprogress.org. It is particularly interested in the 14 neglected tropical diseases identified by WHO.⁵ Its growing network should be of interest to BTRP and to other organizations concerned about biosecurity in developing countries. At the same time, as indicated in Box 4-8, the companies apparently do not consider their assets in developing countries to be at risk. They may be overly optimistic in this regard, because not only are large-scale fermentation, milling, and lyophilization activities of concern but also activities of small firms and academics with connections to the large companies deserve attention. However, the committee has no specific information to indicate that such assets are at risk.

Turning more directly to biotechnology companies, successful firms headquartered in the United States are in the early stages of establishing overseas affiliates in developing countries that have assets that, if misused, could enhance

⁴ Additional details are available online at www.google.org/predict.html. Accessed October 14, 2008.

⁵ A list of these neglected diseases is available online at www.who.int/features/factfiles/neglected_tropical_diseases/ntd_facts/en/index1.html.

BOX 4-8
Security of Assets of
International Pharmaceutical Companies

“Our companies have few, if any, assets—materials or equipment—in developing countries that would be of interest to bioterrorists. At the same time, our companies have tight security to protect their intellectual property. As to the dedication of company employees to company security policies, they value their jobs, for which the salaries are generous by local standards.”

SOURCE: Senior official, Pharmaceutical and Research Manufacturers of America (PhARMA), October 2008.

the capabilities of terrorist groups. The current emphasis of such firms, according to the Biotechnology Industry Organization (BIO), is on greater access to innovative medicines at lower prices, improvements in drug safety, advancement of the agricultural revolution, the growth of renewable energy with near-zero carbon footprints, and a cleaner environment. Of course, compliance with regulations in the United States is very important. BIO has 1,400 member firms, including 1,000 members interested in research and development.⁶

Internationally, BIO’s interest has focused on developments pursuant to the Biological Weapons Convention, which BIO believes should now emphasize expanded confidence-building measures that would increase transparency. Such steps could, of course, intersect with intellectual property concerns of private firms. BIO is currently trying to attract more foreign members. Compliance of a broad membership with the bioethics principle set forth in Box 4-9 would be of direct relevance to BTRP’s interests.

The International Council for the Life Sciences, with initial financial support from the Nuclear Threat Initiative foundation, is one of the most active NGOs in promoting improved disease surveillance and response capabilities in developing countries. Its action-oriented programs have highlighted some of the challenges in upgrading surveillance activities in developing countries and the value of partnerships that include scientists, practitioners, and funders. Embryonic surveillance networks that it is sponsoring are located in the Israel-Palestine-Jordan region and the Mekong Delta.

⁶ Biotechnology Industry Organization. 2008. 2007-2008 Milestones. Available online at www.bio.org/speeches/pubs/milestone08/2007-2008_BIO_Milestones_WEB.pdf. Accessed November 30, 2008.

BOX 4-9

Appropriate Uses of Biotechnology

"The Biotechnology Industry Organization has a long-standing policy of opposing the use of biotechnology to develop weapons of any sort that contain pathogens or toxins aimed at killing or injuring humans, crops, or livestock. We will not undertake any research intended for use in developing, testing, or producing such weapons."

SOURCE: BIO. 2008. Bioethics Statement of Principles. Available online at www.bio.org/bioethics/background/principles.asp. Accessed October 17, 2008.

Recommendation 4-6: As BTRP carries out activities in developing countries beyond the FSU, it should work with the Department of State and other appropriate government departments to encourage the private sector to become more actively engaged in biosecurity activities in these countries. Joint funding of high-visibility projects would be a good beginning in this regard.

In particular, BTRP should significantly expand its partnerships with U.S. companies with biological research and production activities in the developing countries. The experience of the Global Development Alliance Program of USAID, which was discussed above, may offer important lessons as to cooperation with the U.S. private sector in supporting specific projects of broad U.S. interest.

BENEFITING FROM THE EXPERIENCE OF OTHER ORGANIZATIONS

BTRP has experience in interacting with many organizations with complementary interests that have been active in the FSU. In developing countries beyond the FSU, the array of relevant foreign organizations will be larger, with a stronger emphasis on international development and with less experience in some aspects of biosecurity. Sharing experiences among organizations and identifying ways to develop mutually supporting activities are increasingly important as the U.S. government, and particularly DOD, expand biosecurity activities in the developing countries.

In summary, dozens of U.S. government departments and agencies, agencies of other governments, international organizations, pharmaceutical and biotechnology companies, and other nongovernmental organizations are involved in activities related directly or indirectly to biological threat reduction

in developing countries. BTRP can benefit from drawing on the capabilities, experiences, and activities of many of these organizations. At the same time, BTRP interventions could inadvertently disrupt important activities of other external organizations that might not be in a position to match financial incentives offered by BTRP.

Three recommendations are offered to help ensure that BTRP's involvement in developing countries is based on up-to-date information on the activities of other external organizations and takes full advantage of opportunities for partnering that are mutually beneficial. These recommendations recognize the need to involve local officials and specialists in consultations concerning the activities of the multiplicity of donors and other organizations that are involved. At the same time, they recognize the importance of not overburdening local officials with excessive discussions.

Recommendation 4-7: BTRP should expand its highly successful annual program review conferences, which bring together its specialists with specialists from host-country organizations and specialists of other external organizations involved in biosecurity activities in regions where BTRP has programs or plans to initiate programs.

More than 200 officials and specialists from 15 countries attended the 2008 conference in Garmisch, Germany. The discussions of recent developments in the biological sciences, achievements of BTRP-supported projects and future plans, and plans of other funding organizations as well as the FSU countries themselves stimulated considerable interest within both government and scientific circles. The only shortcoming of the conference was the limitation on time that prevented more detailed discussions of particularly interesting developments, a shortcoming that can be overcome by increasing the number of parallel sessions.

Recommendation 4-8: BTRP should station regional or country representatives in areas where new activities are initiated with responsibility for keeping abreast of related activities and for promoting synergies among BTRP activities and related interests of other organizations.

After BTRP begins to engage in a country, the most effective way to keep abreast of activities in the country that intersect or could intersect with BTRP activities is a specialist on the ground in or near the country of interest. The BTRP specialist might be stationed at a DOD overseas research laboratory, at a U.S. embassy, or at another appropriate institution. There are too many local organizations with interests in the life sciences and too many foreign providers of assistance in health, agriculture, and other relevant fields to stay current with developments on the ground only by making occasional visits. Such awareness

of related activities should be a priority interest of BTRP as it seeks to establish its niche in the country.

Recommendation 4-9: DTRA should frequently consult with appropriate local officials concerning coordination of activities of both local and external organizations, but such consultations should be designed so as not to create an excessive burden on limited local capabilities to devote personnel to BTRP coordination concerns.

Once BTRP begins to engage with a specific country, specialists from the two countries should be working together regularly. At the same time, representatives of BTRP should periodically meet with senior officials to ensure that the busy officials are involved in the process to the extent possible, recognizing the many other demands on the time of key officials. Communication channels among specialists and officials within developing countries are not always well developed and utilized, and BTRP can play an important role in ensuring that responsible officials are not caught by surprise as engagement proceeds.

Policy and Program Coordination and Integration

This chapter expands on the earlier discussions of the significance of active participation by representatives of the U.S. Department of Defense (DOD) and the Defense Threat Reduction Agency in a variety of biosecurity coordination activities. An important goal of coordination is to firmly embed the Biological Threat Reduction Program (BTRP) within an integrated U.S. government-wide approach to biological threat reduction. In some countries, BTRP could have the lead among U.S. agencies. In other countries, it might more appropriately play a supporting role. In either case, the significance of coordination is underscored by a broad consensus within the U.S. government that biological threats, both those attributable to nature and those that could be instigated by bioterrorists, can seriously affect both broad U.S. security interests and narrower program interests of several departments and agencies.

Only the Department of State and DOD have substantial funding (in the tens of millions of dollars or more annually) that is devoted explicitly to countering the threat of bioterrorism in developing countries. As has been repeatedly underscored throughout this report, however, local capabilities to counter natural disease outbreaks are in many ways the same capabilities that are needed to counter bioterrorism. Other U.S. government departments and agencies have a responsibility and significant funding to work with foreign partners in combating infectious diseases brought on by nature—particularly the U.S. Agency for International Development (USAID), the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Agriculture (USDA). Thus, bringing together in a coherent manner the activities of the wide range of government programs that are devoted to strengthening important aspects of local biosecurity capabilities is a central challenge in developing an integrated program of biological threat reduction.

This report assumes that the relevant coordination mechanisms that have

been mandated by legislation, executive orders, and other White House directives will remain in place. It is not possible to predict changes that may be introduced by the new administration and the new Congress and how they might be implemented. Also, important U.S. nongovernmental organizations are carrying out extensive studies of approaches to reforming the overall national security framework with particular emphasis on coordination. For example, studies with active participation by congressional staffs are devoted to restructuring the responsibilities of the National Security Council (NSC) and the Homeland Security Council (HSC), as well as establishing a select committee for national security within Congress. In particular, the report of the Project on National Security Reform, *Forging a New Shield* (November 2008, Washington, D.C.: Center for the Study of the Presidency), addresses such issues. In any event, an analysis of possible changes in the structure and responsibilities of organizations within the executive branch or Congress is beyond the scope of this study. At the same time, the suggestions that are presented in this report should be adaptable to almost any structure that could be put in place in the near future.

VENUES FOR COORDINATION IN WASHINGTON

Interagency coordination involving issues of interest to BTRP takes place in many settings, usually under the auspices of Congress, the NSC, the Office of Science and Technology Policy, DOD, other government departments, and U.S. embassies. International venues that provide opportunities for meetings with representatives of international organizations and other countries that support relevant activities in developing countries are also important. Coordination within the developing countries themselves, where many external organizations are usually active, is crucial.

As the BTRP budget continues to grow, Congress has taken an increasing interest in the interfaces between BTRP and related programs. Congressional hearings have included discussions of coordination of biological programs within DOD. Regarding coordination with other U.S. government departments, Congress requested that, as one step, this report should address BTRP's participation in the integration of programs across the government. At the same time, DOD has provided Congress, other departments, and the public with detailed information about BTRP activities and future plans. Such information sharing is an important step in encouraging coordination.

The NSC will undoubtedly continue to serve as a principal interagency policy coordination mechanism for international biosecurity-related activities. In 2004, the President approved the establishment of a biodefense policy to be carried out under the leadership of the NSC and HSC.¹ Within the framework

¹ Biodefense for the 21st Century. 2004. Washington, D.C.: White House Press Office. Available online at www.whitehouse.gov/homeland/20040430.html. Accessed November 29, 2008.

of this policy, a Policy Coordinating Committee (PCC) has been established and is jointly chaired by representatives of the two councils. A working panel of the PCC considers international bioengagement, including the preparation of country-specific overview documents that address the threats and types of responses that are needed in these countries. In support of this effort, studies are under way within the intelligence community to identify the developing countries of highest-priority biosecurity concern in terms of U.S. interests.

A significant aspect of the PCC is the inclusion of USAID as an active participant in its deliberations. The Department of State, DOD, HHS, USDA, the Department of Energy, and the Environmental Protection Agency have for several years comprised a core group of nonproliferation departments and agencies in the biological field. Involvement of USAID should improve assessments of on-the-ground conditions in developing countries and open new opportunities for partnerships within the U.S. government. Also, USAID has a long-term outlook and should be an effective advocate for sustainability of activities initiated by other departments and agencies. See Appendix I for a complete list of the participants in the international bioengagement panel.

The addition of the Department of Treasury to the panel would also be appropriate. Such representation would provide an important link to the World Bank and other international development banks. These international financial institutions play major roles in strengthening important health and agriculture infrastructures in developing countries.

Stimulation by the HSC of greater interest in international biosecurity within the Department of Homeland Security (DHS) could facilitate transfer of international experience and knowledge to the specialists responsible for protecting the United States while encouraging international adoption of selected biosecurity approaches developed for domestic application, such as risk assessment methodologies. In particular, Mexico's expanding interest in biotechnology should be of considerable interest. While there is no available evidence that drug smuggling routes from Latin to North America have been used for illicit trafficking in dangerous pathogens, this possibility cannot be dismissed. Also, the smuggling into the United States of plant disease agents buried in small containers of soil aboard an airplane from anywhere in the world, which is a shared concern of USDA and DHS, could threaten agriculture production.

Another coordination mechanism that brings together departments and agencies is the Nonproliferation Interagency Policy Roundtable (NIPR), which is chaired by the Department of State. This group reviews cooperative biological research projects being considered by U.S. government agencies (primarily the State Department and BTRP) that engage scientists from the former Soviet Union (FSU). These research proposals have usually involved scientists or institutions that had been associated with the Soviet biological weapons program.

All proposed research projects to be supported by BTRP must have interagency approval through NIPR, which concentrates on dual-use concerns.

Should BTRP expand to other countries, such an interagency review will presumably apply to projects involving scientists in these countries as well.

Recently, BTRP has broadened the scope of its research activities to include FSU scientists who have the capability to handle dangerous pathogens on the Select Agent List, regardless of whether they had previously been engaged in weapons-related activities. This is a welcome development that recognizes that nonweapons scientists with certain skills should be of concern comparable to the attention given to possible inappropriate activities of former weapons scientists. This approach has special significance for sponsoring research in countries outside the FSU that were never involved in biological weapons activities.

A third coordination mechanism is the International Biological Engagement Backstopping Group, which is convened by the Department of State. This information-sharing group meets monthly. About 40 officials from a variety of departments and agencies typically attend.

In addition to shared concerns about proliferation and bioterrorism, BTRP's interests intersect with three other types of activities of other U.S. government departments and agencies. Overlaps of BTRP projects with development assistance activities have been repeatedly mentioned in this report. In addition, government departments and agencies that promote U.S. private-sector investments abroad and influence international trade activities can indirectly contribute to biological threat reduction, as discussed in Chapter 4. Finally, U.S. organizations that are responsible for supporting international engagement to enhance scientific interests of the United States have some common objectives with BTRP.

This broad mosaic of overlapping interests provides opportunities for synergism that can contribute to the achievement of multiple government objectives. DOD should be represented in relevant interagency discussions at a sufficiently senior level to ensure that its representatives can speak authoritatively on behalf of BTRP and other DOD entities that support biosecurity-related programs.

Finally, with regard to coordination within DOD, for years there have been internal mechanisms within DOD to develop general guidance for clusters of DOD activities. Many of the health-oriented activities are carried out under the general purview of DOD's Office of Health Affairs. The Veterinary Corps of the Army has a well-developed strategy coordinated throughout DOD that guides its worldwide activities. DOD's overseas research laboratories report to a central coordinating office. Each combatant command has a senior medical officer and staff that could provide a focal point for periodic meetings with BTRP, which should add cohesion to the overall DOD, and indeed the national, effort.

BTRP has not been a central participant in the foregoing efforts within DOD. But it has recently increased its attention to the importance of coordination throughout the Pentagon. Meanwhile, DOD has established on paper

a steering group chaired jointly by the assistant secretary for global security affairs and the assistant secretary for health affairs to bring greater cohesion to the diverse DOD interests in biological threat reduction and related topics. BTRP presumably was to be included in these activities, but effective coordination has yet to emerge.

Given the foregoing discussion, two recommendations are important in helping to ensure coordination of BTRP activities.

Recommendation 5-1: DOD should ensure that the interests of BTRP, as well as other DOD entities, are adequately represented at an appropriate level in a variety of biology-relevant interagency coordination mechanisms that are led by the National Security Council, the Office of Science and Technology Policy, the Office of Management and Budget, other White House offices, and the Department of State.

Recommendation 5-2: As BTRP expands the geographic coverage of its activities, DOD should ensure more systematic interactions among the many DOD units with biology-related programs in developing countries.

STRENGTHENING BTRP'S COORDINATION WITH ITS PARTNERS

At the program level, BTRP transfers funds to other U.S. government departments and agencies and to private-sector entities. This approach allows BTRP to draw on their resources in enabling BTRP to carry out its activities. It also helps ensure that the recipient organizations are aware of the interfaces of their own activities with BTRP interests. Of course, these transfers are year-to-year, so the recipients have difficulties in planning for long-term involvement of key specialists.

BTRP shares information on successes, difficulties, and lessons learned, while obtaining insights as to the activities of other organizations, through a variety of mechanisms. The mechanisms have included the organization of and participation in technical meetings at home and abroad and regular consultations with other important organizations. BTRP's partners are ever expanding in number, as indicated in Appendix D, and this is a positive step.

Coordination at both the global and the regional levels concerning international assistance efforts is also important. They include, for example, the biosecurity efforts of a variety of international organizations, as discussed in Chapter 4. Also, the international development focus of the Organization for Economic Cooperation and Development's (OECD), including its Development Assistance Committee and its International Futures and Biotechnology activities, can be helpful to BTRP. OECD is a hub of relevant information and can assist BTRP in keeping abreast of meetings, studies, reports, and other undertakings of interest.

Drawing on the capabilities and reputations of HHS and USDA deserves special attention. By involving these departments, BTRP should be able not only to expand its capabilities but also to build stronger relationships with governments in developing countries that may be uncertain about the intentions of DOD. To the extent possible, BTRP activities should be integrated with activities supported financially by the other departments themselves. However, if necessary, BTRP should finance the contributions provided by the other departments.

In view of the foregoing discussion, the following recommendation is particularly appropriate.

Recommendation 5-3: The authors of the National Defense Authorization Act should include in the act a provision calling on DOD to utilize as appropriate the capabilities of other U.S. government departments and agencies, and particularly HHS and USDA, to assist in the development and implementation of BTRP activities. To this end, the act should recognize the importance of transfers of BTRP's resources to these organizations as necessary and should call for BTRP to provide Congress within its annual reports information on the extent and effectiveness of such transfers.

COORDINATION IN THE FIELD

The importance of BTRP's coordination in the field as well as coordination in the capitals of providers of international assistance is clear. Dozens of assistance providers, dozens of important international companies, and dozens of nongovernmental organizations concerned with health and agriculture have deep roots in the developing countries and are active in the biosciences. Therefore, special efforts should be coordinated in the field where activities are being planned or are under way.

In the field, coordination mechanisms that are established by the host governments themselves, with or without international assistance, can be helpful—and in some cases essential—in ensuring that activities are complementary. Unfortunately, however, many developing-country governments do not have capabilities even to keep track of all foreign interventions in biology-related activities, let alone effectively influence how these interventions are carried out. The coordination mechanism may be simply one overworked staff member in the ministry for economic development, for example.

Indeed, the coordination task for a country with limited personnel capabilities is often very difficult. For example, there are more than a dozen donors and several dozen nongovernmental organizations with international affiliations that are addressing public health issues in Cambodia. Nevertheless, host governments such as the Cambodian government should have the best possible

overviews, however incomplete, of the totality of both local and international activities that are relevant to biosecurity interests in their countries.

Finally, and of great importance, many U.S. ambassadors in developing countries are active in bringing coherence to the overall U.S. government-supported approaches in the health and agricultural fields. But they simply may not think of BTRP as contributing to basic health and agriculture needs. When such an omission is the reality, it needs correction.

Recommendation 5-4: BTRP should ensure that its activities are an integral component of the coordination portfolios of U.S. ambassadors in countries where BTRP has activities.

To this end, BTRP representatives have the task of not only educating the embassy staffs on the scope and importance of biosecurity but also emphasizing how the embassy can benefit diplomatically from the program—for example, by gaining insights as to important developments in the country, participating in events that recognize BTRP contributions in the country, and establishing stronger contacts with important biosecurity leaders of the country. The embassy should benefit from the good will that is generated by BTRP's involvement in promoting overall public and agricultural health as well as enhanced security.

PRIORITY FOR EFFECTIVE COORDINATION

If BTRP is to have a sustained presence that is welcomed and supported by local institutions and foreign organizations, adequate coordination on the front end of involvement is essential. Such coordination should help ensure that other relevant organizations welcome and do not oppose BTRP's presence. A positive attitude of other important external and internal leaders can return major dividends in the long run. Of course, BTRP must avoid building false expectations regarding its financial resources and its intended involvement in specific countries. Therefore, it is important to follow through on even tentative commitments if at all possible.

The intersections of coordination and public relations will be of great significance in many situations. Foreign political leaders may be far more concerned about whether they may become embroiled in political acrimony by working inappropriately with DOD than in ensuring that the details of project design and implementation are sound. BTRP must be skillful in seeking advice from more experienced organizations and flexible in adjusting its approach as necessary. Nongovernmental organizations can often be helpful in this regard, even though BTRP has had only limited experience in the FSU in working closely with them.

In the developing countries of Africa, Asia, the Middle East, and Latin America, early involvement of potential local partners in shaping BTRP's activities is essential. Consultations with the private sector will help BTRP expand its horizons regarding the roots and routes of bioterrorism and will also help guide innovative approaches to counter biological threats in developing countries. These countries are new terrain for BTRP, but many private-sector organizations are quite familiar with this terrain.

In short, BTRP needs not only to build relations with governments in countries where it will mount programs but also to strengthen the web of institutions devoted to enhancing biosecurity that stretches across and between countries. These institutions may have goals similar to those of BTRP, but they may approach them in different but innovative ways that can help guide BTRP's approaches.

Recommendation 5-5: BTRP should adopt and adapt successful approaches that have been pioneered by other organizations while developing its own niche among the many programs of other external organizations devoted to reducing biological threats in the low- and middle-income countries.

6

Recommendations

This chapter consolidates the recommendations set forth in previous chapters. The recommendations that are of priority importance are so designated below. Determination of whether a recommendation should be classified as a priority recommendation has been based on the committee's judgment as to (1) the importance and potential impact of the recommendation, (2) the likelihood that the recommendation can be successfully implemented, and (3) other factors particular to the specific recommendation, such as the likelihood of sustainability. Many recommendations call for modification of the approaches of the Biological Threat Reduction Program (BTRP) already under way in the former Soviet Union (FSU) before applying them outside the FSU, recognizing that the operating environments in other countries may be quite different.

SECURITY CONTEXT

Priority-Recommendation 1-1: The Department of Defense (DOD) should, within the U.S. government's evolving global biological engagement strategy, promptly expand BTRP into selected developing countries beyond the FSU (page 44).

Priority-Recommendation 1-2: BTRP's initial engagement activities in any developing country outside the FSU should be planned to last for up to 5 years, with consideration then to be given at the end of this period to extending engagement activities up to another 5 years depending on initial successes in reducing biological threats and the future importance of continued engagement (page 45).

CAPACITIES OF DEVELOPING COUNTRIES TO COUNTER BIOLOGICAL THREATS

Priority–Recommendation 2-1: BTRP should continue to emphasize to partner governments the importance of their strengthening on a broad basis the infrastructures necessary to address human, animal, and plant diseases and the underlying scientific capabilities of the countries as essential foundations for addressing threats of bioterrorism (page 50).

Recommendation 2-2: BTRP should give special attention to strengthening the human resource base to address biosecurity challenges (page 53).

Recommendation 2-3: From the outset of engagement with a specific country, BTRP should give attention to encouraging the country to improve its policy framework that affects upgrading of biosecurity capabilities and related activities (page 55).

Recommendation 2-4: BTRP should draw on its extensive experience in providing and upgrading facilities and equipment in the FSU to improve the functioning of important facilities in developing countries, including both scientific and security aspects (page 55).

Recommendation 2-5: An early step in BTRP's engagement efforts with specific countries should be to jointly identify and characterize pathogen collections—both collections established under the auspices of the government and informal collections established under the purview of individuals or groups of scientists. The security aspects of these collections, and particularly the capacity of the government to ensure compliance with internationally acceptable biosafety regulations on a long-term basis, should be given high priority (page 56).

APPLICABILITY OF BIOLOGICAL THREAT REDUCTION APPROACHES IN THE FSU TO OTHER DEVELOPING COUNTRIES

Priority–Recommendation 3-1: As BTRP moves beyond the FSU, the theme of partnerships with counterpart organizations in host countries should be a guiding principle (page 67).

Priority–Recommendation 3-2: BTRP should develop in cooperation with each partner government a Strategic Plan that describes the security situation and particularly vulnerabilities relevant to biological assets in the country, disease burdens and trends, local capabilities to detect and respond to outbreaks, and plans for cooperative threat reduction activities within the context of national plans and capabilities of both countries (page 69).

Recommendation 3-3: As BTRP considers engagement in developing countries outside the FSU with little or no history of biological warfare or bioterrorism activities, BTRP should continue to expand its list of pathogens of interest to include pathogens of high-priority local interest (page 72).

Recommendation 3-4: Projects requiring renovation or construction activi-

ties should be an important aspect of BTRP activities in countries outside the FSU (page 74).

Priority–Recommendation 3-5: BTRP should support cooperative biological research in countries where it engages, even if local research capabilities are limited (page 77).

Recommendation 3-6: In moving beyond the FSU, BTRP should be flexible in the types of formal commitments it requires of partner governments as a basis for cooperation (page 79).

Priority–Recommendation 3-7: DOD should streamline its chain of command for implementing BTRP and simplify the operational process within DOD to enhance efficiency, reduce misunderstandings, and increase transparency concerning U.S. intentions toward the host governments (page 81).

Recommendation 3-8: BTRP should give priority to adequate advanced planning in order to ease visa problems for travel between the United States and partner countries in both directions (page 81).

Priority–Recommendation 3-9: BTRP should continue to develop improved metrics that will help guide evaluations of the impacts of BTRP and provide information for setting priorities for activities designed to reduce proliferation of biological weapons as well as related risks from naturally occurring contagious disease agents (page 84).

Priority–Recommendation 3-10: BTRP should take into account possible local concerns about a large presence of DOD activities in the countries where it engages. Joint projects with other organizations playing important roles and an emphasis on responding to local initiatives should be helpful in this regard (page 85).

Recommendation 3-11: The design and operation of the TADR system should be carefully reviewed by a well-qualified, independent organization that has not been directly involved in the design or establishment of the system before BTRP advocates transportability of the components of the system to other countries beyond the FSU (page 87).

Recommendation 3-12: Before BTRP begins planning construction of central reference laboratories outside the FSU, it should resolve issues concerning the need, location, operations, and international transparency in the long term regarding the facilities to which it has committed in the FSU (page 88).

Recommendation 3-13: BTRP should refrain from advocating high-technology approaches that may be inappropriate in low-technology environments (page 88).

RELEVANT BIOSECURITY ACTIVITIES OF OTHER ORGANIZATIONS

Recommendation 4-1: DOD should continue to be an active participant in the interagency nonproliferation process by responding whenever possible

to requests of the Department of State and the National Security Council to deploy BTRP assets in countries beyond the FSU and by taking the initiative to advocate deployments that can effectively enhance the overall national effort (page 94).

Recommendation 4-2: BTRP should work closely with other DOD entities that are involved in activities that support biosecurity in developing countries, drawing on the familiarity of these entities with conditions on the ground and their sensitivity to important issues in dealing with local leaders of government organizations and facilities in the countries of interest (page 98).

Recommendation 4-3: BTRP should strengthen its relationships with the U.S. Agency for International Development (USAID) in Washington and in the field. One or more jointly funded projects would be an effective step in this regard (page 100).

Recommendation 4-4: BTRP should adopt progress toward the host country's effective implementation of the International Health Regulations, including actions concerning public health emergencies, as an important measurement of success in countries where it mounts major efforts (page 104).

Recommendation 4-5: BTRP should give greater attention to the biosecurity roles of the international development banks and of international and regional organizations. In coordination with the Department of State and USAID, BTRP should regularly consult with these organizations concerning the further development of BTRP activities (page 105).

Recommendation 4-6: As BTRP carries out activities in developing countries beyond the FSU, it should work with the Department of State and other appropriate government departments to encourage the private sector to become more actively engaged in biosecurity activities in these countries. Joint funding of high-visibility projects would be a good beginning in this regard (page 108).

Recommendation 4-7: BTRP should expand its highly successful annual program review conferences, which bring together its specialists with specialists from host-country organizations and specialists of other external organizations involved in biosecurity activities in regions where BTRP has programs or plans to initiate programs (page 109).

Priority-Recommendation 4-8: BTRP should station regional or country representatives in areas where new activities are initiated with responsibility for keeping abreast of related activities and for promoting synergies among BTRP activities and related interests of other organizations (page 109).

Recommendation 4-9: DTRA should frequently consult with appropriate local officials concerning coordination of activities of both local and external organizations, but such consultations should be designed so as not to create an excessive burden on limited local capabilities to devote personnel to BTRP coordination concerns (page 110).

POLICY AND PROGRAM COORDINATION AND INTEGRATION

Recommendation 5-1: DOD should ensure that the interests of BTRP, as well as other DOD entities, are adequately represented at an appropriate level in a variety of biology-relevant interagency coordination mechanisms that are led by the National Security Council, the Office of Science and Technology Policy, the Office of Management and Budget, other White House offices, and the Department of State (page 115).

Recommendation 5-2: As BTRP expands the geographic coverage of its activities, DOD should ensure more systematic interactions among the many DOD units with biology-related programs in developing countries (page 115).

Priority-Recommendation 5-3: The authors of the National Defense Authorization Act should include in the act a provision calling upon DOD to utilize as appropriate the capabilities of other U.S. government departments and agencies, and particularly the Department of Health and Human Services and the Department of Agriculture, to assist in the development and implementation of BTRP activities. To this end, the act should recognize the importance of transfers of BTRP's resources to these organizations as necessary and should call for BTRP to provide Congress within its annual reports information on the extent and effectiveness of such transfers (page 116).

Recommendation 5-4: BTRP should ensure that its activities are an integral component of the coordination portfolios of U.S. ambassadors in countries where BTRP has activities (page 117).

Recommendation 5-5: BTRP should adopt and adapt successful approaches that have been pioneered by other organizations while developing its own niche among the many programs of other external organizations devoted to reducing biological threats in the low- and middle-income countries (page 118).

THE WAY AHEAD

The risk of bioterrorism is too great for BTRP not to be among the leading organizations internationally in addressing the threat outside the FSU. BTRP, in continuing consultation with host-country governments, should emphasize a systems approach to address a range of pathogens—particularly those of day-to-day concern—that strengthens health and agricultural surveillance capabilities, pathogen security, and research activities on a broad basis. BTRP needs to expand cooperation with U.S. and foreign government and nongovernment organizations with overlapping interests. DOD's planning and operational procedures should be streamlined. Sustainability must be at the top of BTRP's priority concerns. Strategic plans and more meaningful metrics developed with host-country governments that respond to the overall interests of the governments need to guide the effort.

DOD should consider this report as more than a series of disconnected recommendations from which it can simply choose. Each recommendation

addresses an important issue that needs to be addressed if BTRP is to find success in its effort to reduce the risks associated with the threat of bioterrorism. This report provides a framework and a starting point to finding the best approaches within the overall framework.

As the first step in developing an action plan, DOD should promptly identify initial target countries outside the FSU. The selection criteria for target countries are numerous but should include (1) the likelihood of significant risk reduction and (2) the near-term likelihood that successes can be sustained over the long term. In some cases, BTRP may be the appropriate lead organizations for the U.S. effort, while in other cases, BTRP may play a supporting role in the national effort. Of course, BTRP must be welcomed in the countries of interest. Whether reconstructing facilities, upgrading surveillance or research capabilities, or providing training and related services, BTRP's activities should be based on a clear vision of how they will improve biosecurity in the next 5 years. In some cases, a broad countrywide approach may be necessary to reduce vulnerabilities significantly. In other cases, a relatively minor contribution by BTRP may make a substantial difference in the biosecurity landscape of the country.

In conclusion, BTRP can make a significant contribution to raising awareness of the governments, specialists, and public in developing countries of the importance of a range of policies and programs for addressing biological threats. An effective mechanism for raising awareness is the launching of cooperative projects that demonstrate the impacts of practical approaches to addressing vulnerabilities while also enhancing economic development and public health. The global community of specialists in the field of biosecurity is small, and information about BTRP cooperative projects will spread quickly. Action-oriented projects rather than vague promises and general discussions should continue to characterize BTRP's approaches.

In time, BTRP activities, as part of an integrated U.S. government approach, should increase respect for U.S. humanitarian-oriented objectives while helping to contain biological assets that could be misused. Achieving these parallel objectives will help reduce the dangers highlighted by the biodefense strategy of the White House that is summarized in Box 6-1.

In summary, BTRP should play an important role in the U.S. government's global response to the growing biological threat, with special attention to potential bioterrorism activities with roots in the developing countries outside the FSU.

BOX 6-1
Threat Posed by Biological Weapons

"Biological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies. Biological weapons attacks could cause catastrophic harm. They could inflict widespread injury and result in massive casualties and economic disruption. Bioterror attacks could mimic naturally occurring diseases, potentially delaying recognition of an attack and creating uncertainty about whether one has even occurred. An attacker may thus believe that he could escape identification and capture or retaliation."

SOURCE: Biodefense for the 21st Century. 2004. Available online at www.whitehouse.gov/homeland/20040430.html. Accessed November 27, 2008.

Appendixes

Appendix A

Presenters at Committee Meetings

Robert Bertram, Agency for International Development
David L. Blazes, Department of Defense, Global Emerging Infections
Surveillance and Response System
Peter Bloland, Centers for Disease Control and Prevention
Jennifer Brewer, Department of Defense, Defense Threat Reduction Agency
Shawn Cali, Department of Defense, Defense Threat Reduction Agency
Robert Emrey, Agency for International Development
Jennifer Gaudio, Sandia National Laboratories
Roger Glass, John E. Fogarty International Center
Floyd Horn, Department of Agriculture, Agricultural Research Service
(retired)
Jack Hume, Bechtel Corporation
John Kilama, Global Bioscience Development Institute, Inc.
Michael Kurilla, National Institute of Allergy and Infectious Diseases
Jason Rao, Department of State
James Reid, Department of Defense, Office of the Secretary
Terrence Taylor, International Council for the Life Sciences
Andrew Weber, Department of Defense
James Wolfram, Civilian Research and Development Foundation
Samuel Yingst, Army Medical Research Institute for Infectious Diseases

Appendix B

Organizations that Provided Background Information

Biotechnology Industry Organization
Center for Global Development
Henry L. Stimson Center
National Security Council
Organization for Economic Cooperation and Development
Pharmaceutical Research and Manufacturers of America
Science Applications International Corporation
World Bank

Appendix C

Summary Reports of Field Visits

The field visits were designed to give members of the committee an opportunity to observe conditions in a few developing countries, representing diverse income levels, economic structure, and scientific and medical capacity. (See Tables 3-1 and 3-2 on pages 63 and 64, which provide data characterizing each of the countries visited as well as several other countries within and outside the former Soviet Union, for purposes of comparison.) There was no expectation that these trips would result in comprehensive assessments of the biosecurity and biosafety situations in individual countries or provide the basis for subsequent programmatic activities by the Department of Defense or other U.S. government agencies.

The brief reports included in this section reflect the views of the travelers based on the limited number of institutions and experts they were able to visit and meet. More detailed oral reports were provided to the full committee.

SUMMARY OBSERVATIONS FROM FIELD VISIT TO THE DEMOCRATIC REPUBLIC OF THE CONGO

Trip Participant: Claire A. Cornelius, D.V.M., U.S. Army, currently Ph.D. candidate, University of Chicago, committee member

Visit Dates: October 25-31, 2008

(1) Biosecurity awareness; pathogens and vulnerabilities of concern; and governmental legislation, regulations, and policies to address vulnerabilities

A major legislative transition occurred in the Democratic Republic of the Congo (DRC) during the visit, precluding any formal meetings with ministry

leaders in the sectors of health, agriculture, national education, scientific and technological research, trade, and environment. However, in discussions with other public health leaders, it was clear that the DRC is both aware of and committed to strengthening its biosafety and biosecurity framework. The DRC is party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety (ratified on February 8, 2005) and, in partnership with the Global Environment Facility administered by the United Nations Environment Program, has begun to establish a national biosafety framework in order to address potential risks associated with the use of modern biotechnology.

Although there are several highly dangerous pathogens endemic to the country, research on these pathogens appears to occur primarily in partnership with other countries that have dedicated biosafety level 3 or 4 (BSL-3 or -4) laboratories and expertise outside Africa. Congolese scientists would like to greatly improve both their capacity and their capability to conduct comprehensive diagnostics and characterization of strains isolated within their borders as well as to have a reference or training laboratory for other institutions in Africa. In the human health sector, Ebola and other hemorrhagic viruses, avian influenza, poliomyelitis, tuberculosis, HIV, anthrax, plague, monkeypox, African sleeping sickness, rabies, diarrheal diseases, malaria, and Buruli ulcers are of high diagnostic priority. From both the veterinary and the conservation perspectives, Ebola (especially in endangered primates), rabies, brucellosis, plague, blackleg, anthrax, foot-and-mouth disease, diarrheal and chronic wasting diseases in hoof stock, and a variety of parasitic maladies represent illnesses of major clinical interest. Although there is a basic disease surveillance system in place, data collection, analyses, alerting systems, and rapid response in remote regions of the country still remain largely inefficient and uncoordinated.

(2) Budget, personnel, and other challenges in upgrading biosecurity

Budgets for biosafety, biosecurity, biomedical education, advanced laboratory equipment, and even basic research at key public health institutes and universities (for example, the University of Kinshasa, the University of Lubumbashi, and the University of Kisangani) are insufficient. More training and career placement are required to develop specialists in biosafety, biotechnology (especially microbiology, molecular biology, and immunology), international law, medicine (human and veterinary), information technology, and public education, especially with regard to the tenets of the Cartagena Protocol.

(3) Interests and programs of foreign organizations and interests of local government in international engagement on biosecurity issues

Ministry officials and researchers strongly support cooperative capacity-building programs with the European Union, the United States, and other

African nations on biosecurity and infectious disease research and welcome new partnerships. Staff members from the Central Veterinary Laboratory have received training from the International Atomic Energy Agency and collaborated with investigators from the University of London, Royal Veterinary College; the Institute of Tropical Medicine (ITM)-Antwerp; the Onderspoort Veterinary Institute in South Africa; and the Centers for Disease Control and Prevention (CDC) in Atlanta. Similarly, the National Institute of Biomedical Research of the DRC Ministry of Public Health has ongoing projects with several countries in Africa (particularly for trypanosomiasis research), ITM-Antwerp, the U.S. Army Medical Research Institute for Infectious Diseases, CDC, and the Pasteur Institute; and it serves as a World Health Organization reference laboratory for poliomyelitis.

List of Institutions Visited

- National Institute of Biomedical Research, DRC Ministry of Public Health, Kinshasa, Kole
- Central Veterinary Laboratory, Kinshasa
- CDC Global Aids Program office, Kinshasa
- Central African Regional Program for the Environment of the U.S. Agency for International Development, Kinshasa
- U.S. Embassy, Kinshasa

SUMMARY OBSERVATIONS FROM FIELD VISIT TO MEXICO

Trip Participants: Joseph Silva, former dean of medicine, University of California, Davis; and Michael Clegg, Donald Bren Professor of Biological Sciences, Department of Ecology and Evolution, University of California, Irvine, and foreign secretary, National Academy of Sciences (NAS)

Visit dates: October 6-10, 2008

(1) Biosecurity awareness; pathogens and vulnerabilities of concern; and government legislation, regulations, and policies to address vulnerabilities

Biosecurity awareness is high across Mexican institutes, agencies, and universities. Planning and implementation of effective programs are under way. While we could not visit all the laboratories in Mexico, we learned that salmonella, anthrax, clostridia, tuberculosis, hantaviruses, multidrug-resistant enteric organisms, dengue, and plasmodium (malaria) are of most concern. In addition, the United States has experienced serious outbreaks originating from Mexican agricultural produce contaminated with *Cryptosporidia* and *Escherichia coli*.

Mexico has more daily interactions with the United States than any other country, including Canada. Specialists are fully aware of problems (especially infectious diseases) related to border control. Mexico is an important hub for distributing or transmitting infections to the United States. The cross-border commercial and tourist traffic is sizeable. Mexico City and Mexico's ocean shoreline cities attract many international travelers by air or cruise ships. Many of these travelers also visit the United States. Several major outbreaks of food-borne diarrhea related to the ready and relatively cheap supply of vegetables and fruit exported by Mexico occur in the United States almost annually. Thus, it is in the interest of the United States to sponsor the development of a rapid surveillance system with accurate and rapid and high-quality diagnostic capabilities in this neighboring developing country. Most of those contacted expressed the view that they have enough laws to control infections, except for the authority to institute total isolation of individual citizens (that is, home or institutional confinement with all its aspects, including body location monitors).

(2) Budget, personnel, and other challenges in upgrading biosecurity

Mexico is a large country facing significant economic challenges, and this may explain in part why federal funding of science and technology is less than 0.4 percent of the country's gross national product (compared to approximately 1 percent for Brazil, the most populous country of Latin America). Despite this low level of investment, Mexico has established good research capabilities; and governmental surveillance for infection is improving, as is the establishment of modern laboratories with well-trained investigators. More funding would accelerate their growth. An occurrence of a natural outbreak with an especially dangerous pathogen (EDP) or international release of an EDP could pose a large threat to the United States because of our border porosity and its migrant crossings. Protection on the Mexican side is provided by 12 national institutes within a system equivalent to the U.S. National Institutes of Health (NIH) system. Of these 12 institutes, 10 also have education in their missions besides research. Owing to the volume of human movement and to the diffuse geographic interconnections between the United States and Mexico, U.S. health security is strongly intertwined with that of Mexico. Thus, it is important to augment current Mexican programs to reduce biological threats in this territorially large and populous country.

We visited a few laboratories in a short period. Thus, any attempt to make estimates of the resources needed to improve biosafety and biosecurity would be superficial. Suffice it to state that all laboratories visited expressed keen interests in upgrading their security systems (new equipment and technologies and especially training). We believe the costs will be modest because of well-developed extant programs. All welcome more one-on-one training for

their personnel in these areas. CDC and NIH are important for the training to date.

(3) Interests and programs of foreign organizations and interests of local government in international engagement on biosecurity issues

Currently, Mexico receives assistance from various U.S. universities, as well as those from Canada, the United Kingdom, and Germany. Local organizations are interested in receiving assistance for biosecurity upgrades and training in biosafety and biosecurity and for construction of additional BSL-3 laboratories with sustained support for personnel, supplies, and equipment. There is also interest in expanding research collaborations with U.S. investigators. U.S. agencies concerned with epidemiology and surveillance responsibilities should review how to better provide more timely information on infectious outbreaks affecting humans, animals, and plants. Some consideration should be given to periodically and regularly incorporating Mexican institutions into a better information network with U.S. agencies.

List of Institutions Visited

- National Center of Epidemiological Surveillance and Disease Control, Mexico City
- Institute of Diagnostic and Reference Epidemiology, Mexico City
- Institute for Biotechnology, Cuernavaca
- National Autonomous University of Mexico, Cuernavaca
- U.S. Embassy, Mexico City
- National Institute of Genomic Medicine, Mexico City
- Ministry of Foreign Affairs, Mexico City
- Center for Research and Advanced Studies of the National Polytechnic Institute, Irapuato
- University of Monterrey, Monterrey
- U.S.-Mexico Foundation for Science, Mexico City

SUMMARY OBSERVATIONS FROM FIELD VISIT TO MALAYSIA

Trip participants: Timothy P. Endy, State University of New York, Upstate Medical University, Department of Medicine, committee member; and Alice Chu, U.S. Embassy, environmental, science, technology, and health officer and control officer

Visit Dates: October 17-21, 2008

(1) Biosecurity awareness; pathogens and vulnerabilities of concern; and government legislation, regulations, and policies to address vulnerabilities

Malaysia is a developing country with an emerging biotechnology base in Southeast Asia. It is a member of the Organization of the Islamic Conference and strongly emphasizes its Islamic roots. Malaysia has several emerging pathogens of interest to this committee. It was the site of a large Nipah virus outbreak in the late 1990s that resulted in hundreds of deaths, the culling of the entire pig population, and economic loss from the pig industry. This outbreak illustrated some of the current issues in Malaysia. The Nipah outbreak resulted in racial tensions in Malaysia, specifically in the form of discrimination against Chinese Malaysians, who, as non-Muslims, are the only ethnic group that raises pigs. There were also initial accusations that the Nipah outbreak occurred as a result of U.S. bioweapons experiments. In addition, Malaysia was one of the countries that experienced cases of severe acute respiratory syndrome in 2001, and it also has current concerns over avian influenza. Select agents that are endemic in Malaysia include Japanese encephalitis, Nipah virus, and melioidosis. The racial tensions in Malaysia are significant.

The U.S. Department of State's Biosecurity Engagement Program sponsored a conference entitled "Biosafety, Biosecurity Asia: Concept, Issues and Challenges" in Kuala Lumpur, Malaysia, on May 21-22, 2007. This was cosponsored by the Malaysian Ministry of Defense and chaired by the Malaysian Science and Technology Research Institute for Defense (STRIDE). The conference's stated objectives were (1) to establish a mechanism for creating biosafety and biosecurity awareness and education, (2) to create a platform to explore issues pertaining to national acts on biosafety and biosecurity worldwide, and (3) to become a catalyst for regional and international cooperation on biosafety and biosecurity issues. The minister of the interior delivered a speech on behalf of the prime minister of Malaysia, stressing that this conference addressed three critical issues for Malaysia: (1) national security, (2) public health, and (3) biotechnology. There were 11 governmental organizations participating in this conference, with STRIDE in the lead. Malaysia is a signatory to the Biological Weapons Convention, has passed its own Prevention of Infectious Disease Act, and has passed and currently is revising a Biosafety Act, including a select agent list.

(2) Budget, personnel, and other challenges to upgrading biosecurity

Malaysia has invested heavily in the creation of modern laboratories, BSL-3 facilities, and applied research. Malaysia funds approximately 400 Ph.D. students per year to receive scientific training outside Malaysia and has an active grants program to attract them back to Malaysia. All institutes visited consid-

ered bioterrorism a low risk and deemed the application of dual-use technology to be possible but also a low risk. They felt that biosafety and biosecurity were on the national agenda, as evidenced by investment in the development of safe laboratory practices and biosecurity.

Malaysia is a developing nation with a high degree of biotechnological investment and potential for dual-use misdirection. They have select agents and endemic pathogens that could be used for bioterrorism. The minority population occupies the most educated parts of Malaysian society, including scientists and researchers. Malaysia has active trade and open borders with other Muslim countries

(3) Interests and programs of foreign organizations and interests of local government in international engagement on the biosecurity issue

Biosafety and biosecurity issues are clearly on the Malaysians national agenda. The Pacific Command, the Department of State, and Sandia National Laboratories have sponsored several workshops on biosafety and biosecurity in Malaysia. CDC is awaiting signature on a memorandum of understanding to place a CDC representative in Malaysia.

All institute officials agreed on the need for better biosafety and biosecurity training, biosecurity collaboration, improved physical security of pathogen collections, and development of a personnel reliability program. When asked which organization is the best to deliver this type of training, they all acknowledged that the World Health Organization and Australian and Singaporean centers are acceptable. Some hesitated regarding CDC, citing mixed experiences with the center, and expressed doubts about the Department of Defense, but all had had good experiences with the Department of State.

In conclusion, I would consider Malaysia a country of concern and a country that would benefit from the tools and training offered by the Biological Threat Reduction Program.

List of Institutions Visited

- National Public Health Laboratory, Sungai Buluh
- Royal Malaysian Customs, Putrajaya
- Science and Technology Research Institute for Defense, Taman Kajang
Utama
- Department of Chemistry; National Biotechnology Division, Putrajaya
- Ministry of Science, Technology, and Innovation, Putrajaya
- Infectious Diseases Research Center, Putrajaya
- Institute for Medical Research, Putrajaya
- Department of Veterinary Services, Putrajaya

SUMMARY OBSERVATIONS FROM FIELD VISIT TO MOROCCO

Trip participants: Richard L. Witter, U.S. Department of Agriculture, committee member, and NAS member; and Kelly Robbins, committee staff

Visit Dates: October 12-18, 2008

(1) Biosecurity awareness; pathogens and vulnerabilities of concern; and governmental legislation, regulations, and policies to address vulnerabilities

The country clearly is aware of biosafety and biosecurity issues and would like to develop self-sufficiency in this area, but the degree of concern varies among the different ministries and laboratories visited. A legislative framework has only recently been put in place, but implementation and enforcement need improvement. The Moroccan government is currently working to create a National Commission on Biosafety and Biosecurity.

Few if any highly dangerous pathogens are being used in Morocco, and no collections of dangerous pathogens were identified. However, there is a desire among Moroccans to become players in this field, pending development of the needed facilities, training of staff, access to strains, and funds to support such programs. They would especially like to have the capability to diagnose such diseases with state-of-the-art technologies.

Security and infrastructure at the two BSL-3 labs visited appeared very good, and the security of the central microorganism collection appeared adequate for the type of strains it contains. All the laboratories visited demonstrated awareness of biosafety, pointed out relevant equipment, and mentioned training for their researchers and students, although some commented that awareness and training could be improved. Less consideration has been given to the possibility of intentional releases, although the anthrax letter incidents of 2001 did raise awareness of Morocco's insufficient response capabilities, even though suspicious letters received by the U.S. Embassy in Rabat and other Moroccan institutions ultimately turned out to be harmless. There may also have been an attempted bioterrorist incident in recent years, although full details were unavailable.

Avian influenza, tuberculosis, HIV, anthrax, and hepatitis were most frequently cited as the most important pathogens for humans and peste des petits ruminants for animals. Rabies was also cited as a serious potential threat for both the human and the animal populations. Most persons characterized the information-technology-based Moroccan disease surveillance system as being very good, with a few respondents taking a somewhat more critical view. Despite the initial favorable assessments offered regarding the system, however, further discussion elicited acknowledgments that the system is not optimal. It was suggested that more training for first responders would be useful, and capacity building for epidemiologists who must analyze and use the data was

cited as a particularly urgent need. We also learned that medical waste disposal is a problem for many facilities, although commercial disposal services exist and their services could be expanded.

(2) Budget, personnel, and other challenges in upgrading biosecurity

Budgets for biosecurity at key research facilities are adequate, but are insufficient for many others. Several researchers cited an urgent need for a mechanism to allow researchers to obtain necessary reference strains from abroad, which would improve their capabilities for diagnosing disease outbreaks. More training for both researchers and first responders and enhanced border control capabilities were also frequent requests. A need for improved awareness of biosafety and biosecurity among students, researchers, officials, and the public was also noted. Some also cited a need for better legislative structures and the means to implement laws and policies. It appears that the Moroccan government is currently working on these issues and providing at least some funds to carry out improvements in the infrastructure to support biosafety and biosecurity. Ensuring cooperation among the government ministries and other entities that will be involved will be a challenge.

(3) Interests and programs of foreign organizations and interests of local government in international engagement on biosecurity issues

Ministry officials and researchers alike strongly supported cooperative and capacity-building programs with the United States on biosecurity and infectious disease research. Although the number of highly skilled scientists in Morocco is not large, existing cooperative research efforts mainly involve Moroccan expatriates and could be expanded to a formal program that would engage more U.S. laboratories and researchers. Many suggested that Morocco is well positioned to serve as a regional center for collaboration and training. A few institutions have already exchanged visits with CDC for training purposes, and the Ministry of Higher Education and the National Institute of Hygiene worked with the Department of State (Biosecurity Engagement Program) to organize a training workshop in Rabat in November 2008. A few researchers also stated that their institutions had worked with Naval Medical Research Unit 3 (NAMRU-3) and were very appreciative of the training and consultative services that had been provided. No one foresaw any problems in working with the U.S. government, and in fact, many gave examples of successful collaboration with the United States in the past. That said, the present level of engagement with U.S. institutions lags far behind that of European institutions, especially France. Various nongovernmental organizations, such as the Verification Research, Training and Information Center, are also assisting Morocco with biosecurity issues. The European Union plans to assist Morocco with biosafety

and biosecurity in 2008, although no details were yet available regarding their proposed activities. Coordination of any cooperative programs with the multiple Moroccan agencies and U.S. and international partners will be crucial to ensure that resources are used most effectively.

List of Institutions Visited

- Directorate of Technology, Ministry of Higher Education, Training, and Scientific Research, Rabat
- National Working Group (*Pôle de Compétance*) for Soil Microbiology and Plant Biotechnology, Rabat
- Department of Biotechnology, National Center for Energy and Nuclear Sciences and Technologies, Rabat
- Pasteur Institute, Casablanca
- Athisa Maroc, Casablanca
- Directorate of Epidemiology and Disease Control, Ministry of Health, Rabat
- World Health Organization Office in Morocco, Rabat
- National Center for Scientific Research and Technology, Rabat
- Laboratories of the Gendarmerie Royale, Rabat
- Office of the Secretary General, Ministry of Higher Education, Training, and Scientific Research, Rabat
- Moroccan Society of Biochemistry and Molecular Biology, Rabat
- Unit of Microbiology, Immunology, and Contagious Diseases, Hassan II Institute of Agronomy and Veterinary Science, Rabat
- National Institute of Hygiene, Ministry of Health, Rabat
- Moroccan Network for Medicinal and Aromatic Plants, Rabat
- U.S. Embassy, Economic Section, Rabat

Appendix D

Organizations Considered by the Biological Threat Reduction Program as Stakeholders in the Program¹

DEPARTMENT OF DEFENSE

Armed Forces Institute of Pathology
Naval Medical Research Center
Naval Medical Research Unit 3 (NAMRU-3)
U.S. Army Corps of Engineers
U.S. Army Edgewood Chemical Biological Center
U.S. Army Medical Research Institute of Infectious Diseases
U.S. Army Medical Research and Materiel Command
U.S. European Command Office of Defense Cooperation
Walter Reed Army Institute of Research

OTHER U.S. GOVERNMENT AGENCIES

Centers for Disease Control and Prevention
Department of Health and Human Services Biotechnology Engagement
Program
Department of State BioIndustry Initiative
U.S. Agency for International Development
Department of Agriculture (USDA) Agricultural Research Service
USDA Animal and Plant Health Inspection Service
USDA Foreign Agricultural Service

¹ This list provided by the Biological Threat Reduction Program (BTRP) in October 2008 includes organizations that provide contractual services for BTRP, receive funding from BTRP through interagency agreements, or consult regularly with BTRP.

PRIVATE CONTRACTORS

Academy for Educational Development, Global Avian Influenza Behavior
Change and Communications Support Activity
Bechtel Corporation
Black & Veatch Corporation
Raytheon Company
Technology Management Company

**INTERNATIONAL ORGANIZATIONS AND FOREIGN
GOVERNMENT AGENCIES**

Canadian Global Partnership Program
Food and Agricultural Organization of the United Nations
International Atomic Energy Agency
United Kingdom Ministry of Defense
United Nations Children's Fund
World Bank
World Health Organization
World Organization for Animal Health

NONGOVERNMENTAL ORGANIZATIONS

American Biosafety Association
Civilian Research and Development Foundation
International Science and Technology Center
Joint University Partnership (Pennsylvania State University and University of
New Mexico)
The National Academies
Vishnevskaya-Rostropovich Foundation

Appendix E

Selected Department of Defense Entities with Relevant Programs

GLOBAL EMERGING INFECTIONS SURVEILLANCE AND RESPONSE SYSTEM

The Global Emerging Infections Surveillance and Response System supports and coordinates infectious disease programs through a global network of military and nonmilitary partners. The four goals of this organization are surveillance and detection; response and readiness; integration and innovation; and cooperation and capacity building. Key priority areas include respiratory diseases (especially pandemic and avian influenza), gastroenteritis syndromes, febrile illness syndromes such as malaria and dengue, antimicrobial resistance, and sexually transmitted diseases and illnesses. (*www.geis.fhp.osd.mil/*)

NAVAL MEDICAL RESEARCH AND DEVELOPMENT

Naval Medical Research and Development (NMR&D) conducts health and medical research, development, testing, evaluation, and surveillance to enhance the operational readiness and performance of Department of Defense (DOD) personnel worldwide. Research is multifaceted and covers the following disciplines: biological defense, infectious diseases (for example, rickettsial diseases), combat casualty care, dental and biomedical research, directed energy bioeffects, environmental health, aerospace medicine, undersea medicine, tropical medicine, bone marrow donation, medical modeling, simulation and mission support, and war-fighter performance, as well as epidemiology and behavioral sciences. This broad range of disciplines is supported by 10 different laboratories scattered across the United States and the globe, including the Naval Medical Research Center (Maryland); Naval Medical Research Unit 3 (NAMRU-3, Cairo, Egypt), with field sites in Ghana and Afghanistan; NAMRU-2 (Jakarta,

Indonesia), with field sites in Cambodia and Singapore; and Naval Medical Research Center Detachment (Lima, Peru), with a field site in Iquitos, Peru. NMR&D also has a medical liaison officer at the World Health Organization in Geneva, Switzerland. (www.med.navy.mil/sites/nmrc/Pages/index.htm)

Following are additional details on some key NMR&D units:

- NAMRU-3 holds cooperative research agreements with institutions in Egypt and other areas in the region for the surveillance of influenza, dengue, and antimalarial drug resistance. Cohort studies are currently being conducted for zoonotic diseases, arbovirus infections, and enteric pathogens in selected communities throughout Egypt. (namru3.med.navy.mil/Default.aspx)
- NAMRU-2, located in Indonesia, has expanded operations to other countries in Southeast Asia, including Laos, Singapore, Thailand, and Cambodia. Recently, NAMRU-2 helped Laos implement the Early Warning Outbreak Recognition system, which provides the only electronic system of disease outbreak recognition and warning in the country. (www.nmrc.navy.mil/namru_2.htm)
- U.S. Army Medical Research Unit-Kenya's activities include comprehensive regional monitoring for drug resistance in malaria and enteric pathogens, etiology identification of undiagnosed hemorrhagic fever, use of remote sensing in assessing risk from vector-borne diseases, and analyses of atypical transmission patterns throughout eastern Africa. (usamrukenya.org)
- Naval Medical Research Unit, located in Peru, works in collaboration with the ministries of health and defense in Peru, Bolivia, and Ecuador. Research interests include antibiotic and antimalarial drugs' resistance patterns in pathogens, arbovirus maladies, and diarrheal diseases. (www.nmrc.navy.mil/nmrud.htm)
- Armed Forces Research Institute of Medical Science, situated in Bangkok, Thailand, operates as a joint American-Thai military medical research institute with both U.S. and Royal Thai Army components. The U.S. component functions as a special foreign activity of the Walter Reed Army Institute of Research (WRAIR) in Washington, D.C., and of the U.S. Army Medical Research and Materiel Command. Scientific publications have covered Japanese encephalitis, hepatitis A, dengue, hepatitis E, traveler's diarrhea, malaria, and drug-resistant scrub typhus. (www.afirms.org)

18TH MEDICAL COMMAND

The 18th Medical Command provides a comprehensive system of Theater Health Support to the Eighth United States Army and all supported forces throughout the Korean Theater of Operations during both peacetime engagements and combat operations. Primary infectious disease concerns for United States Forces Korea include avian and human influenza, hantavirus, Japanese encephalitis, scrub typhus, malaria, pulmonary syndrome, leptospirosis, murine

typhus, ehrlichiosis, anaplasmosis, and spotted fever group rickettsia. Monitoring for vector- and rodent-borne diseases continues to be a public health initiative. (www.seoul.amedd.army.mil/)

WALTER REED ARMY INSTITUTE OF RESEARCH (WRAIR)

Located in Washington, D.C., WRAIR is the largest biomedical research facility administered by DOD. The institute is a subordinate unit of the U.S. Army Medical Research and Materiel Command. Satellite laboratories include the U.S. Army Dental Research Detachment (Illinois); U.S. Army Medical Research Detachment (Texas); Medical Research Unit (Germany); Medical Research Unit (Kenya); and the Armed Forces Research Institute of Medical Sciences (Thailand). WRAIR has made significant contributions to the global mapping and modeling of mosquito vectors, malaria drug resistance surveillance, and malarial diagnostics. (wrair-www.army.mil)

U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES (USAMRIID)

USAMRIID at Fort Detrick, Maryland, serves as the Department of Defense's lead laboratory for medical aspects of biological defense. The institute develops vaccines, drugs, diagnostics, and information to protect U.S. service members from biological warfare threats and endemic diseases. It is the site of DOD's only laboratory equipped to allow the study of highly hazardous viruses (for example, Ebola) that require maximum containment at biosafety level 4 (BSL-4). (www.usamriid.army.mil/)

U.S. ARMY VETERINARY SERVICE

The U.S. Army Veterinary Service provides veterinary medical and surgical care, food and water safety, and biomedical research and development as well as military veterinary expertise in response to natural disasters and other emergencies in the United States and abroad. The Veterinary Service also provides food defense inspection for the army, navy, Marine Corps, and DOD agencies. The Veterinary Service is an essential component of the military medical research team with comprehensive research devoted to developing vaccines against emerging zoonotic diseases and diagnostic devices for rapid detection of infectious agents in the field. Veterinary Corps officers have been involved in evaluating the safety and efficacy of new treatments for combat injuries such as trauma and hemorrhagic shock; studying the effects of directed energy (laser, microwave) exposure; and researching the safety of prophylactic therapeutics that could help save the lives of combatants or civilians potentially exposed to

weaponized or commercial biological and chemical agents. (www.veterinary.service.army.mil/dodvsa.html)

ARMED FORCES INSTITUTE OF PATHOLOGY (AFIP)

Based in Washington, D.C., AFIP is a premier reference and training institute dedicated to world-class consultations on pathologic specimens of human or veterinary origin (domestic and international) and scientific research in the disciplines of environmental pathology and toxicology, infectious diseases, oncology, and forensic sciences. AFIP also has a comprehensive tissue repository. AFIP resources are to be redirected to the Joint Pathology Center as part of the new Walter Reed National Military Medical Center. (www.afip.org/)

CENTER FOR DISASTER AND HUMANITARIAN ASSISTANCE MEDICINE (CDHAM)

CDHAM is located in Bethesda, Maryland, and supports the U.S. armed services with a wide range of health-related activities around the world. Key contributions include (1) the Online Preparedness Education Program, which provides health care professionals with current clinical information to enhance preparedness for a chemical, biological, radiation-nuclear, or explosive mass casualty incident; (2) the Online Disaster and Humanitarian Assistance Portal; and (3) a weekly Grand Rounds seminar series. In addition, there are two key overseas CDHAM initiatives in progress to date: (1) the Afghanistan Medical Reachback, which is designed to facilitate the development of a health care system for the Afghan National Security Force and its beneficiaries; and (2) the Avian and Pandemic Influenza Program, which provides support to the U.S. Combatant Commands. (www.cdham.org/)

NATIONAL CENTER FOR MEDICAL INTELLIGENCE

The National Center for Medical Intelligence at Fort Detrick, Maryland, formerly the Armed Forces Medical Intelligence Center, is charged with monitoring and analyzing health events that could negatively impact the health of U.S. military and civilian populations. Such events include the emergence of pandemic influenza, novel zoonotic diseases, or incidents of bioterrorism.

NAVAL HEALTH RESEARCH CENTER

The Naval Health Research Center in San Diego, California, manages operational medicine research, development, testing, and evaluation programs for DOD and the U.S. Navy. The center's mission is to promote, protect, and maintain the health of navy and Marine Corps personnel and beneficiaries

through biomedical research and to support the medical readiness of the armed services. (*nbrc.navy.mil/*)

NAVY AND MARINE CORPS PUBLIC HEALTH CENTER

The Navy and Marine Corps Public Health Center, located in Portsmouth, Virginia, provides leadership and expertise to ensure mission readiness through disease prevention and health promotion in support of the National Military Strategy. The top arthropod-borne diseases of interest include malaria, dengue, Lyme disease, and West Nile virus. (*www-nebc.med.navy.mil/*)

PACIFIC AIR FORCES

One of the major U.S. Air Force commands, the Pacific Air Forces has received supplemental funding for pandemic and avian influenza. It has trained military and civilian personnel throughout the Asia-Pacific region to respond rapidly to influenza outbreaks. Training exercises have been carried out with Hawaiian public health emergency officers from the military and their civilian counterparts. Other exercises have involved personnel from Malaysia and Cambodia. (*www.pacaf.af.mil/*)

U.S. AIR FORCE SCHOOL OF AEROSPACE MEDICINE (USAFSAM)

Formerly the Air Force Institute for Operational Health, USAFSAM conducts routine, global, laboratory-confirmed influenza surveillance. The goals of the program include detecting local respiratory outbreaks, providing isolates to the World Health Organization, and detecting emerging strains. USAFSAM manages a surveillance program that includes global surveillance among 128 sites worldwide. Unique sentinel sites include activities at three DOD overseas medical research laboratories. (*www.brooks.af.mil/units/airforceinstituteforoperationalhealth/index.asp*)

U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE

The U.S. Army Center for Health Promotion and Preventive Medicine provides worldwide scientific expertise and services in clinical and field preventive medicine, environmental and occupational health, health promotion and wellness, epidemiology and disease surveillance, toxicology, and related laboratory sciences. The center is located at the Aberdeen Proving Ground, Maryland. (*usachppm.apgea.army.mil/*)

COMBATANT COMMANDS

Each of the unified combatant commands listed below includes a medical unit led by a command surgeon with a small staff. The medical units are charged with protecting the health of U.S. forces, as well as enhancing the military medical capacities of partner nations and supporting basic medical care in partner countries, including responding to disasters. One important element of the force protection program is medical threat assessment, which includes strengthening systems for global surveillance and response to infectious diseases, such as those caused by biological pathogens.

- **USAFRICOM** (Stuttgart, Germany)
www.africom.mil
- **USNORTHCOM** (Peterson Air Force Base, Colorado)
www.northcom.mil/
- **USSOUTHCOM** (Miami, Florida)
www.southcom.mil/appssc/index.php
- **USEUCOM** (Stuttgart, Germany)
www.eucom.mil/english/index.asp
- **USPACOM** (Honolulu, Hawaii)
www.pacom.mil/
- **USCENTCOM** (MacDill Air Force Base, Florida, and Qatar)
www.centcom.mil/

Appendix F

Selected U.S. Government Departments and Agencies with Relevant Programs

DEPARTMENT OF STATE

Bureau of International Security and Nonproliferation, Office of Cooperative Threat Reduction

The Biosecurity Engagement Program (BEP) focuses on five areas:

1. Pathogen security and biosafety projects: working with international bioscience laboratories in the areas of pathogen security and biosafety, including assistance in risk assessment, safety and security consultations, and design and implementation
2. Training: training scientists, laboratory managers, and policy makers on surveillance, diagnostics, biosafety, and pathogen security to raise awareness and to promote effective laboratory practices
3. Surveillance and diagnostics: assisting with, designing, and implementing surveillance and molecular diagnostic systems that strengthen infectious disease detection and response
4. Grants Assistance Program: providing funding to institutions for projects that advance BEP objectives
5. Global cooperation: reducing the risk of biological threats by collaborating with partner governments to develop biosafety and pathogen security standards that are consistent with national and international guidelines, norms, and requirements (*www.state.gov/t/isn/58381.htm*)

Bureau of International Security and Nonproliferation, Office of Chemical and Biological Weapons Threat Reduction

The Chemical and Biological Weapons Threat Reduction Office has responsibility for implementing diplomatic efforts to impede and roll back the threat of biological and chemical weapons and to dissuade and impede states and entities from pursuing, using, or proliferating these weapons and related equipment and technology. It has lead responsibility for bilateral and multilateral efforts to implement and strengthen the Biological Weapons Convention (BWC) and the Chemical Weapons Convention. Key functions include the following:

- Developing and promoting dynamic policies and programs on a bilateral basis to combat the threat posed by biological weapons and related materials
- Advancing and protecting key U.S. national security interests within the multilateral framework of the BWC
- Leading the development and implementation of Australia Group export controls and catch-all controls for biological-weapons-applicable items and technology
- Preparing recommendations for bureau and departmental principals on sanctions and implementing sanctions laws and other penalties as they relate to biological weapons and associated technology and equipment. (*www.state.gov/t/isn/16189.htm*)

Bureau of Verification, Compliance, and Implementation

The bureau's core missions are to ensure that appropriate verification requirements and capabilities are fully considered and properly integrated throughout the development, negotiation, and implementation of arms control, nonproliferation, and disarmament agreements and commitments and to ensure that other countries' compliance is carefully watched, rigorously assessed, appropriately reported, and resolutely enforced. In this regard, the bureau is responsible for preparing the President's annual report to Congress on Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments, including the BWC. (*www.state.gov/t/vci/*)

Bureau of Oceans and International Environmental and Scientific Affairs

Two offices within this bureau have programs that contribute to enhanced biosecurity, biosafety, and disease control. These include the Office of Science and Technology Cooperation and the Office of International Health Affairs. The latter office has a mission of promoting U.S. security and global economic growth through global health. It works with agencies throughout the U.S. government to facilitate policy making regarding environmental health, infectious

diseases (for example, severe acute respiratory syndrome [SARS], avian influenza, pandemic influenza, and polio), health in postconflict situations, surveillance and response, bioterrorism, and health security. (www.state.gov/g/oes/)

U.S. Agency for International Development (USAID)

USAID has two central program offices that support activities related to biosafety, biosecurity, and disease surveillance: the Office of Agriculture and the Bureau of Global Health.

The Office of Agriculture provides funding to the Consultative Group on International Agricultural Research (CGIAR). CGIAR is an informal group of donors (about 60 at present) that is headquartered at the World Bank in Washington, D.C. It sponsors 16 international research centers throughout the world (13 in developing countries), which address a wide array of basic food commodities and natural resource issues, including animal and plant health. In addition, CGIAR is currently sponsoring a Challenge Program, which is designed to tackle problems of global and regional importance that bring a wide variety of researchers together. A small number of other international research centers outside CGIAR also carry out important related work. CGIAR itself represents a multilateral activity, but has always had a bilateral dimension in that the centers take on special projects that are national in nature. In either case, the emphasis is on producing public goods that are freely available. The Office of Agriculture also supports the development of biotechnology by integrating technology development and the establishment of policy frameworks to ensure the safe and effective application of the technology in developing countries.

The Bureau of Global Health works to improve global health, including child, maternal, and reproductive health, and to reduce abortion and disease, especially HIV/AIDS, malaria, and tuberculosis. It supports field health programs, advances research and innovation in selected areas relevant to overall agency health objectives, and transfers new technologies to the field through its own staff work, coordination with other donors, and a portfolio of grants and contracts with an annual budget in excess of \$1.6 billion. A major element of the program is the strengthening of developing-country health systems. (www.usaid.gov)

DEPARTMENT OF ENERGY

National Nuclear Security Administration, Office of Nonproliferation and International Security

The Office of Nonproliferation and International Security (NIS) provides technical and policy support for U.S. efforts to implement and improve inter-

national nonproliferation activities. There are three functional offices under NIS and a policy office that coordinates crosscutting activities. NIS advances U.S. government efforts to combat weapons of mass destruction (WMD) proliferation by (1) strengthening nonproliferation regimes and arrangements; (2) expanding the reach of the nonproliferation regime by promoting foreign compliance export controls, safeguards, and physical protection commitments; and (3) verifying the elimination of proliferation programs and stockpiles of WMD materials. The office's international work includes providing policy and technical support to nonproliferation negotiations, bilateral programs with foreign governments, and collaboration within multilateral organizations. (*nnsa.energy.gov/nuclear_nonproliferation/1976.htm*)

Global Initiatives for Proliferation Prevention

This program works to prevent proliferation of weapons of mass destruction. It provides grants, in partnership with U.S. private firms, to former WMD experts in Russia, other states of the former Soviet Union (FSU), Libya, Iraq, and other regions. These grants support the redirection of these experts into sustained nonmilitary employment.

Department of Energy National Laboratories: Sandia National Laboratories, International Biological Threat Reduction Program

Sandia's Global Security Center Program on International Biological Threat Reduction is designed to enhance U.S. and international security. It has three major goals: (1) enhancing safety and containment of dangerous biological agents in bioscience facilities, (2) strengthening capacities to detect and control dangerous biological agents, and (3) improving the understanding and mitigation of biological threats. Its programs include conducting risk, threat, and vulnerability assessments; providing technical assistance to safely transport dangerous biological agents; conducting training; assisting in reviewing and drafting biosafety, biosecurity, and biocontainment procedures; and conducting assessments to understand biological threats and risks. (*www.biosecurity.sandia.gov/home.html*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Health Affairs

The Office of Global Health Affairs represents the department in dealings with other governments, other federal departments and agencies, international organizations, and the private sector on international health issues. It develops U.S. policy and strategy positions related to health issues. It facilitates involve-

ment of the Public Health Service in support of these positions and in collaboration with other agencies, including USAID, and other organizations.

The office also administers the Biotechnology Engagement Program, funded by the Department of State. The program's major objectives are (1) to redirect FSU expertise and resources from military to civilian research and (2) to develop collaborative public health projects involving scientists from Department of Health and Human Services (HHS) agencies. Its three goals are as follows:

1. Nonproliferation: discouraging the proliferation of weapons-related expertise and engaging former weapons scientists in civilian-oriented research
2. Scientific innovation: funding high-quality research projects that facilitate development of new medical and pharmaceutical technologies and provide evidence-based science to support health policy decisions
3. Sustainability: providing technical support and scientific collaboration to enable scientists to patent and market their discoveries and successfully compete for other sources of funding (*www.globalhealth.gov/*)

Centers for Disease Control and Prevention (CDC)

CDC's overarching goal is to ensure that people around the world will live safer, healthier, and longer lives through health promotion, health protection, and health diplomacy. Three of the most relevant programs are the (1) Global Disease Detection (GDD) Program, (2) Field Epidemiology and Laboratory Training Program, and (3) Sustainable Management Development Program. The GDD Program includes efforts to strengthen detection and response capacity for avian influenza, build regional surveillance and reference laboratory capacity, and increase in-country surveillance and outbreak response capacity. The two other programs provide training in applied epidemiology and public health through a competency-based curriculum supporting laboratory-based surveillance and outbreak response and strengthened public health management capacity.

The GDD Program is designed to develop and strengthen global health capacity to identify and respond to emerging infections and bioterrorist threats around the world. GDD Regional Centers are located in Kenya, Thailand, Guatemala, China, Egypt, and Kazakhstan. Programs and resources in these countries are linked to headquarters and connected through a joint mission to respond to disease outbreaks anywhere in the world. The scientists who work in these programs have expertise in infectious disease detection and control (ranging from international leadership in the control of common infectious syndromes such as pneumonia to cutting-edge laboratory detection of rare viruses such as Ebola and SARS coronavirus). During nonemergency settings, the centers work with country partners to build public health capacity in nonroutine

disease detection and response interventions that help to strengthen systems that will be used in times of crisis. However, in response to major international emergencies or large-scale disease outbreaks, the centers typically function as members of the Global Outbreak Alert and Response Network, which is coordinated with the World Health Organization (WHO). (www.cdc.gov/)

Food and Drug Administration

The Food and Drug Administration works with the HHS Office of Global Health Affairs encouraging teams of former weapons scientists from the FSU and U.S. experts to develop joint projects and apply for support and cooperation in areas of research and development that address urgent public health concerns in the FSU. This work will help develop and expand commercial discovery and production of drugs, vaccines, biological test kits, and other quality products and technologies designed to meet current public health needs in the region. (www.fda.gov/)

National Institutes of Health (NIH): National Institute of Allergy and Infectious Diseases (NIAID)

NIAID conducts and supports a global program of research aimed at improving diagnosis, treatment, and prevention of immunologic, allergic, and emerging infectious diseases. This research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. The NIAID strategic plan focuses on the following major themes: HIV/AIDS; other infectious diseases; allergy, immunology, and immune-related diseases; and research resources, infrastructure, training, and communications. In 2007, about \$375 million was available for international research. NIAID provides a wide variety of services to its researchers, including testing, DNA sequencing, and biological research repositories. The institute also has a formal strategic plan for biodefense research. (www.nih.gov/about/almanac/organization/NIAID.htm)

NIH: The Fogarty International Center

The Fogarty Center supports and facilitates global health research conducted by U.S. and foreign investigators. Its Informatics Training for Global Health Program supports training for low- and middle-income country institutions in partnership with U.S. institutions and investigators. This training will increase their ability to conduct multisite clinical trials and international disease surveillance and prevention programs. (www.nih.gov/about/almanac/organization/FIC.htm)

NIH: National Science Advisory Board for Biosecurity (NSABB)

The NSABB was established in 2005 to recommend strategies for overseeing and responsibly handling life sciences research that could yield information and technologies with the potential for benevolent or malevolent application. The NSABB has provided recommendations to the U.S. government regarding dual-use research of concern and is working with international partners to strengthen the management of dual-use research.

The NSABB's international committee has conducted three roundtable dialogues in partnership with WHO. The first, held in February 2007, focused on the importance of life sciences research and the need to protect advances in the life sciences while minimizing risks to international and national security. The second, attended by American and international scientific organizations, considered dual-use research and the need to develop a strategy to engage the international scientific community. The most recent roundtable, held in November 2008 and attended by more than 130 participants from 40 countries, focused on awareness raising and education; a culture of responsibility and codes of conduct; review of guidelines for preparation and review of research proposals; and scientific presentations, publications, and communication. (*obafda.nih.gov/biosecurity/about_nsabb.html*)

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service (FAS)

The main objective of FAS programs is to improve foreign market access for U.S. agricultural goods. In addition, FAS carries out a broad array of international training, technical assistance, and other collaborative activities with developing and transitional countries to facilitate trade and promote food security. Some activities are designed to detect and mitigate animal and plant diseases. To increase the benefits to developing nations participating in global agricultural markets, FAS offers numerous trade capacity-building programs. Also, FAS helps nations understand and prepare for meeting World Trade Organization requirements. (*www.fas.usda.gov/*)

Agricultural Research Service (ARS), Office of International Research Programs (OIRP)

OIRP is the service's principal contact for international activities. Its mission is to enhance the productivity, effectiveness, and impact of ARS's national programs through mutually beneficial international activities. Its goals are (1) to facilitate international cooperation and exchange to benefit U.S. agriculture and the consumer, (2) to participate in activities that promote the strategic interests of the U.S. government, and (3) to extend the capacity of the national

programs to address international problems confronting U.S. agriculture. It also administers two cooperative research grant programs, the ARS-Former Soviet Union Scientific Cooperation Program and the Biosecurity Engagement Program. Both programs use funds from the Department of State that support research on agricultural pathogens and diseases in a variety of foreign countries. (www.ars.usda.gov)

The Animal and Plant Health Inspection Service (APHIS)

APHIS works to protect the health and value of American agriculture and natural resources. Its international mission is to protect and promote agricultural health through internationally based animal and plant health expertise. The International Service develops and implements programs that identify health threats outside U.S. borders to reduce those threats at the source. This activity includes training and technology transfer to help developing countries build their animal and plant health infrastructures, thereby helping to reduce the likelihood of undetected threat pathways into the United States. The service cosponsors cooperative foreign pest and disease operation programs in other countries. Targeted pests include screwworm, fruit flies, and tropical bont ticks. Classical swine fever is also of concern. APHIS also operates a Center for Epidemiology and Animal Health in Fort Collins, Colorado, which is responsible for tracking animal diseases on a worldwide basis. (www.aphis.usda.gov/)

Appendix G

Activities of International Organizations

SELECTED INTERGOVERNMENTAL ORGANIZATIONS WITH PROGRAMS TO REDUCE THE THREAT POSED BY BIOWEAPONS AND BIOTERRORISM

UN 1540 Committee

In 2004, the United Nations Security Council unanimously adopted Resolution 1540, which requires member states “to refrain from supporting by any means non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems.” The resolution requires that member states establish domestic controls to prevent the proliferation of biological, chemical, or nuclear weapons; delivery systems; and related materials. The UN 1540 Committee has a mandate to oversee compliance with the resolution. This mandate was extended in April 2006 for another 3 years, with provisions for assistance expanded. (www.un.org/sc/1540/)

G-8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction

The G-8 global partnership was an initiative agreed to at the 2002 G-8 Summit in Canada. It is designed to provide funding for cooperative projects, initially in the former Soviet Union, focused on nonproliferation, disarmament, counterterrorism, and nuclear safety issues. The Canadian Ministry of Foreign Affairs and the UK Ministry of Defense have played leadership roles in the organization. (cns.miis.edu/research/globpart/)

Australia Group

The Australia Group is an informal forum of countries promoting the harmonization of export licensing procedures in an attempt to ensure that exports of chemicals, biological agents, and dual-use equipment do not contribute to the development of chemical or biological weapons. A list of common technologies with the potential to be used in chemical and biological weapons programs has been developed and is used as the basis for export restrictions. Member countries are all states parties to the Biological Weapons Convention and the Chemical Weapons Convention. Members provide funding for the group's activities.

The activities of the Australia Group have been supported by major chemical and biological industries that are concerned about the possibility of inadvertently providing supplies or equipment that could be used to develop chemical or biological weapons. (www.australiagroup.net/en/index.html)

Interpol—Biocriminalization Project

Interpol, the world's largest police organization, assists law enforcement agencies in more than 180 member countries to combat all types of transnational crime. The Biocriminalization project was launched in September 2006 to identify legislative and regulatory gaps in member countries—seen as a key obstacle in the fight against bioterrorism—and to assist them with drafting and enacting legislation to prohibit and prevent the misuse of biological agents and toxins. (www.interpol.int/)

SELECTED INTERGOVERNMENTAL ORGANIZATIONS WITH PROGRAMS ON BIOSECURITY, BIOSAFETY, OR DISEASE SURVEILLANCE (NOT SPECIFIC TO BIOWEAPONS OR BIOTERRORISM)

World Health Organization (WHO) Programs of Relevance

International Health Regulations

The revised International Health Regulations went into effect in June 2007. The regulations are designed to support the international management of public health emergencies with a focus on preventing the international spread of diseases. Countries are required to develop and strengthen their capacities to detect, report, and respond to public health threats. For low-resource countries, financial and technical assistance is to be available. The shortage of this assistance is seen as a potential barrier to the effective implementation

of the regulation, together with fear of the potential economic consequences of reporting public health emergencies. (www.who.int/csr/ibr/en/) (See also Appendix H.)

Biosafety and Laboratory Biosecurity Program

The Biosafety and Laboratory Biosecurity Program helps member states adopt and implement biorisk management strategies, including workplace practices; the use of protective equipment; and the handling of pathogens in laboratories, during transportation, in field investigations, and in vaccine-manufacturing facilities. There are five collaborating centers, including the Centers for Disease Control and Prevention and the National Institutes of Health, and also joint programs with regional biosafety networks, such as the African Biosafety Network and the Asia-Pacific Biosafety Network. The program publishes several manuals, including *Guidance on Regulations for the Transport of Infectious Substances* and *Biorisk Management: Laboratory Biosecurity Guidance*. (www.who.int/csr/bioriskreduction/biosafety/en/)

Life Science Research and Development for Global Health Security

The Life Science Research and Development for Global Health Security project is designed to raise awareness and provide information and guidance to WHO member states on the possible options for risk management to address dual-use life science research and development activities. It has established a network of experts and prepared a working paper on relevant issues. In addition, it has sponsored or cosponsored several regional meetings and is now preparing a guidance document to evaluate needs and capacities for risk assessment. (whqlibdoc.who.int/hq/2007/WHO_CDS_EPR_2007.4_eng.pdf)

Biorisk Reduction Program

The WHO Biorisk Reduction Program promotes “the use of safe and secure workplace practices, appropriate protective equipment, engineering and administrative controls in the handling of pathogenic organisms in laboratories, during transportation, in field investigations and in vaccine manufacturing facilities, to protect workers, the environment and the community from exposure, infection, and subsequent development of disease.” (www.who.int/csr/bioriskreduction/biosafety/en/index.html)

Epidemic and Pandemic Alert and Response Program

The Epidemic and Pandemic Alert and Response Program is a global system to address epidemics and other public health emergencies based on

strong national public health systems and capacity and an effective international system for coordinated response. It is designed to strengthen biosafety, biosecurity, and readiness to respond to dangerous and emerging pathogens, including severe acute respiratory syndrome (SARS). (www.who.int/csr/disease/en/)

Food and Agriculture Organization (FAO) of the United Nations

FAO supports numerous activities related to biosecurity and biosafety focused largely on protecting against plant and animal pests and diseases as well as zoonoses, genetically modified organisms, and alien species. It has developed biosafety best practices, supported capacity-building programs, and created a Web portal on food safety and animal and plant health. It also has created a Biosafety Resources Web site that links a variety of manuals, reports, and guidelines. (www.fao.org/biosecurity and www.fao.org/sd/2003/biosafety)

World Organization for Animal Health (OIE)

The OIE focuses on preventing the spread of animal diseases, including those transmissible to humans, while also supporting trade in animals and animal products. It has been an active participant in the Biological Weapons Convention (BWC) intercessional processes and has worked with other international organizations to develop generic biosafety and safe transport guidance.

The OIE produces international health standards for animals and animal products, as well as trade standards and biological standards. The standards address the following issues: risk management approaches and principles, identification and traceability of live animals, hygiene, and disinfection. It also produces guidelines for veterinary laboratories in testing infectious animal diseases. Following are examples of OIE publications: Terrestrial Health Code; the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals; the Aquatic Animal Health Code; Quality Standards and Guidelines for Veterinary Laboratories: Infectious Diseases; and the Handbook on Import Risk Analysis for Animals and Animal Products. (www.oie.int/eng/en_index.htm)

Organization for Economic Cooperation and Development (OECD)

Two sections of the OECD have programs of relevance—the Biotechnology Division and the International Futures Program.

The OECD Best Practice Guidelines on Biosecurity, developed by the Biotechnology Division, provide guidance for member countries operating biological resource centers—repositories of biological materials required for research and development activities and for biotechnology applications. The guidelines cover risk management, physical security, management of personnel

and visitors, training, materials control, transport security, incident response, and information security. (www.oecd.org/dataoecd/6/27/38778261.pdf)

The International Futures Program has conducted several workshops and meetings promoting responsible stewardship in the biosciences as well as assessing long-term risks. The Futures group maintains a Web site that includes a broad range of information on the activities of national governments, international organizations, and others related to biosecurity issues, as well as examples of codes and background readings. (www.biosecuritycodes.org)

INTERNATIONAL DEVELOPMENT BANKS

World Bank

The World Bank supports several relevant programs, including major health loans, assistance projects related to avian and human influenza, and extensive work on biosafety.

The bank's new strategy for health, nutrition, and population reflects dramatic changes in health assistance over the last decade, with many organizations earmarking funds for priority diseases such as HIV/AIDS, malaria, and tuberculosis. It emphasizes the bank's comparative advantage by focusing on health systems strengthening at the country level, including health financing and economic considerations. Total health, population, and nutrition funding in 2007 was \$1.8 billion, or 10 percent of the bank's total annual lending. In some cases, these efforts included supporting disease surveillance and response activities, such as a project in India that is establishing a central government surveillance unit, strengthening state and district level efforts, and upgrading local laboratories.

The bank has two mechanisms to address avian and human influenza. The first is the Global Program for Avian Influenza (GPAI) (up to \$500 million in loans and credits) and the second is a multidonor-financed trust fund (now \$125 million). Countries can access GPAI funding to strengthen veterinary and health services to deal with avian flu outbreaks among animals, minimize the threat posed to people, and prepare for and respond to any potential human flu pandemics. The trust fund is designed to help countries (1) prevent or control and eradicate avian influenza and (2) increase preparedness for human influenza pandemics.

The World Bank (through the Global Environment Facility, with support from the UN Development Program and the UN Environment Program) has financed the development of regional biosafety projects in West Africa and Latin America. The West Africa project will support common approaches to biosafety, establish a national reference laboratory in Burkina Faso, and strengthen the ability of local institutions to implement regional laws and regulations on biosafety. (www.worldbank.org)

African Development Bank

An interesting project of the African Development Bank is designed to strengthen institutions for risk management of transboundary animal diseases in southern Africa by establishing a surveillance network, upgrading diagnostic laboratories, and enhancing preparedness for the spread of animal diseases. A special focus is improving a laboratory in Tanzania to serve as a regional reference laboratory. However, the bank allocates less than 4 percent of its funding for health activities, with most of those funds used for expanding primary health care and HIV/AIDS-related services. (www.afdb.org)

Asian Development Bank

The Asian Development Bank has provided several health-oriented loans. It also provides technical assistance for health activities and supports conferences to promote the information sharing among Asian countries on their experiences in implementing policies and regulations on biotechnology and biosafety. Its relatively small health program is currently focused on helping countries meet Millennium Development Goals. (www.adb.org)

SELECTED REGIONAL ORGANIZATIONS

African Networks for Health Research and Development (AFRO-NETS)

Organized in 1997, the African Networks for Health Research and Development is designed to facilitate information exchange among health networks in Anglophone Africa. (www.afronets.org/partnet.php)

Asia-Pacific Economic Cooperation

Asia-Pacific Economic Cooperation has supported a series of policy dialogues on biotechnology and biosafety. For example, in 2006 the organization hosted a meeting on biosafety policy options in preparation for a high-level policy dialogue on agriculture and biotechnology. (www.apec.org)

Bioweapons Prevention Project (BWPP)

Initiated by a group of nongovernmental organizations, the Bioweapons Prevention Project works to reduce the threat of bioweapons by monitoring and reporting throughout the world on compliance with relevant international treaties. (www.bwpp.org)

**VERTIC (Verification Research, Training and Information Center),
United Kingdom**

Founded in 1986, VERTIC is a nongovernmental organization that promotes effective and efficient verification as a means of ensuring confidence in the implementation of international agreements and intranational agreements with international involvement. Its portfolio of interest includes treaties dealing with weapons of mass destruction and biological weapons. (*www.vertic.org/*)

International Food Policy Research Institute (IFPRI)

IFPRI and other members of the Consultative Group on International Agricultural Research (CGIAR) carry out a range of activities related to biosafety issues. IFPRI is coordinating a program on biosafety systems to ensure the development of appropriate biosafety regulations within country-led sustainable development strategies. Activities include policy analysis and development, risk assessment, capacity building in regulatory systems, and communication and public outreach. The program is focused on Africa and Southeast Asia. (*www.ifpri.org/pbs/pdf/pbsbrochure.pdf*) (*www.sciencecouncil.cgiar.org/publications/pdf/Biosafety%20Report%20no%20cover.pdf*)

InterAcademy Panel on International Issues (IAP)

The IAP's biosecurity initiative focuses on the potential impact of biosciences research on global society and, particularly, on the risks associated with the misuse of such research. In 2005, IAP released a statement of principles that could guide development of appropriate biosecurity codes of conduct. Using the results of the 2006 Sixth Review Conference of the States Parties to the Biological Weapons Convention (BWC), the IAP prepared a draft statement on "Considerations, Lessons, Perspectives, and Recommendations." These include the following provisions:

1. Scientists who become aware of activities that violate the BWC or international customary law should raise their concerns.
2. Scientists should be aware of, disseminate, and teach national and international law and regulations aimed at preventing the misuse of biological research.
3. Scientists with responsibility for oversight of research should promote adherence to these principles and act as role models. (*www.interacademies.net*)

International Council for Science (ICSU)

ICSU's mission is to promote international science and encourage the scientific community to address issues of science and society. It has hosted or cosponsored several workshops related to biosecurity, including one on science and technology developments and the BWC. (*www.icsu.org*)

Appendix H

International Health Regulations¹

1. PURPOSE, SCOPE, AND PRINCIPLES

The International Health Regulations (2005), hereafter referred to as “IHR (2005)” or “the regulations,” are a legally binding agreement among World Health Organization (WHO) member states and other states that have agreed to be bound by them (states parties). The IHR (2005) define their “purpose and scope” as “to prevent, protect against, control, and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks and which avoid unnecessary interference with international traffic and trade.”

2. CONCEPTS AND APPROACHES

The IHR (2005) are purposely broad and inclusive in respect of the public health event to which they have application in order to maximize the probability that all such events that could have serious international consequences are identified early and promptly reported by states parties to WHO for assessment. The regulations aim to provide a legal framework for the prevention, detection, and containment of public health risks at the source, before they spread across borders, through the collaborative actions of states parties and WHO.

Notification is required under IHR (2005) for all “events that may constitute a public health emergency of international concern.” In this regard, the broad new definitions of “event,” “disease,” and “public health risk” in the IHR (2005) are the building blocks of the surveillance obligations for states

¹ This material was excerpted from the Web page of the World Health Organization entitled “Ten Things You Need to Know about the IHR (2005).” Available online at www.who.int/csr/ibr/howtheywork/10things/en/index.html.

parties and WHO. *Disease* means “an illness or medical condition, irrespective of origin or source, which presents or could present significant harm to humans.” The term *event* is broadly defined as “a manifestation of disease or an occurrence that creates a potential for disease.” *Public health risk* refers to “a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.” A public health emergency of international concern (PHEIC) is defined as “an extraordinary event which is determined to constitute a public health risk to other states through the international spread of disease and to potentially require a coordinated international response.” Consequently, events of potential international concern, which require states parties to notify WHO, can extend beyond communicable diseases and arise from any origin or source.

3. SHARED REALITIES REQUIRE A MOVE TOWARDS COLLECTIVE DEFENSES

The IHR (2005) introduce a legal framework to support existing and innovative approaches in the global detection of events and response to public health risks and emergencies. Although the IHR (2005) were built in part on the foundations of their predecessor, the IHR (1969), they are primarily based on the recent experiences of WHO and its member states in national surveillance systems, epidemic intelligence, verification, risk assessment, outbreak alert, and coordination of international response, all of which are part of WHO’s decade-long work to enhance international public health security.

The IHR (2005) have a broad scope, provide for the use of a wide range of information, and emphasize collaborative actions between states parties and WHO in the identification and assessment of events and response to public health risks and emergencies. In WHO’s coordination of the international response to public health emergencies of international concern, maximum measures are replaced by formally recommended and context-specific temporary health measures, tailored to the actual threat faced.

4. REJECTIONS AND RESERVATIONS

The IHR (2005) are legally binding following their entry into force on June 15, 2007, for all WHO member states that neither rejected them nor filed reservations thereto by the deadline of December 15, 2006. In fact, no member state notified a rejection, and only two member states notified reservations to the director-general of WHO.

5. NOTIFICATION AND OTHER REPORTING REQUIREMENTS

The IHR (2005) describe key elements of the procedures to be followed by states parties and WHO in sharing information about notified events. Official event-related communications under the IHR (2005) are carried out between the national IHR focal point and the WHO IHR contact point, both of which are officially designated and required to be available 24 hours a day, 7 days a week.

The IHR (2005) specify the following three ways in which states parties can initiate event-related communications with WHO:

1. Notification: The IHR (2005) provide new notification requirements for states parties. These provisions move away from the automatic notification and publication by WHO of cases of specific diseases to the notification to WHO of all events that are assessed as possibly constituting a PHEIC, taking into account the context in which an event occurs. These notifications must occur within 24 hours of assessment by the country. There are four criteria that states parties must follow in their assessment of events within their territories and their decision as to whether an event is notifiable to WHO:

1. Is the public health impact of the event serious?
2. Is the event unusual or unexpected?
3. Is there a significant risk of international spread?
4. Is there a significant risk of international restriction(s) to travel and trade?

Notifications must be followed by ongoing communication of detailed public health information on the event, including, where possible, case definition, laboratory results, source and type of risk, number of cases and deaths, conditions affecting the spread of the disease, and the health measures employed. Figure H-1 illustrates the notification process.

2. Consultation: In cases where a state party is unable to complete a definitive assessment with the decision instrument in Annex 2, states parties have an explicit option of initiating confidential consultations with WHO and seeking advice on evaluation, assessment, and appropriate health measures to be taken.

3. Other Reports: States parties must inform WHO through the national IHR focal point within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by imported or exported human cases, vectors that carry infection or contamination, or by contaminated goods.

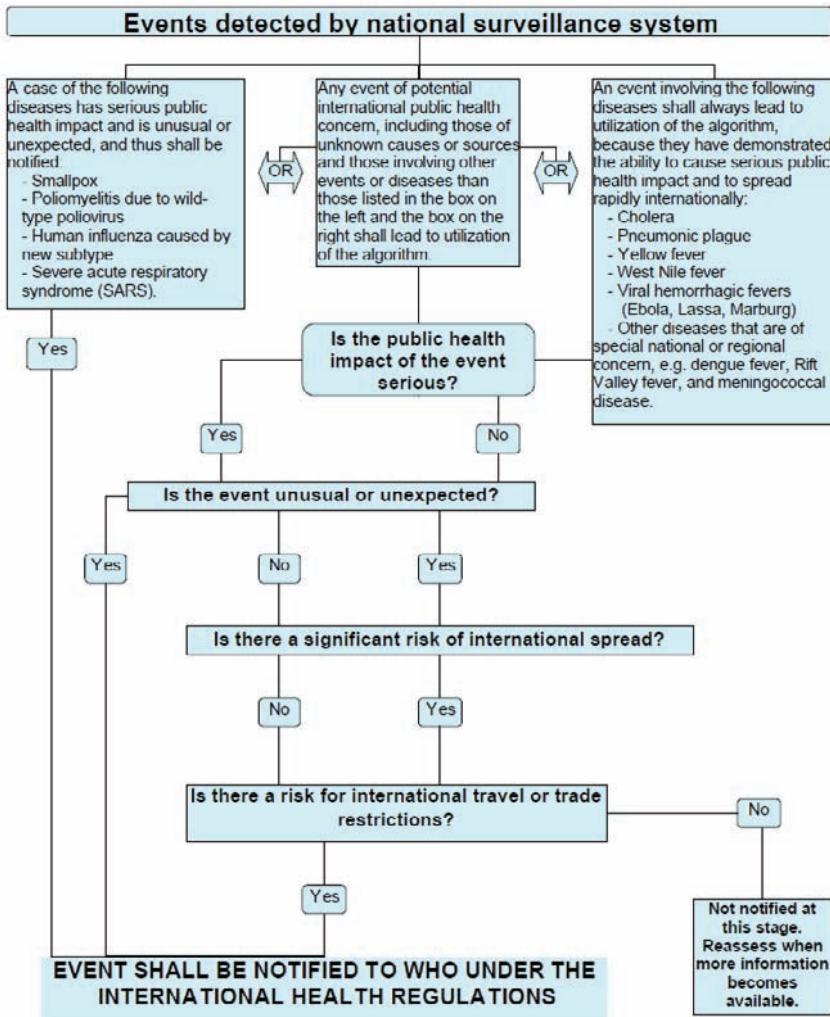


FIGURE H-1 WHO public health event notification process.

6. INTERNATIONAL EVENT DETECTION, JOINT ASSESSMENT, AND RESPONSE

The IHR (2005) underpin WHO’s mandate to manage the international response to acute public health events and risks, including public health emergencies of international concern. The regulations also recognize WHO’s general surveillance obligations and set out specific procedures for concerned

states parties and WHO to collaborate in the assessment and control of public health events and risks, even before such events have been officially notified to WHO.

7. PHEIC DETERMINATION AND TEMPORARY RECOMMENDATIONS

If immediate global action is needed to provide a public health response to prevent or control the international spread of disease, the IHR (2005) give the director-general of WHO the authority to determine that the event constitutes a PHEIC. On such occasions, an IHR emergency committee will provide its views to the director-general on temporary recommendations on the most appropriate and necessary public health measures to respond to the emergency.

In cases where the state party concerned may not agree that a PHEIC is occurring, the emergency committee will also provide advice. The temporary recommendations issued by the director-general are for affected and nonaffected states parties to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

8. NATIONAL SURVEILLANCE AND RESPONSE CAPACITIES

Another fundamental innovation in the IHR (2005) is the obligation for all states parties to develop, strengthen, and maintain core public health capacities for surveillance and response. To be able to detect, assess, notify, and report events and respond to public health risks and emergencies of international concern, states parties must meet the requirements described in Annex 1A of the IHR (2005). Annex 1A outlines these core capacities at the local (community), intermediate, and national levels, including, at the national level, the assessment of all reports of urgent events within 48 hours and the immediate reporting to WHO through the national IHR focal point, when required.

The IHR (2005) require each state party, with the support of WHO, to meet the core surveillance and response capacity requirements “as soon as possible,” but not later than 5 years after the date of entry into force for that country. The IHR (2005) set out a two-phase process to assist states parties in planning for implementation of their public health capacity obligations. In the first phase, from June 15, 2007, to June 15, 2009, states parties must assess the ability of their existing national structures and resources to meet the core surveillance and response capacity requirements. This assessment must lead to the development and implementation of national plans of action.

In the second phase, from June 15, 2009, to June 15, 2012, the national action plans are expected to be implemented by each state party to ensure that core capacities are present and functioning throughout the country and its rel-

evant territories. States parties that experience difficulties in implementing their plans may request an additional 2-year period until June 15, 2014.

9. PUBLIC HEALTH SECURITY IN INTERNATIONAL TRAVEL AND TRANSPORT

International points of entry, whether by land, sea, or air, provide an opportunity to apply health measures to prevent international spread of disease. For this reason, several new provisions have been included. When applying IHR-related health measures to international travelers, for example, it is required that they be treated with courtesy and respect, taking into consideration their gender, sociocultural, ethnic, and religious concerns. They must be supplied with appropriate food, water, accommodation, and medical treatment if quarantined, isolated, or otherwise subject to medical or public health measures under the IHR (2005).

States parties are required to designate the international airports, ports, and any ground crossings that will develop specific capacities in applying public health measures required to manage a variety of public health risks. These capacities include access to appropriate medical services (with diagnostic facilities); services for the transport of ill persons; trained personnel to inspect ships, aircraft, and other conveyances; maintenance of a healthy environment; and establishment of plans and facilities to apply emergency measures such as quarantine.

10. NEW AND UPDATED HEALTH DOCUMENTS

The IHR (2005) require immediate implementation of a range of new or revised health documents at points of entry, including the following:

- Model Maritime Declaration of Health
- Model International Certificate of Vaccination
- Health Part of the Aircraft General Declaration

Appendix I

Selected Foundations

BILL AND MELINDA GATES FOUNDATION

The Gates Foundation is a major supporter of global health programs working with organizations throughout the world and using innovative approaches to improve health conditions in developing countries. Programs target HIV/AIDS, polio, diarrheal disease, tuberculosis, and various vaccine-preventable diseases. Its Grand Challenges in Global Health initiative funds research on major health issues. One of these challenges—measuring health status—includes a component to develop technologies for assessing multiple conditions and pathogens at the point of care, which will allow for the detection of emerging pathogens, better detection and management of outbreaks, and quantification of disease incidences in endemic countries. (*www.gatesfoundation.org/global-health*)

GOOGLE.ORG FOUNDATION

One of the five major initiatives of the Google.org Foundation—Predict and Prevent—is designed to help prevent local outbreaks of emerging diseases from becoming pandemics. Through October 2008, the foundation had committed more than \$30 million in grants to help identify potential disease hot spots, detect new pathogens and outbreaks earlier, and facilitate rapid response to prevent local threats from becoming global threats. For example, the foundation works with partners to develop systems for community-based and cross-sector reporting using mobile phone technologies. It is committed to building laboratory capacity and epidemiology training programs. It will also support improved data collection, sharing, visualization, and analysis to strengthen vulnerability mapping and predictive modeling of weather and

climate patterns that affect disease emergence and thus provide early warning of disease outbreaks. The initial focus of the program is Southeast Asia and sub-Saharan Africa. (www.google.org/predict.html)

NUCLEAR THREAT INITIATIVE—GLOBAL HEALTH AND SECURITY INITIATIVE

The Global Health and Security Initiative promotes the safe and secure practice of the life sciences by encouraging the safeguarding of access to dangerous pathogens, the prevention of misuse of technology and information, and the improvement of global capacity for countering biological threats through enhanced disease surveillance, in particular through early detection and response. (www.gbsi.org)

The initiative also provides support to the International Council for the Life Sciences to establish regional and national networks on best practices, standards, and training in biosafety and biosecurity. It has helped establish two regional disease surveillance consortia—the Middle East Consortium for Infectious Disease Surveillance and, in cooperation with the Rockefeller Foundation, the Mekong Basin Disease Surveillance Network. (www.gbsi.org)

ROCKEFELLER FOUNDATION

The Rockefeller Foundation is providing support for regional disease surveillance networks by building human capacity and promoting collaboration across countries and regions, as well as with global monitoring programs. It has supported the Mekong Basin Disease Surveillance Network (described in Chapter 4 in the section on the Nuclear Threat Initiative's Global Health and Security Initiative) and the East African Integrated Disease Surveillance Network. Several grants have also been provided to ministries of health in the Mekong Basin region. The foundation has provided grants to the International Livestock Research Institute in Kenya to strengthen animal disease surveillance. (www.rockfound.org/initiatives/initiatives_dev/pandemics.shtml)

SLOAN FOUNDATION

The Sloan Foundation supports a range of small projects to address the threat of bioterrorism, including work on citizen preparedness, incentives for business, pandemic preparedness, and dangerous research. Examples of their work include citizens' guides, efforts to enhance building security and improve heating and air conditioning systems to reduce possible exposures to aerosols, and work with WHO to develop avian influenza preparedness guidance for health workers. (www.sloan.org/programs/pg_national.shtml#bioterror)

WELLCOME TRUST, UNITED KINGDOM

The Wellcome Trust supports biomedical research in the United Kingdom and internationally. In recent years, it has supported policy debates examining the risks associated with life sciences research and its potential use for the development of biological weapons. In 2003, it published a position statement on bioterrorism and biomedical research. In September 2005, the Wellcome Trust published a joint policy statement on managing risks of misuse associated with grant-funding activities. This statement, issued in conjunction with the Biotechnology and Biological Sciences Research Council and the Medical Research Council, identified a series of actions to raise awareness and to ensure that potential risks were clearly identified in grant applications. (*www.wellcome.ac.uk/About-us/Policy/index.htm*)

Appendix J

Interagency International Bio-Engagement Working Group¹

The International Bio-Engagement Working Group coordinates U.S. government international efforts in the biological sciences, public health, and security to meet U.S. global biodefense and public health priorities. The activities of the working group include developing engagement strategies for priority countries and regions, reviewing specific program activities and implementation mechanisms, and establishing metrics for program evaluation.

MEMBERS OF THE INTERAGENCY INTERNATIONAL BIO-ENGAGEMENT WORKING GROUP

National Security Council

Homeland Security Council

Office of the Vice President

Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Regional bureau staff members and desk officers

U.S. Agency for International Development

Department of Defense

Office of the Secretary of Defense

Office of Health Affairs

Joint Chiefs of Staff

Armed Forces Medical Intelligence Centers

¹ Information provided by the Department of State, November 2008.

Department of Health and Human Services

Office of Global Health Affairs

Office of the Assistant Secretary for Preparedness and Response

Centers for Disease Control and Prevention

National Institutes of Health (National Institute of Allergy and Infectious Diseases)

Department of Agriculture

Agricultural Research Service

Foreign Agricultural Service

Animal and Plant Health Inspection Service

Food Safety and Inspection Service

Department of Homeland Security

Office of Intelligence and Analysis

Office of Health Affairs

Science and Technology Directorate

Environmental Protection Agency

International Office

Federal Bureau of Investigation

National Counterterrorism Center

National Counterproliferation Center

Central Intelligence Agency

Defense Intelligence Agency

Office of Science and Technology Policy

Appendix K

Relevant Studies

REPORTS OF NATIONAL RESEARCH COUNCIL STUDIES

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Appendix L

Biographies of Committee Members

ADEL A. F. MAHMOUD (Chair), M.D., Ph.D., is a professor at the Woodrow Wilson School of Public and International Affairs and in the Department of Molecular Biology at Princeton University. He recently retired as president of Merck Vaccines of Merck & Company, Inc. Dr. Mahmoud served at Case Western Reserve University and University Hospitals as chairman of medicine and physician-in-chief. Dr. Mahmoud's academic pursuits focused on investigations of the determinants of infection and disease in human schistosomiasis and helminthic infections. He has led the effort to develop new vaccines for measles, mumps, rubella, varicella, rotavirus, shingles, and human papillomavirus. Dr. Mahmoud's leadership in setting global health strategies shaped the agenda of the Forum on Microbial Threats of the Institute of Medicine in recent years by tackling such topical issues as biological threats and bioterrorism; severe acute respiratory syndrome; and pandemic influenza. He is a member of the Expert Advisory Panel on Parasitic Diseases of the World Health Organization. He was elected to the Institute of Medicine in 1987, and he is a member of the National Science Advisory Board for Biosecurity and Committee on Scientific Communications and National Security. Dr. Mahmoud received an M.D. from the University of Cairo and a Ph.D. from the University of London, School of Hygiene and Tropical Medicine.

DAVID A. ASHFORD, D.V.M., is the regional director for international services in the Sao Paulo office of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. Previously, he was team leader for research and special projects in the Public Health Emergency Preparedness Branch of the Centers for Disease Control and Prevention (CDC). While at CDC, he served as team leader for review of epidemiological and scientific issues related to public health emergency preparedness and response, with an emphasis on

biological and chemical terrorism. In addition, he serves as a subject matter expert for biological and chemical threat agents and interagency liaison on environmental health issues related to terrorism preparedness. As an expert on the epidemiology and control of zoonoses, his responsibilities include serving on several international and domestic steering committees, teaching, and developing or contributing to domestic and international guidelines. He has extensive experience in dealing with relevant officials and facilities throughout Latin America.

GAIL H. CASSELL, Ph.D., is vice president, scientific affairs, and Distinguished Lilly Research Scholar for Infectious Diseases at Eli Lilly and Company in Indianapolis, Indiana. Currently, Dr. Cassell is a member of the Science Board of the Food and Drug Administration's Advisory Committee to the Commissioner. Since 1996, she has been a member of the U.S.-Japan Cooperative Medical Science Program responsible for advising the respective governments on joint research agendas. Dr. Cassell served as an advisor on infectious diseases and indirect costs of research to the White House Office of Science and Technology Policy. She has additionally served two terms on the Liaison Committee on Medical Education, the accrediting body for U.S. medical schools. Dr. Cassell obtained her B.S. from the University of Alabama in Tuscaloosa and her Ph.D. in microbiology from the University of Alabama at Birmingham, which selected her as its 2003 Distinguished Alumnus. She is a member of the Institute of Medicine.

Major CLAIRE CORNELIUS, D.V.M., is pursuing a Ph.D. in microbiology as part of a U.S. Army Long-Term Health Education and Training opportunity at the University of Chicago. Her research interests include plague pathogenesis and vaccine design. Previously, she served as post veterinary officer, Guantanamo Bay, Cuba; force veterinarian, Multinational Forces and Observers, Sinai Peninsula, with duty in Egypt and Israel; and branch chief, Yokosuka Branch Veterinary Services, Japan, with additional duty in Thailand, the Philippines, Vietnam, Hong Kong, and Indonesia in support of public health and civic action programs. She has been a member of two research teams investigating malaria and hemorrhagic viruses in the Amazon basin, Iquitos, Peru.

TIMOTHY ENDY, M.D., serves as associate professor of medicine at the State University of New York Upstate Medical University in Syracuse, New York. Dr. Endy specialized in virology and emerging diseases at the U.S. Army Military Component in Bangkok, Thailand, from 1996 to 2001. Dr. Endy subsequently served in the Department of Virology at the U.S. Army Medical Research Institute of Infectious Diseases, as assistant chief and then chief of the division. From July 2003 until his retirement at the rank of colonel in 2006, Dr. Endy served as director of the Division of Communicable Diseases and Immunology

of the Walter Reed Army Institute of Research. He has published extensively on the topic of infectious disease. In 2007, he served on the National Research Council Committee on Prevention of Proliferation of Biological Weapons. Dr. Endy received an M.P.H. from the University of Michigan and an M.D. from the Uniformed Services University.

HARVEY RUBIN, M.D., Ph.D., is a professor at the University of Pennsylvania School of Medicine, where he has served as faculty since 1983. He also serves as professor of computer and information sciences at the University of Pennsylvania School of Engineering and Applied Sciences. Dr. Rubin is additionally director of the university's Institute for Strategic Threat Analysis and Response and serves as a member of the School of Medicine Curriculum Committee. He was house officer in medicine at the Peter Bent Brigham Hospital in Boston and did his fellowship in infectious diseases at Harvard and the Brigham and Women's Hospital. As a member of the International Committee of the National Science Advisory Board for Biological Security, Dr. Rubin regularly follows developments involving dual-use issues throughout the world. He received his Ph.D. in molecular biology from the University of Pennsylvania and his M.D. from Columbia University.

RICHARD L. WITTER, D.V.M, Ph.D., served as a veterinary medical officer with the U.S. Department of Agriculture-Agricultural Research Service (ARS) Avian Disease and Oncology Laboratory (ADOL) in East Lansing, Michigan, for 38 years (1964-2002). He currently serves as collaborator with the ADOL and as adjunct professor with the Department of Pathobiology and Clinical Investigations at Michigan State University. Dr. Witter helped develop the first successful vaccine in the United States against Marek's disease and has documented the evolution of this virus to greater virulence. He has received numerous awards and recognition for his research. For more than 22 years, as director and research leader of ADOL, Dr. Witter administered a multidisciplinary research program on the biology of important avian viral neoplasms, as well as programs on recombinant DNA vaccines, immunogenetics, transgenic chickens, and genome mapping. He returned to the bench in 1998, where he pursued his personal research on Marek's disease and avian leukosis until his retirement in 2002. He has been active in international activities involving grants programs in the Middle East and Central Asia. He helped initiate the ARS-Former Soviet Union Scientific Cooperation Program and has served as a scientific consultant to this program since its inception. Dr. Witter received his B.S. and D.V.M. from Michigan State University and his M.S. and Ph.D. from Cornell University. He was elected to membership in the National Academy of Sciences in 1998.

