



The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships

Committee on Prevention of Proliferation of Biological Weapons, Office for Central Europe and Eurasia, National Research Council

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**The Biological Threat Reduction Program
of the Department of Defense:
From Foreign Assistance to Sustainable Partnerships**

Committee on Prevention of Proliferation of Biological Weapons

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

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Glenn E. Schweitzer, Director, Office for Central Europe and Eurasia

Anne Harrington, Director, Committee on International Security and Arms Control

Kelly Robbins, Senior Program Officer

Amy Moore Mercer, Program Associate

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The committee expresses its gratitude for the time that these many colleagues devoted to helping ensure that this report reflects a variety of views from specialists and observers who have been interested for many years in the types of activities of priority interest to BTRP.

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that assist the institution in making its published report as sound as possible and ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report: Richard A. Berman, Manhattanville College; Jesse L. Goodman, U.S. Food and Drug Administration; John Hay, University at Buffalo; Christopher P. Howson, March of Dimes Foundation; Michael Moodie, independent consultant; Sue Partridge, U.S. Centers for Disease Control and Prevention; Kim Savit, Science Applications International Corporation and Denver University; and Richard L. Witter, U.S. Department of Agriculture.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by Mary Jane Osborn, University of Connecticut Health Center. Appointed by the National Academies, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Summary

During the past 15 years, the Department of Defense (DOD) has supported a variety of international security-oriented biological activities within the framework of DOD's Cooperative Threat Reduction (CTR) program. For 10 years, these activities have been referred to by DOD as the Biological Threat Reduction Program (BTRP) and have been implemented by the Defense Threat Reduction Agency (DTRA). They have been carried out in Russia, Kazakhstan, Uzbekistan, Georgia, Azerbaijan, and Ukraine. BTRP is one of several U.S. government programs that have been developed and implemented within an interagency framework to prevent the proliferation of expertise, materials, equipment, and technologies that could contribute to the development of biological weapons. These other programs are referred to in this report as "related" programs.

The U.S. Congress included in the National Defense Authorization Act of 2007 a provision calling for a study by the National Academy of Sciences of the activities carried out by BTRP and activities that should be considered in the future. The legislation calls for the study to (1) assess relevant cooperative activities that have been carried out in Russia and other states of the former Soviet Union (FSU) with support by BTRP and other U.S. government programs, and (2) identify activities that should be considered for further cooperation, particularly BTRP activities. This report addresses the Congressional mandate.

BTRP and its predecessor programs have involved a number of ministries and several dozen institutions in the six countries. The cost to the U.S. government has been more than \$430 million from Fiscal Year (FY) 1998 through FY 2007, with expenditures in earlier years very limited. DOD plans call for significantly increased funding for BTRP beginning in FY 2008, with the appropriation estimated to be about \$200 million for FY 2008.

Over the years, BTRP and its predecessor programs have made significant contributions to preventing the proliferation of biological weapons. The categories of activities and expenditures through FY 2007 are as follows:

- *Biological Infrastructure Elimination*, with three facility dismantlement projects completed in Kazakhstan and Georgia and on Vozrozhdeniye Island in the Aral Sea: \$15.2 million (3.5 percent of the program)
- *Biosafety/Biosecurity*, which involves facility upgrades, training, and related activities throughout the region and initial steps in establishing the Threat Agent Detection and Response (TADR) network in Georgia, Azerbaijan, Uzbekistan, and Kazakhstan: \$271.4 million (63 percent of the program)
- *Cooperative Biological Research*, with research laboratory upgrades and research projects carried out in Russia, Kazakhstan, Uzbekistan, Georgia, and Azerbaijan: \$62.4 million (14.5 percent of the program)
- *Program Administration*, involving supporting activities by a variety of organizations, including a contractor-led Threat Reduction Support Center and contracts to cover costs of shipments of materials and equipment to partner countries: \$81.9 million (19 percent of the program)

Recommendations

Summarized below are recommendations for building on BTRP's successful contributions in preventing the proliferation of biological weapons. For the purposes of this report, biological weapons are defined as any biological materials that, if deliberately misused, could cause significant harm to human health or agricultural resources.



Recommendation 1: The U.S. government should provide strong and sustained support for BTRP and related programs.

Within the former Soviet Union, BTRP activities have strengthened the containment of biological materials, technologies, equipment, and expertise that, if misused, could result in serious biological threats. Specific changes in the region that can be attributed at least in part to BTRP have included the following:

- Unprecedented transparency at dozens of important facilities with dual-use capabilities that had not previously been open to foreign specialists
 - Dismantlement and/or conversion of production and research facilities established to support biological weapons activities, including transformation to civilian activities of more than a dozen important components of the weapons-oriented Biopreparat complex
 - Redirection to civilian pursuits of hundreds of senior biological scientists, engineers, and technicians who were formerly engaged in defense programs
 - Attraction and retention of hundreds of younger specialists working in basic sciences and in the fields of public health and agriculture
 - Adoption by local institutions of standard international approaches to project management and to fiscal accountability
 - Participation in scientific conferences and training programs abroad by specialists from the region who had not previously traveled abroad
 - Increased publication by local scientists in peer-reviewed international journals of research findings, which demonstrate their capabilities to participate effectively in international scientific activities
 - Enhanced quality of local research projects and technology transfer activities that have taken advantage of the experience and expertise of international collaborators
 - Improved biosecurity and biosafety at biological research institutions, particularly with regard to consolidation and physical protection of dangerous pathogen strains
 - Opening and sharing of local databases with international collaborators
 - Construction and equipping of modern research, public health, and agriculture facilities where activities of interest to international partners are carried out
 - Development of local regulations and related training programs concerning the safety and security of biological materials and good laboratory practices

The foregoing and other results of engagement activities supported by BTRP and related programs have led to the establishment of continuing international linkages based on friendships and common professional interests. These personal contacts help build mutual

respect and trust that are 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 importance. Finally, intergovernmental cooperation in the biological sciences and biotechnology, exemplified by BTRP, offers important opportunities for political and scientific leaders from the United States and partner countries to discuss common security and health interests and to develop complementary approaches for combating threats of global terrorism.

In short, past U.S. government investments in BTRP have provided substantial benefits to national security, and the opportunities for future contributions are many fold. At the same time, there will continue to be difficult implementation problems due to different objectives and priorities of BTRP and partner organizations, a legacy of mistrust in sensitive technical areas, and administrative problems in matching U.S. approaches with interests of partners. A long-term U.S. government commitment to the program is essential in overcoming these problems and increasing the positive impacts of cooperation.



Recommendation 2: The White House should exert strong leadership to ensure integration of BTRP with related biological threat reduction activities supported by the U.S. government.

Reducing security risks associated with a wide variety of biological research and technology activities that have dual-use dimensions is a complex task. Programs to this end involve many types of expertise that are available within different U.S. government departments and agencies that support biological nonproliferation programs in the former Soviet Union. In addition to DOD, they include the Departments of State (DOS), Agriculture (USDA), Health and Human Services (DHHS), and Energy (DOE) and the Environmental Protection Agency (EPA). Each of these entities has international partners with similar interests and therefore has comparative advantages in engaging in specific types of cooperative activities. However, USDA, DHHS, and EPA have only small nonproliferation budgets made available through the Department of State, and these budgets are shrinking. Therefore, the authorizing legislation for BTRP should include a provision that helps ensure that BTRP will engage other departments as appropriate and will provide them with financial resources to this end when necessary.

Interagency coordination mechanisms have been in place for many years. However, past efforts to integrate the interests and capabilities of the six Executive Branch departments and agencies have been inconsistent, with lost opportunities to advance the nation's nonproliferation agenda. Of particular concern is the level of representation from the departments and agencies in the interagency deliberations and the leadership roles of the participants in interagency deliberations within their own departments. In the future, the participants should be senior officials who collectively can ensure sustained, high-level attention to international biological risk reduction throughout the government. These officials should be in a good position to develop common government-wide strategic goals that help guide BTRP and related on-the-ground programs supported by the U.S. government and to assess the cumulative security and health impacts of programs of different departments and

agencies. Also, they should be able to identify opportunities for using the results of BTRP research, while identifying international research competencies developed by BTRP that are of interest to their departments.



Recommendation 3: BTRP should be transformed from a Washington-directed program of assistance to a genuinely collaborative program of partnerships with governments of the states of the former Soviet Union, built on strong relationships between important scientific, public health, and agriculture institutions and specialists in these states and counterparts in the United States. Should BTRP expand into other geographical areas, collaboration rather than assistance should be a guiding principle whenever possible.

Development of strong partnerships is essential to sustain program activities initiated through BTRP or related programs. To this end, a critical early step is for BTRP to fully engage partner governments, institutions, and specialists in the selection and design of proposed cooperative activities from the outset. Greater attention should be given to the priorities of partners, and BTRP should be flexible so that BTRP activities can be effectively integrated with partner priorities. The likelihood of sustainability by partners of activities initiated through BTRP must be considered before projects are undertaken to ensure that important activities which are launched will be continued for the indefinite future and that newly acquired dual-use biological assets in the region, such as Biosafety Level 3 (BSL-3) facilities, will be used appropriately.

A key issue in encouraging local partner governments to buy into BTRP activities is selection of the disease agents and disease syndromes to be addressed in surveillance and research projects. The governments in the countries where BTRP has been active are most interested in diseases that are of continuing public health or agriculture concern. They are less interested in highly dangerous pathogens that seldom pose public health or agriculture threats but have been identified by the U.S. government and by international bodies as being of special terrorism concern. When diseases of local interest (e.g., tuberculosis, influenza, or respiratory diseases) are included in projects along with pathogens of global terrorism concern, local support for the program increases and the likelihood of sustained support and engagement is greatly enhanced.

Selection of the institutions and scientists to be involved in projects is a second important issue. BTRP should encourage partner governments to select for collaborative activities those institutions and scientists, and particularly young scientists, that are well positioned to play leading national roles in research and surveillance activities. The final selection should be made jointly by partner governments and BTRP.

Among the many other important issues that should be addressed to help ensure genuine collaboration that leads to sustainability are the following:

- *Collaborative development of a country science plan for each country where BTRP has activities.* This plan should provide a shared vision of the goals of the program and a framework for designing activities that reflect priority interests of partner governments as well as achieve BTRP objectives. Also, the plan should be consistent with overall U.S. government policy and program approaches in the country.

- *Joint strategic planning for proposed national Central Reference Laboratories, which may cost \$60 million each to build and equip.* This planning should ensure that the anticipated long-term health and agriculture benefits, particularly the benefits derived from expensive BSL-3 laboratory capabilities, warrant both the initial and life-cycle costs. These benefits should not only be cost-effective but should also outweigh the possibility that in the long term the facilities might be misused for nefarious purposes due to unanticipated political developments in the region.

- *An early region-wide evaluation of the health and agriculture benefits of the TADR network that is being established initially in Georgia to help ensure that similar BTRP investments in other countries are well targeted and result in discernible benefits that will encourage future local investments.* Of special importance is the eventual integration of the TADR network with existing national and regional surveillance networks within the participating countries.

- *Joint programs to ensure that important pathogen strains that can be obtained within the region are available at local facilities to international investigators, thereby reducing the need for controversial transfers of such strains to the United States that raise questions over BTRP objectives and unnecessarily delay projects.*



Recommendation 4: BTRP should give greater emphasis to a comprehensive, multi-faceted approach to international engagement for achieving biosecurity, public health, and agriculture objectives. The approach should include development of countermeasures to bioterrorism, enhanced facility security, collaborative surveillance activities, expanded cooperative research, development of common biosafety procedures, adoption of good laboratory practices and good manufacturing practices, development of human resources, and related activities.

BTRP has supported a variety of research and surveillance activities aimed at improving human and animal health as well as upgrading security in facilities where dangerous pathogens are located. These activities are commendable and reflect a broad approach. They should receive even greater support in future years. While the short-term payoffs from investments in research and surveillance are difficult to measure, in the longer term they may be the most significant activities that BTRP undertakes in some countries to help detect misuse of pathogens and to respond promptly to incidents resulting from misuse.

Within the interagency process, BTRP should continue to play a prominent role in U.S. efforts directed to containment of highly dangerous pathogens and associated activities. At the same time, BTRP, together with DHHS and USDA, needs to be a strong advocate for and active participant in dealing with broader health and agriculture issues that are important in addressing infectious diseases.



Recommendation 5: DOD should work through existing scientific networks and establish new models as appropriate to reinvigorate BTRP in Russia by supporting cost-shared collaborative research projects, scientific conferences, and other scientific activities that

promote both Russian and U.S. national security interests through engagement of outstanding established and young scientists in the two countries.

To this end, a competitive grants program funded by BTRP that initially emphasizes projects sited in Russia and then expands to other countries should be considered.

DOD has had difficulties in dealing with the Russian government, perhaps due in part to Russian suspicions over DOD motivations; and therefore the department plans to terminate almost all activities in Russia. However, the country's biological assets are too important not to engage Russian researchers on a broad scale in future BTRP activities. Although the economic situation in Russia is stabilizing, the future of a number of large biological institutions is in flux; and many former weapon scientists remain trapped in uncertain circumstances that could raise serious proliferation concerns. There are mechanisms established by other U.S. departments and nongovernmental organizations that could be used by BTRP for engaging important Russian institutions and specialists in cooperative activities that circumvent the need for new formal agreements with recalcitrant Russian ministries and agencies. Also, there are approaches to engagement that no longer require involvement of BTRP's integrating commercial contractors, thereby eliminating problems associated with logistics teams based in Russia.

The emphasis should be on high-impact research activities of mutual interest jointly funded with Russian partners. In this way, BTRP can capitalize on its past investments in research in Russia, recognizing that Russia now has stronger technical capabilities than a decade ago and that the Russian need for financial assistance has diminished.



Recommendation 6: To improve program management, DOD/DTRA should ensure availability of adequate internal technical staffing for BTRP and should recognize that while there is a need for commercial integrating contractors for construction projects, assistance in management of research projects and related training programs can be more appropriately provided by U.S. government, academic, or nonprofit organizations.

Strengthened internal DTRA staff capabilities are essential to reduce the outsourcing of contacts with important foreign participants and of technical judgments to integrating contractors and to improve the efficiency of the entire management system. DOD and DTRA simply have not assigned sufficient internal personnel with strong technical capabilities to develop, manage, and evaluate a program that requires constant judgments to assess scientific uncertainties.

Commercial integrating contractors play an important role in ensuring that complicated construction activities are carried out as planned, that construction funds are properly managed, and that quality control in designing and constructing facilities is maintained. However, with regard to support of research projects, there is less need for these types of contractors to be involved. Other government departments, such as the Department of Health and Human Services, and nongovernmental organizations, such as the U.S. Civilian Research and Development Foundation, have strong scientific reputations and considerable experience in providing technical guidance and establishing mechanisms for transferring

funds to partner institutions and to specialists for salaries, laboratory supplies, and research equipment.

The Way Ahead

As biotechnology capabilities continue to spread throughout the world, opportunities for misuse of biology that can seriously harm U.S. interests at home and abroad are rapidly growing. Current U.S. government programs for redirecting former weapon scientists in Russia and the other states of the FSU to peaceful pursuits and for upgrading the security of facilities in that region and elsewhere which house dangerous strains of pathogens have never been more important. But the programs are only a beginning. Potential problems associated with the spread of dual-use technologies are so widespread that global engagement that enhances transparency and promotes common interests in preventing diseases on a broad basis is essential.

To this end, BTRP can and should play a central role in supporting development of international networks of institutions and specialists with common interests in biological research, public health, agriculture, and biosecurity. Joint efforts can continue to improve the quality of research and related activities throughout the region while enhancing transparency and strengthening personal contacts directed to common problems. Near-term emphasis should continue to be on taking projects to the state of sustainability within Russia and the other states of the FSU.

International networks are a key to preventing the proliferation of biological weapons. They are an essential mechanism in building trust among governments engaged in activities with dual-use dimensions and in providing insights as to intentions of colleagues at the facility level. At the same time, BTRP can use such networks in joint efforts to help provide early warning of disease outbreaks, contribute to development of safe and affordable vaccines and drugs, and provide pathogen detection devices.

In short, U.S. security interests can be served in many ways by a robust and broadly based approach by BTRP and related programs.

Introduction

The U.S. Congress included in the National Defense Authorization Act of 2007 a provision calling for a study by the National Academy of Sciences of programs carried out under the Cooperative Threat Reduction Program (CTR) of the U.S. Department of Defense (DOD) that have been designed to prevent the proliferation of biological weapons (Pub. L. 109-364, Title XIII, Section 1304). These biology-oriented activities are currently referred to by DOD as the Biological Threat Reduction Program (BTRP). The legislation calls for the study to

- assess relevant cooperative activities that have been carried out in Russia and other states of the former Soviet Union (FSU) with support by BTRP and other U.S. government programs, and
- identify activities that should be considered for further cooperation, particularly BTRP activities, within the interagency context.

The National Research Council (NRC), acting on behalf of the National Academy of Sciences, has followed closely the evolution of BTRP during the past decade and has observed substantial progress through BTRP and other U.S. government-supported activities in containing biological weapon capabilities within the FSU. At the same time the NRC has from time to time made a number of suggestions to DOD for enhancing BTRP approaches. Therefore, the NRC welcomed the opportunity to undertake this study of the critical role of BTRP in promoting U.S. security interests.

In February 2007, the NRC entered into a contract with the Defense Threat Reduction Agency (DTRA), acting on behalf of DOD, to carry out the study. This report sets forth the findings and recommendations of the *Committee on Prevention of Proliferation of Biological Weapons* established by the NRC to undertake this study (see Appendix A for biographical information on the committee members).

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 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 a number of countries.

Addressing the Dual-Use Dilemma

The rapid diffusion of scientific knowledge and technical capabilities has enabled many countries to benefit from recent advances in biological science and biotechnology. These developments have improved medications and medical procedures, increased agricultural productivity, diversified sources of energy, and spawned new industrial processes. But research directed to dangerous human, animal, and plant pathogens and to biotechnology activities in a variety of fields has also led to dual-use technologies that can be employed not only for the betterment of the lives of people but also for the development of advanced biological weapons for use by military forces, terrorist groups,

or disgruntled individuals. For example, research to understand the characteristics of anthrax or foot-and-mouth disease, while important for public health and agriculture, can also attract the attention of groups or individuals who are interested in using these pathogens as weapons of terrorism. This dual-use dilemma underlies the concerns set forth in the legislation calling for the study and this report.

As is widely recognized, many naturally occurring diseases continue to threaten health and agriculture on local, regional, and international scales. Each day, tens of thousands of people throughout the world die from infections, and untold quantities of animals and food supplies are lost on every continent due to the spread of lethal diseases. A global consensus has emerged that all nations need to work together to prevent pandemics due to naturally occurring diseases and to respond vigorously when outbreaks occur. The recent national responses to the outbreaks of Severe Acute Respiratory Syndrome (SARS) and avian influenza, within a framework of coordination established by several international organizations, are good examples of constructive international efforts. Experience from these efforts should help shape responses to bioterrorist-instigated diseases, particularly those that cross international borders.

Still, effective international responses to the threat of deliberately introduced diseases by terrorist groups are not easy to mount. Perceptions of different governments as to the severity and the nature of emerging threats differ. Also, overcoming the bureaucratic challenges and the technical uncertainties in formulating international policies and programs that cut across many government agencies at the national level is formidable.

Several decades ago, concerned governments responded to the potential threat of biological weapons by taking initial steps in constructing a legally binding international regime to ban the use, development, stockpiling, and production of such weapons and to prevent countries and sub-national groups from acquiring them. This regime is based on the Geneva Protocol (entered into force in 1928) and the Biological and Toxin Weapons Convention (entered into force in 1975), supplemented by the Australia Group's export control guidelines (updated on a regular basis). At the time the components of the regime were initially developed, the primary concern was over hostile states, not terrorist groups, acquiring biological weapons. However, even with regard to activities of states party to the agreements, let alone to amorphous terrorist groups, effective measures for ensuring that illicit activities are not being carried out have been elusive, and there are only limited procedures for addressing suspected violations of the agreements.

In recent years, the U.S. government has led the international effort to develop new approaches to address the threat of bioterrorism while advocating compliance with treaty obligations. To this end, and in response to an initiative of the U.S. Congress in 1991 to establish the CTR program, during the 1990s DOD developed a number of programs that are now carried out through BTRP. BTRP is a very important component of the U.S. government's programmatic approach for preventing the proliferation of biological weapons consistent with its legislative charge. BTRP is the primary focus of this report.

Scope of the Study

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

An NRC committee of experts will be formed to conduct a study and prepare a report that identifies areas for future cooperation with Russia and other states of the FSU under the CTR program of DOD in the specific area of prevention of proliferation of biological weapons.

Specifically, the study will include the following:

1. A brief review of any ongoing or previously completed U.S. government program (whether conducted through the CTR program or otherwise) in the area of prevention of proliferation of biological weapons.
2. An identification of further cooperative work between the United States government and foreign governments, including technical scientific cooperation, that could effectively be pursued in the area of prevention of proliferation of biological weapons, related materials, technologies, and expertise and the objectives that such work would be designed to achieve.
3. An identification of any obstacles to designing and implementing a nonproliferation program (whether conducted through the CTR program or otherwise) that could successfully accomplish the objectives identified pursuant to paragraph (2), together with recommendations for overcoming such obstacles, including recommendations in the area of coordination among relevant United States government departments and agencies.

BTRP has been carried out within the framework of an interagency effort directed to the prevention of proliferation of biological weapons. According to BTRP officials, the interagency guidance from the National Security Council advocates a comprehensive approach to the prevention, detection, control, and therapy of human and agricultural diseases through the strengthening of relevant physical, human, and administrative infrastructures in the countries of interest. The approach involves programs administered by the Departments of State, Health and Human Services, Agriculture, and Energy and by the Environmental Protection Agency in addition to DOD, as discussed in Chapter 3. In this report, the nonproliferation activities of these departments and agencies, including DOD activities beyond BTRP, are referred to as “related” programs.

The legislative charge emphasizes that the study should concentrate on programs undertaken in cooperation with the governments of the states of the FSU. At the same time, the committee also recognized the potential for proliferation in other geographical areas. Of particular concern is Southeast Asia. Officials of the Department of State have informed the committee that there have been indications of terrorist groups exploring access to inadequately controlled biological facilities and materials. Clearly, the challenges in countering proliferation in countries beyond the former Soviet Union deserve additional study beyond the effort associated with this report.¹

As called for in the legislation, the committee reviewed the nonproliferation programs of not only DOD but also other U.S. departments and agencies. However, as to

¹ Senate Report 110-77, National Defense Authorization Act for Fiscal Year 2008, Section 1306, calls for a subsequent study by the National Academy of Sciences to identify areas for cooperation with states other than states of the former Soviet Union under the CTR program to prevent the proliferation of biological weapons and dual-use materials. Available on-line at <http://origin.www.gpoaccess.gov/serialset/creports/>. Accessed June 14, 2007. This proposal is still being discussed by Congress.

recommendations for future programs, the focus is on BTRP. While the future of related programs is also important, the NRC committee considered that its limited financial resources and time could be most effectively used by concentrating on BTRP, which is the primary interest of the Congressional committees responsible for the legislation that calls for this report. Consultations with relevant Congressional staff members confirmed the appropriateness of this orientation. DOD has concurred with this approach. Other U.S. departments and agencies will continue to support relevant activities in the FSU and elsewhere through their nonproliferation programs and through other international programs for which they have important responsibilities in promoting U.S. interests, thus offering the possibility of synergies with BTRP activities.

The committee also took note of relevant programs, including foreign assistance programs, supported by (1) other governments and particularly Canada and the countries of the European Union, (2) international organizations such as the World Health Organization and the World Organization for Animal Health, (3) international development banks, (4) private foundations, (5) professional scientific societies, and (6) international medical and agricultural companies. However, the committee did not consider the details of these activities. They deserve further study.

Over the years, BTRP has supported hundreds of individual projects. Committee members have personally observed implementation of a number of these projects. Also, they have participated in annual reviews of BTRP's overall research program. This close scrutiny of BTRP activities provides a good basis for committee comments on the quality and impact of the programs. Nevertheless, as the program continues to grow, more intensive evaluations of the program are highly desirable. Such evaluations should include involvement of carefully selected specialists from partner countries.

The legislation calls for the study to address proliferation of "biological weapons." The committee has interpreted "biological weapons" to include any biological materials that could be deliberately misused to cause significant harm to human health or agricultural resources. This definition includes a very broad spectrum of pathogens.

The committee was asked to address the "prevention" of proliferation of biological weapons. In recent years, much of the prevention effort supported by the U.S. government in the former Soviet Union and elsewhere has been directed to (1) encouraging redirection of research activities of former defense scientists to civilian pursuits, (2) strengthening international agreements, national export control regulations, and internationally acceptable biosafety guidelines, (3) consolidating strains of dangerous pathogens dispersed in many locations into a limited number of secure locations, and (4) upgrading the configuration of facilities and the security practices at those facilities where dangerous pathogens of concern are located. All of these steps are important, particularly in reducing the threat of establishment of covert offensive biological weapons programs, and should be encouraged.

At the same time, the committee recognized that scientists and engineers with potential dual-use skills, equipment with dual-use applications, and materials that could be used for illicit as well as appropriate applications are widespread. Also, many of these intellectual and technical assets are integral to the successful operation of public health and agriculture infrastructure facilities. Thus, the committee considered a wide range of approaches that are needed to effectively address concerns over deliberate misuse of pathogens.

This report draws on information about U.S. government programs and plans that was available as of July 15, 2007. In responding to the tasks set forth in the legislation, this report is organized into six chapters.

- Chapter 1 discusses the international security context for considering BTRP activities.
- Chapter 2 identifies BTRP achievements to date and discusses reasons for successful activities.
- Chapter 3 describes other U.S.-sponsored cooperative programs carried out by a variety of U.S. government departments and agencies (i.e., related programs). It gives particular attention to the importance of an interagency approach that integrates BTRP with these related programs.
- Chapter 4 discusses the obstacles encountered in the carrying out of BTRP and suggests steps that can be taken to reduce these obstacles.
- Chapter 5 presents suggestions for expanding the positive impacts on national security of BTRP in the years ahead with particular attention to the importance of ensuring sustainability of activities initiated through BTRP that build on established collaboration and research partnerships.
- Chapter 6 consolidates the recommendations set forth in earlier chapters.

Information Sources

The committee and staff reviewed many relevant reports and studies prepared by officials and scientists from throughout the FSU and by American and other international officials and observers interested in the topics considered in this report. A few of the key documents are cited in the text, footnotes, and appendixes of this report.

Two recent reports prepared by the National Research Council are of particular relevance. The reports are *Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security*, National Academies Press, 2005; and *Letter Report on the Threat Agent Detection and Response System Database*, 2006. The recommendations included in these reports are set forth in Appendix B.

Also, the Institute of Medicine and other components of the National Academies have prepared a number of reports that address many programs to enhance global health research and surveillance. Particularly relevant reports are identified in Appendix C.

During the past decade, the Government Accountability Office (previously named the General Accounting Office) has also prepared a number of reports on the nonproliferation efforts of the U.S. government, including efforts to prevent the proliferation of biological weapons. Recent reports of interest are identified in Appendix D.

Complementing the literature review were important consultations in the United States and abroad during early 2007 by committee members and staff with participants in the activities of BTRP and related programs. In Washington, discussions were carried out with key officials, BTRP contractor employees, and American collaborators on BTRP projects (See Appendix G). Overseas, the committee organized structured discussions concerning BTRP with more than 100 specialists and officials from the six countries where BTRP has been active (See, for example, Appendix H). These recent consultations

complemented more than a decade of related discussions by committee members and staff with U.S. officials and foreign colleagues concerning BTRP. The committee considers that the individual comments set forth in the boxes throughout the report are a good sampling of commonly held views about the strengths and weaknesses of the program.

1

Security Context for the Biological Threat Reduction Program

For many years, leading scientists and security specialists throughout the United States and other countries have issued warnings about the threat of bioterrorism, including attacks that could kill tens of thousands of people or other attacks that could lead to widespread social and economic disruption. The U.S. and many other governments have mounted major programs to prevent and to defend against such attacks. The following recent incidents suggest that these warnings and preparations must be taken seriously:

- Anthrax letters disseminated in the United States in 2001
- Plans for bioterrorism set forth in documents recovered from al Qaeda training camps in 2001¹
- The discovery of “makeshift ricin laboratories” in the Pankisi Gorge adjacent to Chechnya and a “do-it-yourself guidance sheet” on how to make ricin found in the possession of a killed Chechen insurgent in 2003²
- An investigation launched in 2007 by the Procurator’s office in Moscow of alleged unsuccessful efforts to attack a large suburban chicken marketplace by introducing chickens affected with avian influenza virus, which would cause the market to close and business to shift to a competing marketplace³
- An attempted theft targeted at the pathogen collection at the central reference laboratory for animal health in Indonesia in May 2007 that was thwarted by security systems installed by the U.S. government⁴

As indicated in these examples, 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. Today, the international concern is not bomblets in missile warheads containing infectious viruses that could be released on impact. The focus is on more compact, but also devastating scenarios, such as the dissemination of a few grams of high quality anthrax spores in a major subway system or the introduction of the foot-and-mouth disease virus into a stockyard.

Dangerous biological agents are available in nature, and their potential use for malevolent purposes is increasingly understood by both our allies and our adversaries throughout the world. Intention on the part of a capable, but disgruntled scientist or

¹ See <http://archives.cnn.com/2001/WORLD/asiapcf/central/11/14/chemical.bio/index.html>. Accessed on May 23, 2007.

² Speech by Russian Defense Minister Sergei Ivanov at the Munich Conference on Security Policy, August 2, 2003. Available at <http://www.securityconference.de/konferenzen/rede.php?id=104&sprache=en&>. Accessed on May 30, 2007.

³ Comments made by Russian officials to visiting committee members and staff in March 2007.

⁴ Information provided by the U.S. Department of State in July 2007.

perhaps more likely a group of misguided scientists to use such knowledge and do harm is a critical concern. Early detection of intention is essential to reduce the likelihood of misuse or proliferation of dangerous biological assets. In short, security systems surrounding virulent pathogen collections are of course important but cannot alone hold potential terrorists at bay. Gaining insights as to intentions is just as important as efforts to constrain through physical barriers and security procedures access to collections of strains of dangerous pathogens.

One way to understand—and perhaps even alter—nefarious intentions regarding the misuse of biological agents is through development of close personal working relationships between American and counterpart scientists abroad, which introduce considerable transparency into scientific activities. Also, international projects can improve our understanding of foreign environments that might attract irresponsible groups seeking to misuse biological assets.

This chapter discusses important aspects of the security context for consideration of BTRP. It highlights scientific engagement promoted by BTRP and other programs as a promising avenue for understanding intentions.

Historical Perspective of Developments in Russia

During the Cold War, the Soviet Union and the United States, along with several U.S. allies, particularly the United Kingdom, developed large offensive biological warfare programs. The United States and its allies halted their efforts by 1969. The USSR continued its program until 1992, when President Boris Yeltsin declared that the development of biological weapons was illegal. The committee is unaware of any evidence that indicates continuation of illegal activities in Russia since that time, although others have lingering concerns. Fortunately, neither the United States nor the Soviet Union has used biological weapons.

The Soviet program is reported to have involved 30,000 to 40,000 specialists working in up to 40 facilities, primarily in Russia. Many of the facilities were grouped under the umbrella organization Biopreparat. In addition, the Soviet program also obtained specialized scientific support from a number of internationally known civilian-oriented research institutes. Research activities were highly compartmentalized, both within and between institutions. Production facilities were also closely shielded. They were capable of producing annually hundreds of tons of biological materials for weapon filling, particularly anthrax.⁵

Shortly after President Yeltsin's announcement, U.S. and British teams of specialists visited four Biopreparat facilities in Russia that were suspected of having supported weapons research and production activities. These visits were carried out within the framework of a Trilateral Agreement signed by the United States, United Kingdom, and Russian Federation. Following the visits and subsequent reciprocal visits to U.S. and British facilities by a Russian delegation of experts, negotiations began to lay the groundwork for additional visits to military facilities. However, the negotiations dragged on for months and eventually terminated without leading to such visits.⁶

⁵See, for example, Mangold, T. and Goldberg, J. 2000. *Plague Wars*. New York: St. Martin's Press, chapters 6 and 13.

⁶ *Ibid*, chapters 13, 15, and 17.

Meanwhile in 1991, Senators Sam Nunn and Richard Lugar co-authored legislation to establish the Cooperative Threat Reduction (CTR) Program within the Department of Defense (DOD).⁷ This program encompassed nuclear, chemical, and biological weapons. The objectives of the program were to (1) dismantle Soviet weapons of mass destruction and associated infrastructures, (2) consolidate and secure Soviet weapons of mass destruction and related technology and materials, (3) increase transparency and encourage higher standards of conduct, and (4) support defense and military cooperation, with the objective of preventing proliferation.⁸

With regard to biological weapons, these objectives have been pursued through BTRP and its predecessor programs. In parallel, other U.S. government departments and agencies have also undertaken related programs that have been authorized in other congressional mandates.

At the outset of bilateral engagement during the 1990s, it was more difficult for DOD to engage Russian counterparts in addressing biological problems than nuclear and chemical issues. The inherent dual-use nature of facilities, equipment, and personnel capabilities inhibited effective interactions between former adversaries. Also, there had not been an offensive biological weapons program in the United States for more than 20 years, and the redirection of biological activities in Russia to match the reoriented U.S. activities was slow and difficult to carry out in a country with a weak pharmaceutical sector. In particular, adjusting former Soviet defense activities to meet Russian regulatory requirements for the development of vaccines, drugs, and diagnostics—the most likely products that would come from redirected activities in the biological weapons sector—was inhibited by a tradition of secrecy and exemption of defense activities from civilian oversight.

In time, leaders of Biopreparat facilities and some of their Russian partners within the civilian sector became interested in cooperative activities with American counterparts. In 1994, the International Science and Technology Center in Moscow began to support projects at these facilities involving American collaborators. Soon thereafter, other governments became interested in cooperation with Russian organizations.

Direct contacts between DOD and organizations affiliated with the Russian Ministry of Defense have been limited, however. Specialists from the Military Medical Academy and the Military Microbiology Laboratory, both in St. Petersburg, have occasionally attended workshops and related consultations supported by the U.S. government. Also, in recent years a number of newly retired military specialists who had been affiliated with Ministry of Defense organizations have participated in BTRP projects. But the primary Russian military research laboratories have not shown interest in engagement: for example, laboratories in Sergiev Posad, Yekaterinburg, and Kirov.

As previously noted and as will be discussed at greater length in Chapters 2 and 3, several U.S. departments and agencies have developed collaborative projects that have been involving former Soviet weapon scientists for more than a decade. Almost all of these programs began with the goal of stemming proliferation of expertise and materials. The initial focus was on keeping former weapon scientists in Russia occupied with non-threatening research. Soon, increased emphasis was placed on supporting projects that were truly of international scientific interest and on facilitating commercialization of the

⁷ The Soviet Nuclear Threat Reduction Act of 1991 (Title II of Pub. L. 102-228).

⁸ See <http://www.dtra.mil/oe/ctr/index.cfm>. Accessed on August 22, 2007.

results of applied research. The importance of the programs for retaining the scientific workforce in Russia is highlighted in Box 1-1. The goal is now more broadly defined to encompass activities that promote the biological sciences, public health, and agriculture protection on a far-reaching basis as discussed throughout this report.

BOX 1-1

Importance of Cooperative Programs

“U.S. programs have provided critical support for thousands of Russian scientists who otherwise would have left the research system of the country, and particularly young scientists.”

Senior Russian research manager, March 2007.

An important milestone for BTRP was the 1997 report of the National Research Council (NRC) *Controlling Dangerous Pathogens: A Blueprint for U.S.-Russian Cooperation*. The report established the rationale and the framework for eight pilot projects in Russia that became the beginning stage of BTRP. Since that time, a great deal of transparency has been introduced at facilities of the former Soviet weapons program through collaborative projects. More than a dozen key laboratories and production facilities of the Biopreparat complex that participated in BTRP are now largely open and redirected to peaceful purposes. Also, many strain collections at Biopreparat and related facilities have been physically secured, and biosafety/biosecurity programs have been upgraded through BTRP. Education and awareness training concerning good laboratory practices, good manufacturing practices, animal welfare, and research ethics have facilitated the development of a culture of greater responsibility within the facilities. Some activities have been carried out in partnership with large American pharmaceutical companies. “Accountability” of biological assets is replacing “control” as an important objective. But, as noted above, key research institutes affiliated with the Ministry of Defense that carry out both classified and unclassified activities remain closed to foreign visitors.

In 2005, a second NRC report, *Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security*, underscored the importance of the evolution of a stronger, more flexible public health system in Russia. This system should be increasingly integrated into global networks as the country responds to endemic and emerging diseases. Enhanced capabilities could contribute to a significant reduction of vaccine-preventable and drug-curable infections in both humans and animals in Russia.

The 2005 report sets forth four key themes, or pillars, for countering infectious diseases in Russia. They are (1) improving surveillance and response, (2) meeting pathogen research challenges, (3) realizing the promise of biotechnology, and (4) strengthening the human resource base. The report also strongly supports the cross-cutting theme of international cooperation.

All the while, providing assurance of compliance of states with international agreements that are designed to limit biological activities has been an important goal of the U.S. and other governments. However, even with intrusive inspections and with a continued laboratory presence at selected facilities by external observers, obtaining

complete assurance of compliance is not possible. Too many facilities, too much equipment, and too many specialists have dual-use capabilities. As for biological terrorism, the laboratory requirements and the devices that are assembled may be small and easily hidden. With the use of such devices, common infectious or contagious agents such as influenza viruses could be introduced by terrorists with limited scientific training into crowded facilities without great difficulty.

At the same time, Russian scientists are increasingly trying to succeed in the domestic and world markets for human and veterinary pharmaceuticals, medical devices, human and animal food products, cosmetics, and other consumer goods. There are regulatory issues, facility issues, personnel training issues, and enormous market barriers. Breaking into U.S. or Western European markets is still, for most, a distant dream. Russian markets have been limited, but with improving economic conditions there now seem to be more opportunities. Development of international private sector partnerships is becoming more realistic than in the past. If they develop, such partnerships could help improve overall intergovernmental relations while contributing to pharmaceutical and biotechnology advancements in the United States and Russia.

Also of importance, Russian government funding for basic biomedical research, while limited, is slowly increasing. The Ministry of Education, Science, and Technology has established several competitive grants programs that support research on infectious diseases as well as on other topics. The Russian Academy of Sciences, despite harsh criticism by the government for failure to use its resources wisely, contends that it has retained its status as a strong advocate of increased funding for research.⁹

Overall, collaborative efforts have contributed significantly to upgrading biological research and biotechnology development in Russia and to building scientist-to-scientist relationships across the oceans. Ideas are regularly exchanged, electronically and face-to-face. Collaborations in fundamental and applied science are increasing, and many collaborators have become long-term friends. Scientist-to-scientist programs are addressing “intent” as a normal aspect of cooperation. But patience is needed, as intent is influenced one scientist at a time through BTRP and other international engagement programs. Since BTRP is the largest program in this field, it plays a particularly critical role in addressing the issue of intent. However, until greater international confidence at both the political and technical levels is developed that Russia no longer is interested in an offensive biological weapons capability, cooperative efforts will have their detractors in Washington and other international capitals.

Remnants of the Soviet Biological Weapons Program in Other Former Soviet States

While the largest portion of the Soviet biological weapons complex was located on the territory of Russia, a number of important components were located in other states of the former Soviet Union (FSU) as well. Of course, these scattered facilities operated under strict control of Moscow. In some cases, leaders of these facilities were sent there from Russia, but much of the leadership was entrusted to local specialists.

Since the collapse of the USSR in 1991, many facilities have retained strong although eroding capabilities of relevance both to biological weapons and to broader

⁹ Discussions by project staff and committee members with senior officials of the Russian Academy of Sciences, Moscow, March 2007.

public health, agriculture, and biotechnology interests. Some of the scientific leaders from the Soviet era have retired or have been replaced by younger managers. Those who are still at the facilities are approaching retirement age.

Several important biological weapons facilities were located in Central Asia. A large anthrax production plant and an associated research institute were established in Stepnogorsk, Kazakhstan. An anthrax weapons storage and testing site was located on Vozrozhdeniye Island, which is now geographically divided between Uzbekistan and Kazakhstan.

In Kazakhstan and in a number of other regions, a network of anti-plague stations had been established that provided support for research on locally occurring disease agents that were considered relevant to developing biological weapons as well as being of local public health interest. These stations are still operating with civilian-oriented research and surveillance agendas.¹⁰ In addition, a number of civilian-oriented biological research institutes throughout the USSR carried out special biological research projects under contract with the Soviet Ministry of Defense, and most if not all of these institutes are believed to have also redirected such efforts to peaceful pursuits.

With the splintering of the Soviet Union into 15 independent states, U.S. government access to non-Russian facilities where research related to biological weapons was carried out has usually been possible. As economic conditions deteriorated, most institutions were eager to accept U.S. financial support to help restore their scientific laboratories and to provide paychecks for highly skilled specialists. Indeed, assistance through BTRP and other U.S. programs has been important in helping to stabilize conditions at some of these facilities. While specialists at many facilities maintain long-standing ties with Russian institutions, they increasingly look westward for international connections and financial support (see Box 1-2). Ensuring that the United States is a preferred partner is important, particularly in maintaining the transparency that developed during the initial stages of BTRP.

BOX 1-2

Reach of BTRP

“Eight percent of the biology researchers of the country are engaged in BTRP activities.”

Deputy Minister of Health, Republic of Georgia, March 2007.

A special concern is that local dual-use capabilities that are upgraded as a result of BTRP activities not be used in the future for malevolent purposes. This issue is addressed in Chapter 5 with regard to new Biosafety Level 3 facilities, but it is a much broader issue. Of course, hostile groups could hone their dual-use skills on their own or in cooperation with unconcerned international partners regardless of the policies of the U.S.

¹⁰ Ben Ouagrham-Gormley, S., A. Melikishvili, and R.A. Zilinskas. 2006. The Soviet anti-plague system: an introduction. *Critical Reviews of Microbiology* 31:1. Available on-line at <http://cns.mii.edu/research/antiplague/index.htm>. Accessed on May 23, 2007.

government. In any event, long-term engagement that builds transparency and shared values as to appropriate use of biological assets on a broad basis is the best means to prevent abuse of capabilities. In the geographical areas where BTRP has been active, the risks of adverse consequences from upgraded capabilities are outweighed by the benefits of sustained efforts to responsibly address infectious diseases, in the judgment of the committee.

As discussed below, the economic conditions in all of the countries of the former Soviet Union have been poor. Only recently have several countries with oil and gas resources begun to achieve significant economic progress. Laboratories with outdated experimental equipment are commonplace throughout the region. An absence of young biological investigators is noticeable almost everywhere. Research results seem to have little impact on international science or on economic development. In short, the scientific infrastructures in all of the countries need upgrading.¹¹

Biological Risk in Other Countries of Concern

While this study did not address in depth facilities outside the FSU, committee members are aware of poor security conditions at some facilities in other regions of the world that handle dangerous pathogens. Their impressions concerning the lack of adequate security at facilities throughout South Asia, the Middle East, Africa, and Latin America are consistent with reports to the committee by U.S. government specialists who have visited a number of the facilities. In short, rudimentary security precautions are lacking at many facilities as the revolution in biological research and biotechnology spreads worldwide.

Some vulnerable facilities are located in developing countries in Africa and Southeast Asia where reports suggest that there are safe havens for terrorist cells. As one example of the countries' concern, the 2007 Association of Southeast Asian Nations (ASEAN) Convention on Counter Terrorism provides a political umbrella for collaborative efforts to address biological terrorism. ASEAN has entered into a number of agreements with member states and other interested parties directed to countering biological terrorism threats along with other types of threats.¹² As U.S. companies expand their outreach into these countries, the opportunities for U.S. leadership in promoting responsible use of biological assets should increase.

Security Implications of Changing Economic Conditions

Depressed economic conditions have been an important consideration in BTRP's decisions to carry out programs not only in Russia but also in Central Asia and the Caucasus region. Following the collapse of the economies in all of the states of the FSU during the early 1990s, which was intensified during the financial crisis of 1998, the

¹¹ See, for example, National Research Council Committee on Science and Technology in Kazakhstan. 2007. *Science and Technology in Kazakhstan: Current Status and Future Prospects*. Washington, D.C.: National Academies Press. Chapters 3 and 4. Available on-line at http://books.nap.edu/catalog.php?record_id=11808. Accessed June 13, 2007.

¹² Yong, O.K. 2005. ASEAN's contribution to regional efforts in counterterrorism. Speech delivered at the National Security Australia Conference, Sydney, February 21, 2005. Available on-line at <http://www.aseansec.org/17274.htm>. Accessed on May 30, 2007.

governments of the region greatly reduced expenditures to support health, agriculture, and scientific activities as a part of across-the-board budget reductions. Inadequate security conditions at facilities housing pathogens and equipment with dual-use applications became a serious concern. Also, important biological specialists became desperate in their search for economic relief as their paychecks became less dependable and lost their purchasing power. Easy access by terrorist groups to biological agents with potent characteristics was a major concern as BTRP's predecessor programs began providing funds that helped stabilize conditions at some critical facilities. From the outset, BTRP recognized that stabilization involves not only protection of physical assets but also engagement of scientists with important dual-use skills who are eager to become part of the international scientific community.

With the advent of dramatically higher prices for exports of oil in the early 2000s, several oil-rich countries of the region—Russia, Kazakhstan, and Azerbaijan—provided higher levels of funding for upgrading research and development infrastructures. In each of these countries, government budgets for disease-related activities, along with budgets for other government-supported activities, increased. Also, in Russia the private sector began to invest in biotechnology and became interested in partnerships with a few former defense facilities and with civilian institutions. Nevertheless, serious security deficiencies remain in many facilities where dangerous pathogens are used or stored.

Thus, national security considerations for international scientific engagement remain strong even as the economies slowly recover. But the level of external funding that is required to upgrade facilities in some countries, given more favorable economic conditions, is declining (see, for example, Box 1-3). Appropriate divisions of costs with partner institutions for strengthening infrastructures are becoming more significant.

BOX 1-3

Importance of Continuing Contact

“We are now just as interested in maintaining contacts with American specialists as in financial support from the United States. Interactions of specialists are very important in staying abreast of developments in the field and in sustaining research efforts initiated through BTRP.”

Director of former Biopreparat Institute in Russia. May, 2006.

There are other countries with dual-use biological assets within and outside the region that are not in a favorable economic status, including Georgia, Ukraine, and Uzbekistan. Depressed economic conditions should remain an important consideration in targeting activities to prevent proliferation. Of course, the long-term strategy in any country should be to encourage the partner government to find finances from diversified sources to sustain efforts initiated by BTRP. But for the next few years, depressed economic conditions will remain an important inhibition on locally financed biosecurity upgrades and improved environments for scientific work forces with important dual-use capabilities. Even in a more prosperous Russia, the time needed to modernize dozens of

important facilities and to reorient many institutions to self-sustainability is a number of years into the future.

Facilities of Special Interest

BTRP has given considerable attention to the selection of facilities that should be of program interest based on on-the-ground assessments of the risks if biological assets at the facilities are obtained by irresponsible governments, terrorist groups, or hostile individuals. One approach has involved assessments of (1) hazards that would result from theft and misuse of the most potent biological pathogens at the facility, (2) potential importance to terrorist groups of the dual-used equipment that is maintained at the facility, and (3) scientific expertise and technical information at the facility that are relevant to biological weapons. Then the physical security and biosafety/biosecurity practices at the facility are considered. At the same time, insider threats are probably more important than outsider threats. A particularly important concern is the prevalence of criminal and terrorist-related activity in the geographical area where the facility is located.¹³

This analytical approach is clearly important when considering security in a narrow sense. However, when addressing biosecurity in a comprehensive manner, which is the thrust of this report, many other factors are important. For example, the role that the facility plays in the public health or veterinary system of the country is a crucial consideration. In particular, the responsibilities and capabilities of the facility to conduct research and surveillance activities that are essential in detecting and responding to disease outbreaks are significant. Of course, the selection of facilities that should receive priority attention for cooperative activities should and will be greatly influenced by the views of partner governments, which will have their own criteria for establishing priorities.

In any event, considerable care should be given to the selection of organizations, facilities, and specialists. The selection should be based not only on the current conditions and responsibilities of the facilities. Selection should also be based on plans of partner governments for future development of the public health and agriculture infrastructures of the countries. (See Box 1-4 for two views of the importance of local participation in selection of facilities of special interest.)

¹³ See, for example, Pilch, R.F. 2006. Building the Babylon tower: Biological weapons proliferation prevention in Russia. Photocopy, provided by DTRA, April 2007.

BOX 1-4

Selection of Facilities for Upgrading

“We have been involved in every step of the development of BTRP activities in our country, including the selection of facilities of interest and modifications of those facilities.”

Azerbaijani institute director, March 2007.

• • •

“We have provided our new Biotechnology Center with \$50 million to become the national focal point for biological research and development related to the prevention of diseases, including coordination of international cooperative programs.”

Deputy Minister of Education and Science, Kazakhstan, September 2006.

Benefits from International Scientific Engagement

In looking ahead, the challenge is to balance the costs and benefits of activities to enhance and sustain biosecurity that are being considered for support by the U.S. government in general and by BTRP in particular. Short-term financial costs of planned activities can be predicted with some degree of certainty, but the political costs—measured in terms of the risk that upgraded capabilities might be misused—may be substantial. Meanwhile, some of the most important benefits discussed below are diffuse and can only be judged in a very general sense.

Benefits may be realized many years into the future. They may not even be recognizable at present. For example, interactions with political leaders that usually characterize high profile biological engagement activities may set an important tone for subsequent national and international dialogues on the prevention of proliferation of biological weapons. Also, cooperative activities usually build good will among important segments of societies, particularly if they enable partner countries to use high-technology achievements (see, for example, Box 1-5).

BOX 1-5

Use of High-Tech Achievements

“Through BTRP, we are mapping plague and brucellosis infections with the assistance of the Global Positioning Satellite system.”

Senior Uzbek scientist, March 2007.

Often, it is not possible to separate the impact of BTRP from impacts of other overlapping U.S. government and international programs. In some cases, the international relationships developed by other U.S. departments have been critical in setting the stage for BTRP activities. A few of the types of impacts of interest are as follows:

1. Reducing the likelihood that irresponsible governments, terrorist groups, or embittered individuals will gain access to materials or expertise that could be used in constructing biological weapons. Among the steps that can be taken are dismantling facilities that produced materials for use in biological weapons; monitoring international and national commerce of such materials; upgrading physical security at institutions that house such materials; enacting national and facility security regulations that call for severe penalties for breaches of security; supporting redirection of research activities from military to peaceful applications; and instilling norms and codes of responsible scientific behavior at the international, national, and institutional levels.

2. Improving capabilities of countries to detect and to respond to naturally occurring and deliberately triggered outbreaks of diseases. Achieving this objective can be enhanced by establishing modern disease detection, surveillance, and information systems; improving capabilities to respond to disease outbreaks; and establishing biological forensic capabilities. Improving capabilities to counter threats of biological terrorism will also enhance public health and animal disease prevention and control programs in dealing with naturally occurring diseases.

3. Building confidence among nations that dual-use activities are not intended to support illegitimate activities. Transparency is a key factor in this regard. The greater the engagement, the greater the confidence-building through transparency and the attendant insights as to intentions.

4. Enhancing the security of American military and civilian assets abroad. Given the repeated anti-American pronouncements of terrorist groups throughout the world, early warning of disease outbreaks ascertained through cooperative activities and through activities of other governments that were initiated through cooperation can contribute to strengthened security of American military and civilian facilities abroad.

5. Containing the spread of infectious diseases. Public health and agriculture infrastructures of partner governments that are strengthened through cooperative programs can help contain infectious diseases at the international, national, and local levels through early detection and appropriate response measures. Global efforts to contain Severe Acute Respiratory Syndrome (SARS) and avian influenza are good examples of how capabilities of other countries have contributed to the protection of American interests at home and abroad.

6. Contributing to international science and to global biotechnology capabilities. Partner institutions often have unique technical capabilities that can contribute directly and indirectly to scientific and technical advances that are of considerable interest to the United States. Inexpensive diagnostic techniques, improved understanding of various strains of disease agents of concern such as anthrax, and better formulations for vaccines and drugs have already been realized from BTRP efforts. Also, cooperative programs may identify appropriate sites for testing vaccine and drug formulations in disease-endemic areas.

Box 1-6 highlights important achievements by the U.S. government. These and other achievements that demonstrate the benefits identified above are set forth in Chapter 2. They support the case that, given the dual-use nature of many activities in the biological sciences and in biotechnology, a comprehensive approach to engagement can have many security benefits for the United States.

BOX 1-6

Importance of DOD Programs

“The last decade has opened many doors in the former Soviet Union. The U.S. government’s footprint is large and DOD’s is the largest in the region. The U.S. government has done much good in supporting science, improving scientific methods in the region, providing a wide breadth of training, improving communication networks from telephones and computers to high-speed Internet access and subscriptions to international journals. Yet there is much to be done.... The threat of dual-use technologies and bioweapons expertise is still present in the region.”

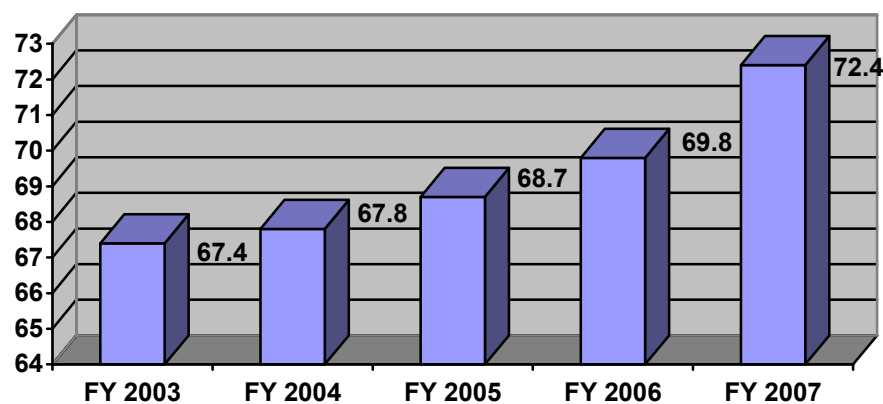
Former manager of a U.S. government biological nonproliferation program,
July 2007.

2

Achievements of the Biological Threat Reduction Program

During the past 15 years, the Biological Threat Reduction Program (BTRP) of the Department of Defense (DOD) has carried out activities in Russia, Kazakhstan, Uzbekistan, Georgia, Azerbaijan, and Ukraine. The activities have involved a number of ministries and several dozen institutions in the countries. The cost to the U.S. government has been more than \$430 million from Fiscal Year (FY) 1998 through FY 2007, with expenditures in earlier years very limited. Figure 2-1 illustrates the trend in BTRP funding in recent years.

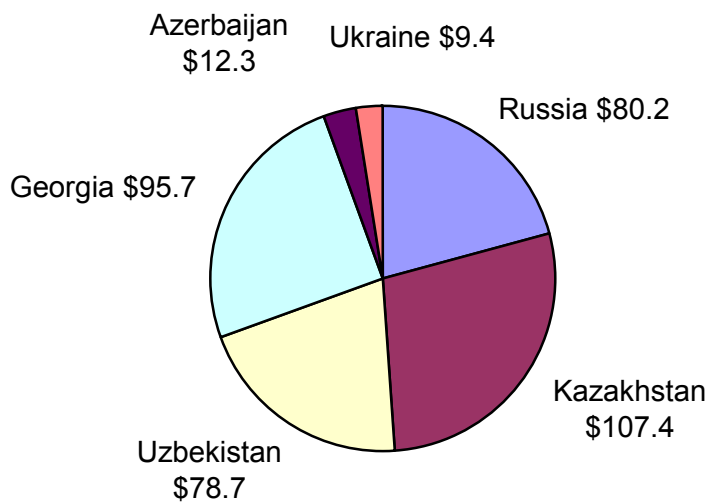
FIGURE 2-1 BTRP funding in recent years (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, June 6, 2007.

The distribution of funding by country is shown in Figure 2-2.

FIGURE 2-2 BTRP funding by country, FY 1998-2007 (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, April 2007.

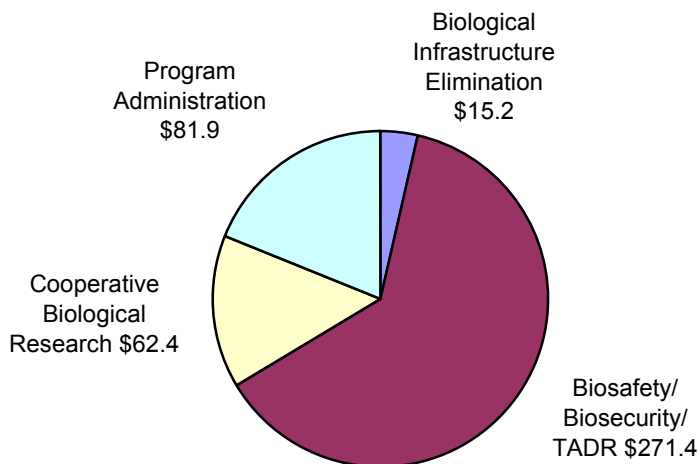
NOTE: Additional program administration costs of \$81.9 million that have affected programs in all countries are not included in this figure.

BTRP and its predecessor programs have addressed key aspects of the overall U.S. effort to prevent the proliferation of biological weapons. The categories of activities are as follows:

- *Biological Infrastructure Elimination*, with three facility dismantlement projects completed in Kazakhstan and Georgia and on Vozrozhdeniye Island in the Aral Sea
- *Biosafety/Biosecurity*, which involves facility upgrades, training, and related activities throughout the region and initial steps in establishing the *Threat Agent Detection and Response (TADR)* network in Georgia, Azerbaijan, Uzbekistan, and Kazakhstan
- *Cooperative Biological Research*, with research laboratory upgrades and research projects carried out in Russia, Kazakhstan, Uzbekistan, Georgia, and Azerbaijan
- *Program Administration*, involving supporting activities by a variety of organizations, including a contractor-led Threat Reduction Support Center that supports a staff of more than 30 analysts and advisers for BTRP and contracts to cover costs of shipments of materials and equipment that must be handled carefully, undertakings that consume more than one-half of the funds available for this program element.

The distribution of expenditures among these four program categories is set forth in Figure 2-3.

FIGURE 2-3 BTRP funding by program category, FY 1998-2007 (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, April 2007.

The committee has not analyzed in detail the financial aspects of BTRP. However, several concerns about levels of expenditures are expressed later in this report. At the same time, the committee is aware of the political, administrative, and logistics difficulties in carrying out programs in the former Soviet Union. It recognizes the need for substantial resources to mount effective programs. In any event, the Government Accountability Office (GAO) has informed the committee that it will again examine BTRP beginning in late 2007, and GAO's financial expertise should be helpful in identifying ways to improve program efficiency.

Positive Impacts of BTRP

During the past decade, committee members have observed first hand in the former Soviet Union (FSU) a wide variety of BTRP activities. Many activities have facilitated professional ties among important specialists in the region and the United States and have enhanced the containment of biological materials, technologies, equipment, and expertise that, if misused, could result in serious biological threats. From these observations, it is clear that there have been important changes in the region that can be attributed at least in part to BTRP. The changes include

- Unprecedented transparency at dozens of important facilities with dual-use capabilities that had not previously been open to foreign specialists
- Dismantlement and/or conversion of three production facilities and dozens of research institutes that supported biological weapons activities

- Redirection to civilian pursuits of hundreds of senior biological scientists, engineers, and technicians who were formerly engaged in defense programs
- Attraction and retention of hundreds of younger specialists working in basic sciences and in the fields of public health and agriculture
- Adoption by local institutions of American-style approaches to project management and to fiscal accountability
- Participation in dozens of scientific conferences and training programs abroad by specialists from the region who had not previously traveled abroad
- Increased publication by local scientists in peer-reviewed international journals of their research findings, which demonstrate their capabilities to participate effectively in international scientific activities
- Enhanced quality of a number of local research projects and technology transfer activities that have taken advantage of the experience and expertise of international collaborators
- Improved biosecurity and biosafety at biological research institutions, particularly with regard to consolidation and physical protection of dangerous pathogen strains
- Opening and sharing of local databases with international collaborators
- Construction and equipping of modern research, public health, and agriculture facilities where activities of interest to international partners are carried out
- Development of local regulations and related training programs concerning the safety and security of biological materials and good laboratory practices in six countries.

BTRP engagement activities have led to many international linkages based on friendships and common professional interests. These personal contacts are important in building mutual respect and trust that are necessary for successfully addressing technical issues with dual-use implications. They also provide insights as to present and future scientific aspirations and intentions of foreign colleagues and their institutions in areas of national security importance.

In addition, intergovernmental cooperation in the biological sciences and biotechnology, exemplified by BTRP, offers opportunities for political and scientific leaders from the United States and partner countries to discuss common security and health interests. Such discussions can lead to the development of complementary approaches for combating threats of global terrorism. For example, the discussions of transnational diseases and potential bioterrorism problems during the G-8 Summit in St. Petersburg, Russia, in 2006 were undoubtedly enriched by the extensive interactions between U.S. and Russian specialists through BTRP and related programs over many years.

The participants from the region in BTRP activities seem very pleased with the support they have received (see, for example, Box 2-1). They are particularly enthusiastic about their upgraded laboratories and related facilities, with (1) improved research conditions for both well-established scientists and young scientists, (2) new opportunities to participate in activities of interest to the international scientific community, and (3) better control of biological materials. Meanwhile, some are disappointed that they have not received longer term support, particularly in Russia.

BOX 2-1

Observations on BTRP by Foreign Colleagues

- “BTRP provides us with important assistance in gaining access to international scientific information, participating in international conferences, publishing internationally, and learning modern research methods.” Director of Kazakhstani research institute.
- “BTRP’s approach of allocating up to 70 percent of its research funds for infrastructure development, equipment, communications, consumables, and security upgrades has resulted in a significant network of well-equipped laboratories.” Russian senior scientist.
- “Facility upgrading and training on biosafety have increased the interest of young scientists in activities at our facilities.” Azerbaijani scientist.
- “BTRP provides good opportunities to learn new approaches and to operate new equipment.” Uzbek senior scientist.
- “The links of research projects to public health and agriculture—including to TADR—are important. The projects have helped maintain our scientific potential, both in technology and personnel.” Georgian senior scientist.

SOURCE: Comments obtained by project staff, consultants, and committee members, April 2007.

In short, past BTRP investments have provided substantial benefits for national security. Also, they have set the stage for continuing access to important biological expertise in the former Soviet Union. The task of preventing proliferation has only begun, and the opportunities for future contributions by BTRP to national security are many fold. Therefore, **the U.S. government should provide strong and sustained support for BTRP and related programs.**

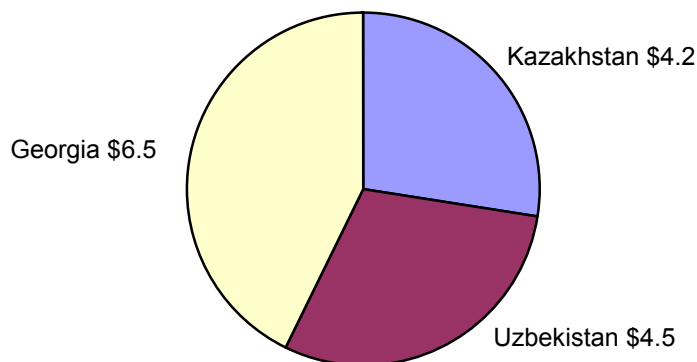
In the first instance, the Department of Defense (DOD) must be a strong advocate for BTRP. Such advocacy currently seems to be the case, given future budget projections that have been approved within DOD and forwarded to the Congress as will be discussed in Chapter 5. The White House, and particularly the Office of Management and Budget and the National Security Council, should give continuing support and encouragement to BTRP. Also, Congress needs to continue its recognition of the importance of BTRP.

This is not to say that BTRP should continue its current course without adjustments. The program was developed at a time of unprecedented economic deprivation in the region and in the wake of the Soviet era. Indeed, in many ways the next phase of BTRP activities should be significantly different from the early start-up phase. Throughout this report, suggestions are offered on modifications that could enhance the positive impacts of BTRP on the national security interests of the United States and partner nations as BTRP adapts to the changing environment in the years ahead.

Biological Weapons Infrastructure Elimination

The expenditures to date for this program component have been allocated as shown in Figure 2-4.

FIGURE 2-4 Funding of biological weapons infrastructure elimination by country, FY 1998-2007 (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, April 2007.

Activities have included dismantlement of the anthrax production facility at Stepnogorsk in Kazakhstan; destruction of 150 tons of anthrax weapons agent buried in pits adjacent to the open air testing facility on Vozrozhdeniye Island, which is surrounded by the Aral Sea; and destruction of dual-use facilities capable of producing viral animal pathogens at Biokombinat in Georgia. These efforts should be completed during FY 2008. No additional activities are currently planned.

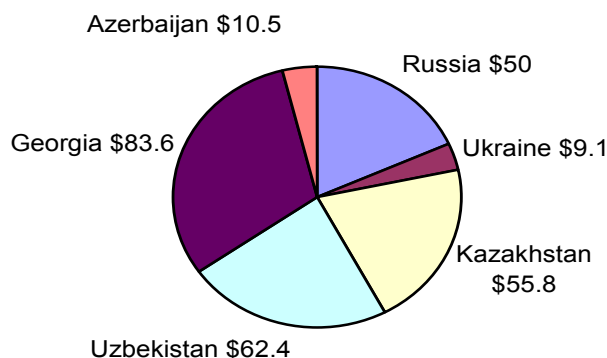
The importance of destroying industrial capabilities that were designed to produce and test ingredients for biological weapons seems obvious. The political and technical aspects of dismantling these facilities have been complicated. Nevertheless, despite lengthy delays and high costs, BTRP activities are being carried to completion in cooperation with local specialists.

BTRP did not conduct infrastructure elimination activities at other production facilities such as those located in Omutninsk, Berdsk, and Pokrov in Russia. At each of these facilities, steps have been taken by the Russian government, either directly or through support of privatization efforts, to change the facility's profile to peaceful uses. The Department of State has been an active partner in some of these developments. Other production or test facilities of importance may be located at Russian military facilities, but international access to such facilities seems unlikely. In short, the committee is unaware of other production, storage, or testing facilities in the former Soviet Union where BTRP should focus future infrastructure elimination activities.

Biosafety/Biosecurity and Threat Agent Detection and Response (TADR)

The funds allocated for this program activity through FY 2007 are shown in Figure 2-5.

FIGURE 2-5 Funds allocated for biosafety/biosecurity and TADR by country (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, April 2007.

This budget category is by far the largest. It includes the widest diversity of activities. DOD describes the activity as follows:

This project consolidates and secures especially dangerous pathogen (EDP) collections in safe, centralized facilities to prevent terrorist acquisition of BW seed materials; improves biosafety and biosecurity; enhances recipients' abilities to detect, diagnose, and respond to disease outbreaks; and ensures safe, secure storage handling of EDPs used for beneficial research against accidental release, theft, and exposure. DOD and recipient states are developing a network of disease surveillance and diagnostics laboratories at the national, state, and county level (referred to as the Threat Agent Detection and Response [TADR] network) that are linked with an Electronic Integrated Disease Surveillance System to facilitate rapid reporting of outbreak data to national authorities and U.S. government counterparts. Another electronic database called the Pathogen Asset Control System will inventory, store, and control access to select agents. Eventually, countries' networks will link with regional partners to enhance disease monitoring, reports, and containment, and ensure early warning of potential bioattacks and pandemics. DOD created training modules to improve diagnostic and epidemiological capabilities of the scientific and technical staff; promote bioethics, biosafety, and biosecurity; and ensure sustainment, effectiveness, program investment, and strategic relevance.

In non-Russian states, BTRP develops national Central Reference Laboratories (CRLs) with state-of-the-art diagnostics capabilities on an information technology backbone, and modern communications. These laboratories provide Mobile Outbreak Response Units with diagnostics

and epidemiological teams for rapid response to potential incidents and with veterinarians and clinicians who conduct population-based surveillance in areas where EDP cases may occur. The regional-level Epidemiological Monitoring Stations survey suspicious disease outbreaks, analyze epidemics, and collect disease reports from veterinarians, clinicians, or epidemiologists.

Lacking a BTRP implementing agreement with Russia, BTRP provides only safety and security upgrades at selected former BW facilities still working with dangerous pathogens.¹

At present, BTRP is finishing security upgrades and biosafety programs in Russia at institutes in Golitsino, Pokrov, Vladimir, Koltsovo (Vector), Obolensk, and Kazan. In the other former Soviet states, construction and renovation to improve security at a variety of facilities are under way. Most of the activity in these non-Russian states relates to the establishment of the TADR system, such as upgrading epidemiological monitoring stations, consolidating strains in central repositories, and training in epidemiology, diagnostics, biosecurity, and information technology. While BTRP is emphasizing within TADR laboratory diagnostic, surveillance, and reporting capacity, relatively little attention is being given to strengthening the human dimension of epidemiology systems—particularly the field dimension.

Committee members have observed BTRP-supported security upgrades at a number of facilities. In each case, the physical upgrades were needed, and the resulting security arrangements are impressive. Given the large number of facilities where pathogens are located, the need for additional upgrades seems clear. BTRP, in cooperation with partner governments, should continue to carry out detailed analyses of additional facilities as the basis for targeting future security-oriented upgrades.

Security is more than physical protection of biological assets. It requires a strong culture among the staffs of the facilities concerning proper handling of sensitive materials and appropriate use of dual-use equipment. Unfortunately, BTRP's commercial integrating contractors do not always appreciate the long Soviet history of security measures in the region and the attendant commitment of personnel to protect virulent strains. They sometimes do not recognize the positive aspects of this history in their zeal to establish made-in-America security systems according to compressed timetables. While prompt installation of modern approaches is important, BTRP should build on past practices and should not develop systems that cast aside valuable experience of counterparts. Also, American experts employed by BTRP as trainers should not offer counterparts overly simplistic courses in biosecurity and biosafety, a practice that committee members have observed.

Protection of a wide variety of strains of dangerous pathogens is a particularly important issue. BTRP's current approach is to assume that all strains of certain pathogens must be housed in appropriately equipped centralized facilities without segregation of pathogen strains according to virulence. Strain collections reflect endemic diseases, and live cultures need to be maintained locally for use in diagnostics and research. However, retention of strains at smaller laboratories and at field stations requires diagnostics equipment and reliable supplies of reagents and consumable supplies together with appropriately trained staff. BTRP should enroll experienced researchers as well as biosafety experts to assist in developing plans for handling and protecting strains

¹ This description of the TADR Program was provided by DTRA to project staff on April 11, 2007.

both in centralized facilities and in local facilities where they are readily available for researchers.

Turning to the TADR network, it was designed by BTRP with only limited consultations in the region. Since that time, BTRP has been attempting to convince partner governments to participate in the network. BTRP has had considerable success, at least as long as BTRP is to provide financial resources. As advocated in Box 2-2, BTRP should give greater emphasis to local “needs assessments” as the basis for TADR investments, which would include consideration of endemic diseases that are not linked to especially dangerous pathogens.

BOX 2-2

Importance of 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 process of partnership and local ownership and helps build sustainability by breaking down barriers among disciplines and among local government agencies.”

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

In 2006, the National Research Council carried out a review of the plans for and early stages in development of the TADR network, with particular emphasis on the electronic data system and the General Data Repository that is to be located in the United States. This review concluded that the TADR network is an important initiative that has the potential to enhance U.S. security interests in a variety of ways. The recommendations of the review are set forth in Appendix B. The continued progress in developing the network since the completion of the review is welcomed. However, several important recommendations that emerged from the review deserve special attention, namely,

- Sustainability of the TADR network after BTRP completes its participation in the development and operation of the network is critical. An assessment that sets out on a country-by-country basis the near-term benefits from the network for those local officials and specialists responsible for disease control is clearly needed. The assessment should address the likely sources of funding for TADR, from national and international sources, after BTRP support terminates. Not only are activities directly related to dangerous pathogens of interest, but also integration of new capabilities with existing programs to address day-to-day public health challenges is particularly important. The assessment should be prepared by the partner governments in cooperation with BTRP as soon as possible.
- A related element of sustainability of the TADR network is the broadening of the focus of the network from the limited number of disease agents, classes of agents, and

syndromes of primary interest to DOD for proliferation reasons. A wider focus that encompasses high incidence agents and diseases that are of great human and animal health significance to the host governments is essential. Such an approach should increase the interest of local and national officials in information that is obtained and should encourage them to embrace the system as an important component of their national efforts. A good example of BTRP flexibility is the current BTRP effort to address an outbreak of swine flu in Georgia, and this type of flexibility should become routine within BTRP.

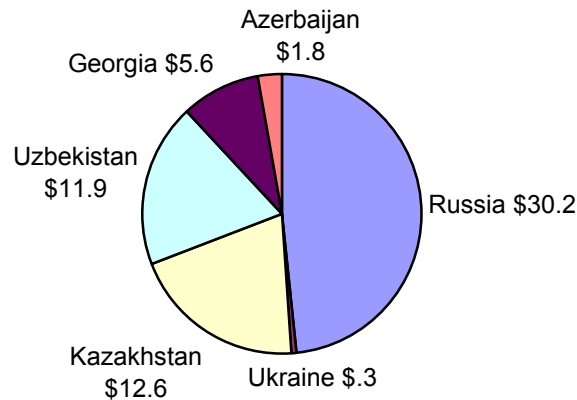
- Automatic transmission through the TADR network of all data that are collected by physicians, laboratory specialists, and other participants in the program will surely result in many false alarms due to abnormalities in trends and outbreaks. BTRP should establish mechanisms for limiting the data that are entered into the system to information that appears to be significant. BTRP should work with partner governments to ensure that such filtering of data in the partner countries is done in an appropriate, timely, and responsible manner. The committee questions the DOD viewpoint that the advantages of the fully automated data exchange features of the system outweigh the difficulties posed by false alarms generated by the unfiltered data. DOD apparently is not concerned about false alarms since American specialists at the Centers for Disease Control and Prevention presumably will be available to identify them. However, in the long run, local institutions will have the responsibility for assessing the evidence of possible false alarms, as well as leading any response efforts, and they should accept these responsibilities from the outset.

The strong training aspect of the biosecurity and TADR components of BTRP is commendable. In Soviet times, most training courses for specialists were held in Russia and to a lesser extent in Kazakhstan. When the USSR splintered into 15 states, many specialists from Central Asia and the Caucasus region lost their training opportunities. Thus, partner institutions are enthusiastic over BTRP training efforts. Also, they welcome opportunities to establish training centers in their own countries. It is particularly important that BTRP, in cooperation with counterpart institutions, ensure that preparations for adequate personnel to work in new and renovated facilities keep pace with construction schedules. If modern and well-equipped laboratories are not fully utilized by trained personnel, the program could lose much of its credibility.

Cooperative Biological Research

This component of the program has distributed funds to date as shown in Figure 2-6.

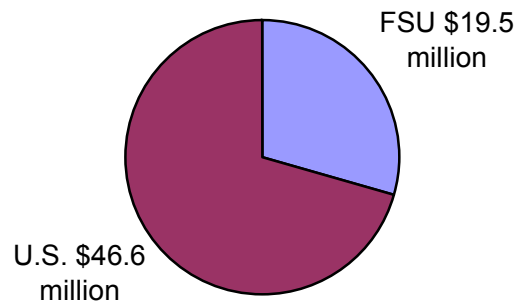
FIGURE 2-6 Funding for cooperative biological research, FY 1998-2007 (in millions of U.S. dollars).



SOURCE: Data provided by DTRA, April 2007.

Figure 2-7 illustrates the breakdown of expenditures between U.S. and FSU partners.

FIGURE 2-7 Recipients of CBR Program funds, FY 1998-2007 (rounded to nearest \$.1 million).



SOURCE: Data provided by DTRA, April 2007.

Tables 2-1 and 2-2 provide more detailed cost itemizations on the U.S. and FSU sides, respectively.²

² Data for Figure 2-6 and Tables 2-1 and 2-2 provided by DTRA to National Academies staff in May 2007.

TABLE 2-1 U.S. cost distribution, FY 1998-2007.

Contractor management and fees	\$11,473,000
Concept/proposal development	\$ 6,429,000
U.S. collaborators/visiting scientists/training	\$11,363,000
DoD collaborators	\$ 2,603,000
Logistical support	\$ 1,220,000
Advisory and assistance services	\$ 4,544,000
Conferences, training, and workshops	\$ 1,728,000
Government (travel, fees, shipping)	\$ 7,226,000

TABLE 2-2 FSU cost distribution, FY 1998-2007.

Institute overhead	\$ 464,000
Grant payments	\$ 9,025,000
Equipment and materials	\$ 7,258,000
Travel (conferences, workshops, training)	\$ 738,000
Other direct costs	\$ 1,493,000
Renovations	\$ 547,000

Figure 2-7 shows that almost 75 percent of funds available for CBR are provided to U.S. organizations. This large percentage does not encourage international enthusiasm for the program and needs to be reduced, particularly as the program grows. As noted in Box 2-3, high levels of funding of U.S. institutions should soon begin to decline, at least in the countries where BTRP has been engaged for a number of years and facilities are in improved condition.

BOX 2-3

Upgrading Institutes

“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 infrastructure is in terrible shape, and we try to modernize it. A large portion of the costs on the U.S. side are 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.”

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

A list of the research projects that have received support is set forth in Appendix F. In addition to funding these research projects, a number of investments have been

made in upgrading research facilities. Only some of the renovation costs are reflected in Table 2-2, since the biosecurity and biosafety programs also at times support renovations in areas where research is carried out.

Initially, BTRP involved a number of Russian institutions and scientists that had been directly involved in biological weapons development. Immediate redirection to civilian topics of key weapon scientists took priority over the scientific importance of their research topics. Quickly the focus of BTRP narrowed to a concentration on extremely dangerous pathogens with greater emphasis on the importance and scientific quality of the research projects.

As support for research activities moved from Russia to the other countries, the emphasis shifted to research that supported the TADR network, particularly with regard to enhancing epidemiological and diagnostics capabilities. Also, BTRP became increasingly concerned about promoting standards of openness, research ethics, and international health partnerships that can be helpful in countering bioterrorism threats.

This activity has been driven largely by the interests of BTRP, although partner governments are now having greater input as to which types of research are the most important. However, American specialists are more familiar with research opportunities within BTRP's mandate and therefore quickly persuade counterparts to accept BTRP's priority topics. While scientists in the region are responsible for preparing proposals, the opportunities for stretching beyond the specific topics of interest to BTRP have been limited. Nevertheless, high quality research, measured against international standards, has been carried out, particularly in Russia.

This component of BTRP has opened a number of doors into sensitive areas of biological activities. Researchers who played key roles in the Soviet biological weapons program have been participants in BTRP, particularly in Russia. The skills of a number of researchers have been widely acclaimed by American counterparts.

However, DOD has apparently been concerned for a number of years that the Russian government would misuse the results of BTRP-supported research projects concerning dangerous pathogens, although the committee is unaware of any indications of such misuse. DOD has repeatedly introduced delays into the program in Russia due to a lack of confidence in Russia's reliability as a responsible partner in dealing with dangerous pathogens, and the program is now limited to research related to smallpox. DOD has shown little interest in future security or scientific payoffs from engagement in other activities in Russia in its decision to sharply reduce activities in Russia (see, for example, Box 2-4). Meanwhile, Russian authorities are suspicious of DOD's motivations in the biological area. The issues surrounding the future of the program in Russia will be discussed in Chapters 4 and 5.

BOX 2-4

Capitalizing on Past Investments

"Russian scientists are gravely concerned about reduction of BTRP research funding, particularly after initial investments in training in modern project management methods as well as provision of equipment that would enable both Russia and the United States to benefit much more from future projects."

Senior Russian scientist, March 2007.

Turning to the other former Soviet states, a limited number of research projects have been supported. Almost all can be characterized as applied research. As the investigators have greater access to modern equipment and are able to stay abreast of international research activities, basic research may play a more significant role in the program. But it seems appropriate for BTRP now to stress research that can lead to relatively near-term applications.

Activities of Special Concern

Within the foregoing program elements, several topics deserve special attention.

- BTRP has taken the excellent initiative to develop country science plans that are to provide a programmatic framework in each country for BTRP activities. However, this approach needs more active involvement by partner governments. The plans should clearly reflect local priorities. Of course, they should be consistent with overall U.S. government country approaches and take into account programs supported by other external parties. The BTRP plans should include not only descriptions of BTRP activities but also BTRP exit strategies that will help ensure that activities are sustained over the long term. Emphasis should be given to the engagement of leading scientists and promising young researchers of the partner countries in BTRP activities and the likelihood of attracting the interest of strong American collaborators.
- BTRP is establishing a Central Reference Laboratory (CRL) in Georgia at a cost of \$60 million, with annual operating costs estimated at more than \$5 million. A large portion of the cost is due to inclusion within the facility of a Biosafety Level 3 (BSL-3) laboratory. The committee is concerned about the sustainability of the CRL, and particularly the BSL-3 laboratory, over the long term. Joint strategic planning for this and other CRLs should ensure that the anticipated long-term health and agriculture benefits, particularly the benefits derived from expensive BSL 3 capabilities, warrant both the initial and life-cycle costs (see also Chapter 5).
- An early evaluation of the health and agriculture benefits of the TADR network that is being established initially in Georgia is needed. The key question is whether the information obtained through the TADR network is a significant improvement over data collected through traditional methods and is useful in improving human health. This evaluation will help ensure that similar BTRP investments in other countries are well targeted and result in discernible benefits that encourage future local investments.
- Returning to the issue of pathogen strain collections, joint programs should ensure that strains that can be obtained within the region are available at local facilities to international investigators. Investigating the characteristics of strains that are unique to specific regions has special importance in understanding actual and potential disease burdens, possibilities for transborder transmissions of diseases, and development of natural immunities. Of course, the facilities must have appropriate biosafety environments. Opportunities to examine strains in the region will reduce the need for controversial transfers of such strains to the United States that raise questions over BTRP objectives and unnecessarily delay projects. Inclusion of sequencing data from these

investigations in GenBank and noteworthy findings in international journals would be significant scientific contributions. DOD has included one-way strain exchanges as a requirement in its intergovernmental agreements and has been successful in receiving strains from Georgia and Azerbaijan. However, future one-way exchanges are not assured, especially from other countries in the region, and the partner governments should be given the option of joint investigations locally as an acceptable alternative to strain exchanges.

Moving Forward

BTRP achievements provide a strong base of experience and of demonstrated success that can enable the U.S. government to continue to make important contributions to preventing the proliferation of biological weapons. Of particular importance has been BTRP's adoption of a broadly based approach to protecting the public from both naturally occurring and deliberately induced diseases (see Box 2-5).

BOX 2-5

Integrating Diverse Biological Interests

"Integration of specialists from the health care sector and veterinary services, researchers and practitioners, and representatives of the basic and applied sciences within the framework of joint projects makes it possible to hope for additional scientific and practical results through the synergetic interaction of specialists united by a common goal—reducing the threat of biological pathogens and making the population safer."

Director of Kazakhstani research institute, March 2007.

BTRP, in coordination with the Department of State, was the first U.S. biological nonproliferation program on the ground at many facilities in Russia and other former Soviet states. Thus, it is not surprising that BTRP developed an array of technical capabilities that largely fall within the province of other departments, such as the Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA). As the other departments became involved through different Congressional mandates, the need for coordination of efforts and avoidance of duplication was clear, as will be discussed in Chapter 3. Now, as the budget of BTRP continues to grow while the nonproliferation budgets of the other departments decline, BTRP has an increased responsibility to draw on the best U.S. capabilities present in the other departments in support of BTRP's expanding interests in public health and agriculture. Indeed, the BTRP budget during FY 2008 will probably be much larger than the budgets for DHHS and for USDA, and BTRP will have to make aggressive financial outreach efforts to encourage DHHS and USDA to continue their interests in nonproliferation. To this end, the authorizing legislation for BTRP should explicitly call on BTRP to utilize the assets and expertise of these departments to the fullest extent that is practical and to provide financial support to the other departments for facilitating joint activities.

3

U.S. Government-Wide Biological Threat Reduction Programs and Interagency Coordination

The Biological Threat Reduction Program (BTRP) of the Department of Defense (DOD) that has been discussed in Chapter 2 is one of a group of U.S. government efforts aimed at limiting the proliferation of expertise, materials, facilities, and technologies that could be used in development of biological weapons. Nonproliferation programs are also carried out by the Departments of State (DOS), Health and Human Services (DHHS), Agriculture (USDA), and Energy (DOE), and by the Environmental Protection Agency (EPA). DOS receives from Congress the funds for DHHS, USDA, and EPA and passes them through to these organizations. The important role of interagency coordination is underscored in Box 3-1.

BOX 3-1

Importance of an Interagency Approach

“Nonproliferation engagement should be a multi-tiered, multi-agency, multi-sectoral, shared mission overseen by active National Security Council and White House leadership and regularly coordinated domestically and implemented internationally.”

Former manager of a U.S. government biological nonproliferation program, July 2007.

As discussed in this and other chapters, a number of factors that can lead to program success should be considered across the government in a consistent manner in developing programs. These factors include the approach in setting priorities, the review and selection process for individual projects, the approach to reviewing program progress, the process in selection of project participants, the importance of communications among departments and agencies, and the integrity of personal relationships that are established with foreign partners. At the same time, weaknesses in interagency coordination efforts are a special concern.

Table 3-1 indicates the distribution of Fiscal Year (FY) 2006 and 2007 nonproliferation program funds among the responsible U.S. government organizations. While BTRP received a considerable increase in funding for 2007, as discussed in Chapter 2, the funding for other departments declined.

TABLE 3-1 Distribution of worldwide bio-related nonproliferation funds in FY 2006 and 2007 (estimated, in millions of U.S. dollars rounded to the nearest \$0.1 million).

Program	FY 2006	FY 2007
DOD Biological Threat Reduction Program^a		
• Program Administration	\$ 21.6	\$ 15.5
• Infrastructure Elimination	\$ 1.3	\$ 0.5
• Biosecurity and TADR	\$ 45.8	\$ 48.7
• Cooperative Biological Research	\$ 1.0	\$ 6.1
DOS		
• Science & Technology Centers	\$ 0.7	\$ 0.9
• Bio-Industry Initiative	\$ 10.0	\$ 7.0
• Global Biosecurity Engagement Program	\$ 3.9	\$ 8.0
• Bio-Chem Engagement Program ^b	\$ 15.1	\$ 5.7
➤ DHHS: Biotechnology Engagement Program (BTEP)	\$ 7.6	\$ 2.3
➤ USDA/Agricultural Research Service	\$ 6.0	\$ 2.0
➤ EPA	\$ 1.5	\$ 1.4
DOE: Global Initiative for Proliferation Prevention (GIPP)	\$ 3.6	\$ 2.2

NOTES: For the Science and Technology Centers, figures cited include only U.S. party-funded projects in the biological sciences. They do not include costs of project management or workshops that may be funded through the general U.S. contribution to the Centers. The HHS/BTEP Bio-Chem numbers shown above reflect only U.S. side program costs. Unspent BTEP funds at ISTC need to be spent down (more than \$10 million left over between FY 2005 and FY 2007). HHS/BTEP funds were reduced in FY 2007 to spend down those funds before additional funding for FSU program costs could be allocated.

^a The DOD figures for FY 2007 do not include unallocated funds of \$1.4 million and withheld funds of \$ 0.2 million.

^b These funds are transferred to DHHS, USDA, and EPA, as listed on the lines below. Also, these funds provide some support for redirection of the activities of former chemical weapons specialists as well.

SOURCE: Figures provided by DOD, DOS, and DOE in June and July 2007.

Table 3-2 identifies activities of the different departments and agencies. The costs for supporting some activities such as dismantlement and facility upgrades are generally higher than costs for other activities such as training and research investigations. BTRP has supported many of the most expensive endeavors, which explains some of the differences in levels of funding that have been made available. But still, the difference in funding levels is striking. No other department has received financial support that compares to the support for BTRP.

TABLE 3-2 Examples of U.S. government nonproliferation activities.

	DOD	DHHS	USDA	DOS	DOE	EPA
Dismantlement	*			*		
Physical security of facilities	*			*	*	
Laboratory biosecurity	*			*	*	
Physical infrastructure upgrades	*			*		
Salaries and equipment for researchers	*	*	*	*	*	*
Biosafety	*	*		*		*
Regulatory training (IP, GLP, GMP, IACUC)	*	*	*	*		*
Disease surveillance, public health	*	*	*	*		
Joint development for public or private sector markets	*		*	*	*	*

NOTES: IP, intellectual property; GLP, good laboratory practices; GMP, good manufacturing practices; IACUC, institutional animal care and use committee.

There are substantial tangible and intangible benefits to U.S. national security from these nonproliferation programs. However, more attention should be given to documenting benefits. For example, specific scientific payoffs from cooperation should be available in making the case for joint research efforts. This chapter presents several examples of projects that have led to scientific and technical discoveries, as well as contributing more directly to reducing specific security concerns.

Unfortunately, there are no systematic mechanisms for linking results of individual nonproliferation projects to the U.S. government's broader interests in the biological sciences and biotechnology. Greater attention should be given to enhancing the flow of new science and technology achievements attributable to BTRP and related programs into other U.S.-funded activities. Such a step will help set the stage for establishing sustainable partnerships between researchers in other countries and the broad U.S. government-supported research community.

Program Overviews and Future Directions

The program of each department has a nonproliferation objective. However, the selection and design of individual projects are greatly influenced both by staff expertise and experience and by international programs carried out by the departments that have been called for under other Congressional mandates. This departmental orientation is of particular importance in selecting diseases that are of interest and in orienting international activities to complement domestic research programs that are under way in the United States.

Department of State

DOS is responsible for four programs that address global biological threats. Several different legislative authorities govern these programs, thereby providing the department with

considerable implementation flexibility.¹ All programs share a nonproliferation mission, but they approach this task in different ways.

In 2006, more than one-half of the budget of the Cooperative Threat Reduction Office of the Bureau of International Nonproliferation of DOS (ISN/CTR) was applied to biothreat projects in the former Soviet Union. However, declining overall budgets within DOS for cooperative threat reduction activities and expanding program responsibilities will likely result in reduced DOS-funded activity for biology-oriented projects in the region in FY 2007 and beyond. This trend will affect DOS projects implemented directly through the Science and Technology Centers (STCs) that are discussed below and programs funded from the department's budget and carried out by DHHS, USDA, and EPA. It also may affect DOD/BTRP's ability to implement certain aspects of its program that are dependent on support by the STCs.

- *Science and Technology Centers* (International Science and Technology Center-Moscow [ISTC]; Science and Technology Center in Ukraine-Kyiv [STCU]): The two STCs are multilateral organizations that share a broad mandate to redirect former Soviet weapons scientists, engineers, and technicians to sustainable non-military activities. DOS projects carried out through the STCs include substantial funding to counter biological threats. In addition to being a mechanism for developing and funding projects, the STCs serve other functions that have evolved over the years (for example, advice on intellectual property rights, training seminars, and international conferences). They would be difficult to replace as a nonproliferation program implementation tool or even as a mechanism for facilitating international scientific collaboration.

However, the ISTC has experienced a number of administrative obstacles in recent years, in large measure due to Russian government actions and at times inaction. Long-standing issues involve problems concerning the hiring and rotation of Russian staff, disputes over the tax exempt status of the ISTC, and disagreements over the reimbursement to the ISTC by the Russian government of value-added taxes that should not have been collected from project budgets in the first place. At the same time, Russia has not completed the internal procedures necessary for the entry into force of the intergovernmental agreement establishing the ISTC, specifically ratification of the agreement by the Duma. As a result, the ISTC has had only temporary legal status for the past 13 years. The U.S. and other participating governments are well aware of these difficulties and are attempting to improve Russian government support for the ISTC.

- *Bio-Industry Initiative*: The Bio-Industry Initiative (BII) was established in the wake of 9/11. It combines nonproliferation and counterterrorism approaches to reduce terrorist access to biological weapons, facilities, and expertise. More broadly, it joins the United States with Russia to combat bioterrorism by (1) transforming former biological weapons production facilities, their technology, and their expertise for sustainable, commercial applications, and (2) accelerating drug and vaccine production through research and development partnerships between U.S. and Russian scientists that address infectious and communicable diseases prevalent in the former Soviet Union and other regions.

BII has been designed to be flexible and responsive to interests of foreign partners. The program works directly with individuals and institutes, through the STCs, and through other organizations to implement its projects. It plans to continue to operate in Russia and other countries of the former Soviet Union, although with significantly reduced funding. BII has a

¹ These authorities include the Freedom Support Act (Pub. L. 102-511) and the Defense and Emergency Supplemental Appropriations Act for FY 2002 (Pub. L. 107-117).

good reputation in the United States and abroad for effective program design and implementation, and some of its approaches deserve consideration as global models for related efforts within other programs (for example, see Box 3-2 for an interesting approach).

BOX 3-2

BII Support of Facility Redirection

BII is helping to reconfigure the Berdsk Biological Preparations Plant, a large-scale fermentation plant in Russia, into peaceful commercial activities. The now privately-owned facility produces industrial enzymes and animal feed additives. BII is providing support to optimize commercial production and to improve the enzyme manufacturing with the goal of sustainable employment for 180 former weapon scientists.

SOURCE: Information provided by DOS, May 2007.

- *Biological-Chemical Redirection Program (BCR)*: This program provides funding to USDA, DHHS, and EPA for programs listed separately below: As the U.S. government focused on redirection of former Soviet biological weapons expertise in the late 1990s, DOS quickly recognized that knowledgeable experts with skills necessary for program implementation and oversight resided in a number of other U.S. government departments and agencies. Therefore, DOS worked with the Congress to augment its legislative authorities, which now allow DOS to include expertise from other U.S. government departments and agencies in biological threat reduction efforts and to provide funding for their program activities. This expanded authority led to programs carried out by DHHS, USDA, and EPA. Each of these organizations receives annual fund transfers from DOS as discussed below.

- *Global Biosecurity Engagement Program (BEP)*: In 2006, the National Security Council (NSC) tasked ISN/CTR to draft a strategy for strengthening global pathogen security. The effort identified potential proliferation problems in critical geographical areas. The strategy, as approved by the NSC, identified roles for U.S. government departments and agencies and assigned the lead engagement effort to ISN/CTR. At the time, other departments and agencies, such as DOD, DHHS, and USDA, lacked either the requisite funding, the legislative authority, or both, to assume the lead. In some ways, the NSC strategy mirrors a related strategy dealing with homeland security that links reduction of biological threats to improving threat awareness, developing prevention and protection tools, enhancing surveillance and detection, and developing response and recovery capabilities.²

BEP's objective is to promote legitimate bioscience research while recognizing the confluence of bioterrorism threats, emerging infectious diseases, and the rapid expansion of biotechnology. BEP's initial focus areas are South Asia, Southeast Asia, and the Middle East; and programs emphasize ensuring the physical security of pathogens, upgrading laboratory biosafety procedures, and improving approaches for combating infectious diseases. Pilot efforts in Indonesia and the Philippines include conducting risk assessments; developing country-level strategies for bilateral engagement on laboratory biosafety, biosecurity, disease surveillance, and

² See National Security Policy Directive 33, Biodefense for the 21st Century, signed June 12, 2002. Available on-line at <http://www.whitehouse.gov/news/releases/2004/04/20040428-6.html>. Accessed May 30, 2007.

diagnostics; and developing a grants assistance program to promote meaningful research collaborations involving U.S. and local institutions.

Planned future activities include engaging Japan on ways to minimize biological threats, developing Asian biosecurity standards, engaging Egypt on threat reduction, continuing workshops and related activities in Thailand and Malaysia, and conducting preliminary discussions with Pakistan and Yemen.

Department of Health and Human Services

The Biotechnology Engagement Program (BTEP) of DHHS operates in the former Soviet Union with the following three mandates developed by DHHS in consultation with other government departments:

- Discourage the proliferation of weapons-related expertise and engage former biological and chemical defense scientists in civilian-oriented research
- Apply scientific expertise toward urgent public health needs in the region, thereby advancing public health policy via evidence-based science
- Promote Western scientific practices and strong international cooperation, provide experience that will enable successful pursuit of competitive research funding, and promote commercialization of technology developed in projects

BTEP had 33 active projects in Russia, Georgia, Kazakhstan, and Armenia as of February 2007. It had completed an additional 29 projects and had 14 projects under development. Projects focus on dangerous and emerging infectious disease, endemic health problems and vector-borne diseases. Of the 62 active and completed projects, nearly one-half have addressed tuberculosis or HIV/AIDS.

BTEP has played a particularly important role in working with BTRP to support cooperative research with Russian specialists on development of medical countermeasures to smallpox during the past few years. These projects, carried out at the Institute for Virology and Applied Biotechnology (VECTOR), have provided scientific results of considerable interest while also developing U.S. partnerships with important Russian investigators who have unique experience in addressing this highly dangerous disease that is one of the world's most feared agents of bioterrorism. While the future of bilateral collaboration in this field is uncertain, the connections that have been developed between American and Russian scientists should continue to provide important international windows into highly sensitive activities in Russia.

Unfortunately, only one full-time mid-level Public Health Service Officer is currently assigned to program management and implementation within DHHS after a decade of assignment of stronger and more empowered staff resources to the program. BTEP works through the STCs and uses a commercial contractor to assist with proposal development, monitoring and evaluation of projects, program and logistical support, and procurement of supplies and material. U.S. collaborating partners on BTEP projects are responsible for technical and financial review of the projects and for approving requests for project changes.³

³ According to a November 2006 BTEP briefing presented to the committee on February 7, 2007, U.S. collaborators are drawn from the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and the Agency for Toxic Substances and Disease Registry.

For the future, DOS has asked BTEP to enhance its engagement of former chemical weapons scientists, which could erode its focus on biological scientists. At the same time, BTEP plans to develop regional, cross-border biology projects in the former Soviet Union. Also, it plans to initiate additional activities in countries that are linked to the STCU.⁴

Department of Agriculture/Agricultural Research Service (USDA/ARS)

USDA began its Scientific Cooperation Program in the former Soviet Union in 1998 with funding from DOS. Built on a strong existing base of ARS global activity, the program had 55 projects active as of February 2007, with 16 additional projects already completed and 17 more under development.⁵ The program supports projects in Russia, Kazakhstan, Uzbekistan, and Tajikistan with the following objectives:

- Reduce the threat of chemical and biological weapons development and deployment
- Advance agricultural science by supporting types of expertise of particular importance in the region
- Enhance the effectiveness and productivity of ARS research programs
- Improve Eurasian economies through advances in agricultural technology

Projects focus on the three broad areas of animal health and production, natural resources, and crop health and production. Each project must have one or more U.S. collaborators from the USDA/ARS laboratory system. These ARS collaborators with the consistent support of ARS leadership are the cornerstones of the strong scientist-to-scientist collaborations that have made the USDA program a model that provides value to all parties at modest cost.

During 1998-2006, USDA/ARS received about \$44 million in transfers of funds from DOS, but USDA's FY 2007 budget has been significantly reduced from previous years to \$2 million. Despite the funding decrease, USDA/ARS will continue with limited new initiatives. The program includes joint projects with BII to (1) support establishment of a pilot production plant in Russia for antibiotics, and (2) cooperate with veterinary institutes in Ukraine, Kyrgyzstan, and Tajikistan.

As discussed in Chapter 2, international exchanges of strains of dangerous pathogens have become difficult to implement, regardless of the research rationale of validating research results in laboratories of both collaborators on specific projects. While USDA researchers may continue to seek agreement with partner ministries for such exchanges, they should consider arranging for joint analyses in the region, under appropriate laboratory conditions. This approach would avoid the time-consuming, and often fruitless, political and administrative discussions concerning strain exchanges.

⁴ As of February 2007, the countries belonging to the STCU included Azerbaijan, Canada, the European Union, Georgia, Moldova, Ukraine, the United States, and Uzbekistan.

⁵ Information provided to the committee by USDA on February 7, 2007

BOX 3-3

USDA Addresses Avian Influenza

“An aspect of the collaboration is getting a handle on the basic ecology of avian influenza....Russia is crossed by two major migratory flyways....The collaborative group has found that some avian influenza variants not previously found in Russia were isolated during this project. Data also suggest that one variant, H4N6, has expanded its host range and that aquatic mammals, mainly muskrats, are involved in maintenance of the virus in nature.”

SOURCE: Durham, S. 2005. International partnership for poultry safety. *Agricultural Research* 53(11):9-11. Available on-line at <http://www.ars.usda.gov/is/AR/archive/nov05/poultry1105.htm>. Accessed July 24, 2007.

Environmental Protection Agency

EPA’s program is the smallest of the DOS-funded programs. EPA responds to important environmental protection and remediation problems and has carried out more than 20 projects. The agency’s Office of International Affairs provides overall program and financial management, and its Office of Research and Development provides scientific and technical experts for individual projects.

As one example of its activities, EPA has played an important role in supporting the development and implementation of environmental assessments in Kazakhstan. Of particular interest have been the activities of a former biological weapons laboratory in Stepnogorsk to develop new nature preserve areas where there are environmental health problems that require isolation from the general public.

Department of Energy

Since 2003, DOE’s total funding for biothreat projects has been more than \$23 million. Of the available program funds for all types of redirection projects in the former Soviet Union, approximately 20 percent has been devoted to engaging biological institutes.

The Initiative for Proliferation Prevention (IPP), DOE’s most relevant program, has the objective of engaging in peaceful and sustainable commercial pursuits former Soviet scientists, engineers, and technicians who had been involved with weapons of mass destruction. This program is implemented through cooperative projects involving former Soviet weapons specialists, DOE’s national laboratories, and U.S. industry. IPP is designed to identify non-military, commercial applications for former Soviet technologies, with the aim of providing new technology sources and markets for U.S. companies, while creating commercial opportunities and income for former Soviet weapon specialists.

IPP has funded biology-related projects with institutes in Russia, Kazakhstan, Uzbekistan, Ukraine, Armenia, and Georgia. More than 90 percent of these projects have been in Russia. In 2005, IPP’s boundaries of activities were extended to other parts of the world, including Iraq.

One example of a successful IPP project has been the development of microbes that can assist in oil pollution bioremediation. The Russian partner has isolated four strains of

microorganisms with high efficiencies for remediation of surface water and selected soils. Field trials indicate microbial persistence in soil with continuous hydrocarbon degradation. According to DOE, this approach should allow re-vegetation in one to three years, depending on the climate.

IPP's activities complement other DOE biothreat prevention programs. These programs include training in international export control procedures such as identification of sensitive biology-related commodities; support of the interagency working group and the U.S. delegation responsible for the Biological and Toxin Weapons Convention (BWC); improvement of physical protection of biological materials in laboratories in Indonesia; and conduct of biosecurity workshops in India, Jordan, and Pakistan. These activities are carried out under DOE's Global Security and Engagement Program.

It is likely that future IPP projects will continue to engage biological institutes in the states of the former Soviet Union, predominately in Russia. Although the funding levels and numbers of projects will depend on the merits of individual projects, DOE anticipates that biology projects will continue to command 15 to 20 percent of the total available funding for redirection activities. Areas of interest will probably continue to center on the technologies involved in bioremediation, decontamination, biological detectors, and crop protection products.

Interagency Coordination

The Nonproliferation Interagency Roundtable (NPIR) was initially established to review research proposals to be carried out in the former Soviet Union (FSU) but not to coordinate nonproliferation activities across departments. While some coordination results from NPIR reviews, potential synergies between the agencies' programs are not always recognized. Nonproliferation activities probably can be improved through better coordination as discussed below.

An Interagency Success Story

An early U.S. goal during the 1990s was to help former Soviet research facilities distance themselves from the Biopreparat organization, which served as a civilian umbrella organization for the Soviet biological weapons program. After a decade of engagement activities, that goal has largely been met, in part due to such engagement. In particular, two of the largest Biopreparat facilities that dealt respectively with viral and bacteriological pathogens—namely, the State Research Center for Virology and Biotechnology (VECTOR) and the State Research Center for Applied Microbiology—were transferred to the Ministry of Health and Social Development in 2006. The institutes' missions are now oriented to focus exclusively on public health, with an emphasis on diseases endemic to Russia. The Russian government is providing greater budgetary resources to support activities directed to public health problems than was the case in the past. These transitions benefited significantly from U.S. government program support of the following activities:

- Cooperative research (DOS [STCs, BII, BCR], DOD/BTRP, USDA/ARS, DHHS/BTEP, DOE/IPP)
- Increased physical security (BTRP)
- Training and certification on laboratory animal care and use (STCs, BII, BTRP)

- Travel grants to attend professional association and scientific meetings (STCs, BII, USDA/ARS, DHHS/BTEP, BTRP)
- Business and English language training (STCs, BII, BTEP)
- Pursuit of business development opportunities (IPP, BII)

In short, a number of U.S. programs have supported these research facilities with projects to help facilitate the transition to public health and agriculture activities. The cooperation has led to unprecedented levels of access and transparency for program activities and financial audits and to long-term professional relationships that should help ensure future transparency. These successes demonstrate the payoff of coordinated action through multiple programs.

Improving Interagency Coordination

Overall guidance for program direction is promulgated by the NSC, as noted above. This guidance is reviewed periodically by the NSC and updated as appropriate. An important element of this guidance is project review and coordination which has been carried out through the NPIR. This process has allowed the interested departments and agencies to review each other's proposed projects with particular attention to potential dual-use risks and to nonproliferation benefits while reducing unnecessary duplication of effort.

In general, the NPIR process appears to function well. The effectiveness of the DOS-led monthly interagency meetings, which include representatives of BTRP, was reviewed by the Government Accountability Office (GAO) in 2005 as well as in earlier years. GAO observed that biological redirection programs have "clearly delineated roles and responsibilities, regular interaction, and dispute resolution procedures."⁶ The report goes on to say that the agencies implementing programs reported no coordination difficulties and that the NSC guidelines and regular information sharing ensure that the departments and agencies are aware of each other's program activities and help avoid duplication of efforts. The interagency process also benefits from department-level internal scientific and policy reviews that feed into the interagency process.

In addition to serving as a platform for project review and information exchange, the NPIR process has been used by the NSC as a venue for developing strategies and program approaches that apply across programs. At times coordinated strategies for regions, countries, and even specific institutes have been developed, but this has not been systematic. A current weakness of these strategies is that they encompass only nonproliferation programs. They do not reach out to broader departmental, national, or international activities. There does not seem to be sufficient interest at senior official levels to integrate nonproliferation programs with related programs that address other objectives. For example, the link between the DHHS/BTEP projects on multi-drug resistant tuberculosis and much larger DHHS efforts in this field is weak. Also, traditional foreign assistance activities in the fields of public health and agriculture are carried out on separate tracks from nonproliferation activities, even in the same countries.

A related coordination challenge, particularly with regard to BTRP, is the development of parallel country strategies by different programs. As discussed in Chapter 2, BTRP is preparing country science plans. These plans focus on BTRP and partner government interests, and they set

⁶ U.S. Government Accountability Office. 2005. Weapons of mass destruction: nonproliferation programs need better integration. GAO-05-157. Available on-line at <http://www.gao.gov/cgi-bin/getrpt?GAO-05-157>. Accessed on May 30, 2007.

forth in considerable detail BTRP's planned activities in each country. At the same time, they do not give adequate attention to the interests of other U.S. government departments and agencies that may intersect with BTRP interests in specific countries. Still, BTRP should be commended for its initiative and encouraged to seek broader coordination.

Given funding uncertainties, the different interests of different departments, and the importance of adjusting priorities quickly when problems emerge, a unified plan for each country does not seem realistic. Of course, there should be good information exchange to promote complementarity when possible. An annual interagency report that would be publicly available describing programs and achievements would provide a good background mosaic for a number of organizations interested in supporting related programs. At present, some agencies prepare regular reports to support budget submissions, and this effort could be part of the basis for an interagency effort that would standardize program data in such annual reports.

The 2006 strategy requested by the NSC for "global" biosecurity engagement is intended to apply to all departments and agencies and foresees a number of activities in biosafety and biosecurity with an initial focus in Southeast and South Asia. DOS is proceeding to implement programs, working in some cases with experts from other agencies. DOS efforts to promote consolidations of strain collections, increase physical security at biological facilities, and improve disease surveillance mirror BTRP programs, but they are being undertaken thus far without BTRP participation. BTRP has not been tasked to expand into these regions although it has resources and experience that should be helpful. Congress may earmark BTRP funds for use outside the FSU, which will require greater attention to the most effective use of BTRP as well as capabilities of related programs in other countries.

As previously noted, BTRP receives by far the largest share of funding available to the departments and agencies for biological threat reduction activities, and BTRP's proportion of the overall budgets for cooperative threat reduction funding is increasing. However, BTRP's success in addressing the threats depends in part on scientific and technical expertise that is available in other departments and agencies such as DHHS, USDA, and EPA, which in turn may depend on DOS funds and limited internal budget allocations. If the non-BTRP programs do not receive funding to carry out their parts of integrated programs, there are of course broader implementation difficulties. An important approach is a BTRP budget strategy that includes other departments working in close coordination with BTRP to carry out key components of interagency programs. In this regard, BTRP is aware of the importance of drawing on the expertise of other departments. It has consistently provided substantial resources to the Centers for Disease Control and Prevention to assist with specific tasks and is currently attempting to arrange for support by USDA/ARS using BTRP funds. Also, as previously mentioned, BTRP cost shares with DHHS support of smallpox-related research in Russia. But, as suggested in Chapter 2, an amendment to BTRP's authorizing legislation could call on BTRP to use the expertise of DHHS and USDA to the fullest extent that is practical and to provide financial support to these departments for facilitating joint activities.

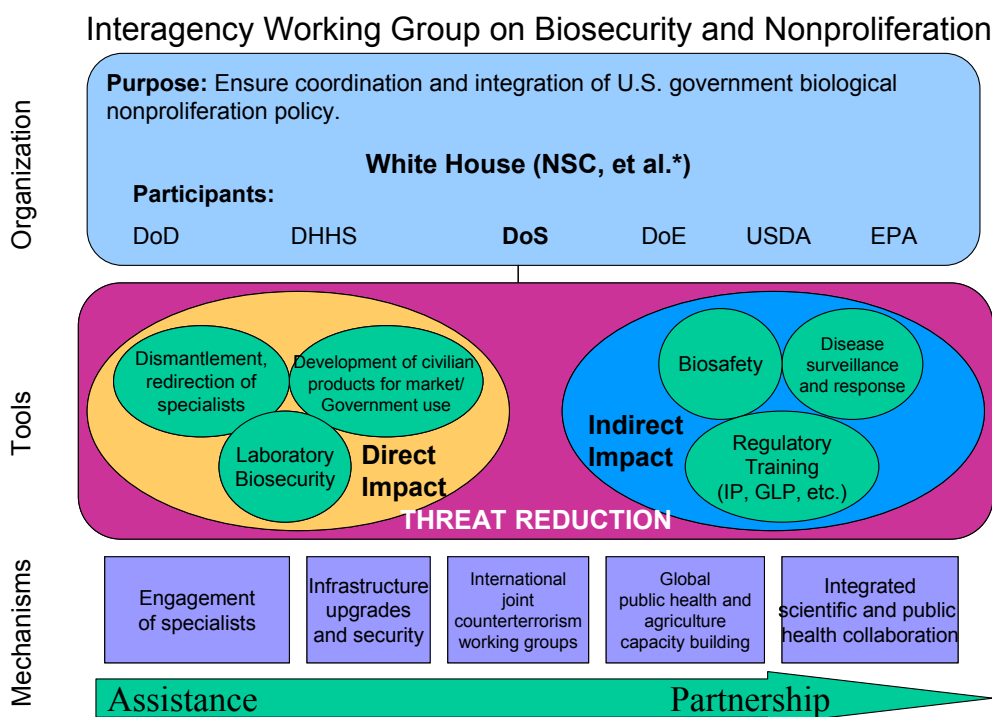
Proposed Model for Interagency Coordination

Given the geographical expansion of biological threat reduction programs already under way and the need to maximize program impacts, a new model of U.S. government interagency coordination to promote synergies and reduce duplication may be needed. One approach would

call for an NSC-led Interagency Working Group on Biosecurity and Nonproliferation, with senior agency officials as participants. The Working Group would help ensure coordination and integration across U.S. government programs, including global health security, biosafety, and nonproliferation efforts. Participants would be drawn from DOS, DOD, DHHS, USDA, DOE, and EPA, with support from the intelligence community and inputs from other departments with relevant international programs.

Such a structure could help match interagency policy-driven objectives to program implementation mechanisms and capabilities across a spectrum of activities ranging from initial engagement of former weapons specialists to broadly based scientific collaboration. The U.S.-Japan Cooperative Medical Sciences Program, which has operated since 1965, offers important lessons in this regard, particularly the mutual benefits from sustained research engagement on a wide variety of research issues. Developing broad program approaches could facilitate better tracking of interactions of direct impact programs, such as biosecurity, on other broad objectives including, for example, increased disease surveillance. Figure 3-1 suggests an expanded model of the current interagency approach.

FIGURE 3-1 Integrating U.S. government nonproliferation efforts.



* Assure coordination/liaison with other U.S. government international activities of Homeland Security Council, Office of Science and Technology Policy, National Science Foundation, U.S. Agency for International Development, Department of Commerce, Department of the Treasury, Office of Management and Budget, Department of Homeland Security, etc.

Whatever the model, **the White House should exert strong leadership to ensure integration of BTRP with related biological threat reduction activities supported by the U.S. government.** The key is the involvement in policy formulation of senior officials from all of the principal departments and agencies who collectively can ensure sustained, high-level attention to international biological risk reduction throughout the government. These officials

should be in a good position to develop common government-wide strategic goals to help guide BTRP and related on-the-ground programs supported by the U.S. government and to assess the cumulative security and health impacts of programs of different departments.

Lessons Learned from Department and Agency Experiences

The experiences of the departments and agencies that have been engaged in biological threat reduction programs are substantial. Set forth below are a few of the key lessons that have been learned in recent years based on observations of the NRC committee.

1. There can be significant value to strategy-driven, coordinated efforts within the U.S. government and with other international partners. The number of inter-related program activities supported by the U.S. government is large, let alone relevant programs supported by others. A strategic framework that helps guide individual programs could be very useful. Time is too short and funding is too limited not to take advantage of the insights and achievements of other organizations and agencies. Almost every important biological facility in the former Soviet Union now has multiple international funders, and the need for coordination seems obvious.

2. High quality U.S. and other collaborators are a key to success. No longer is the objective simply to provide opportunities for non-threatening research by former weapon specialists. The objective should be to support activities that will command sustained support in the future due to the contributions of local activities to public health, agriculture, and international science. Experienced collaborators who recognize the scientific importance of well-designed programs and can ensure that they meet international standards are essential in setting the stage for sustainability of complicated biological activities.

3. A larger segment of the American academic community should become involved in nonproliferation programs. Most government departments and agencies have relied primarily on their own specialists to provide advice on appropriate approaches to engagement and to serve as collaborators on projects. Greater efforts are needed to engage a larger segment of the American academic community with relevant expertise and with the interest to remain engaged with foreign counterparts over the long term. BTRP's attempt to have a consortium of universities that could recruit scientists for overseas assignments has not worked very well. Most of the participants were not well embedded in American universities or research centers but were simply taking on overseas assignments as temporary career moves with little likelihood of continued engagement through the university consortia after one- or two-year stints abroad.

Consideration should be given to establishing a global competitive grants program funded and administered on an interagency basis to encourage American academics to become engaged in international biological programs with important nonproliferation benefits. Project development grants could facilitate initial scientist-to-scientist contacts. Larger grants could subsequently support joint projects that have been developed. Open competitions should help ensure that important projects and well-qualified investigators are chosen.

4. Program priorities should respond to threat assessments that take into account both individuals and facilities. Assessments of all biological assets that could be of interest to hostile groups should be carried out. Usually, the experience and reliability of human resources at the facility level are an important concern, and programs should be highly selective to ensure that key specialists, as well as key facilities, are appropriately involved in engagement activities. Because of the pervasive nature of biotechnology and its high degree of dual-use application, in

some cases, programs should include specialists who have never had any connection to biological weapons programs.

5. Projects that link a strong foreign institute in the lead working with one or more secondary institutes help create networks and provide project mentoring for less experienced institutes. Networking was not a strength of the scientific community within the former Soviet Union. In security-related areas in particular, institutes were deliberately separated. However, in the modern world of science, networking is essential. While it has become commonplace for strong institutes to reach out to international partners, much greater effort is needed by these institutes to work with other institutions locally to help strengthen the overall infrastructure of the countries, and BTRP should support such activities.

High-level leadership within participating U.S. departments and agencies is essential. Ensuring biosecurity requires a long-term commitment that will only be sustained if the leadership within the participating departments and agencies recognizes the importance of global engagement and gives nonproliferation activity a high priority. One reason for the high degree of effectiveness of the USDA efforts stems from the strong support it has received at senior levels. The result has been a strong integration of the program into the Agricultural Research Service (ARS) infrastructure with the program designed to have clear benefit to USDA and ARS. It does not detract from, but indeed supports, the domestic mission while serving a broad nonproliferation mission.

High-level international support is also critical. A “cooperative” approach is an essential aspect of threat reduction. Without the active support of the government or governments on whose territory projects are carried out, lasting impact is unlikely. For these programs to have significant nonproliferation benefit, they must be sustainable into the future. With improving economic profiles in some countries, particularly Russia, the host government must in time assume the burden for sustaining activity into the future, and particularly a commitment to appropriate levels of training, certification, and standards. The goal of the U.S. government should be to establish long-term self-sustaining collaborations in biotechnology and the health and agriculture sciences.

In summary, the growing contributions of the life sciences to improving the lives of people throughout the world together with the relative ease of developing biological materials that can cause immeasurable harm and disruption to these same populations are strong reasons for the U.S. government to accord a high priority to promoting appropriate use of dual-use biological technologies. The responsibility and capability for achieving this objective are shared by a number of U.S. government departments and agencies. These departments have good track records in using nonproliferation funds to direct biological assets of countries in political transitions to useful scientific endeavors. Partner governments, private firms, charitable foundations, research institutes, and universities have resources of critical importance as well. BTRP is by far the largest U.S. government engagement program dedicated to countering international biological terrorism that could impact on the United States; therefore this program is especially well suited to catalyze and leverage the vast, high-quality educational, scientific, and entrepreneurial resources of the nation in the struggle with bioterrorism.

4

Overcoming Obstacles Confronting the Biological Threat Reduction Program

Many obstacles have been encountered in development and implementation of the Biological Threat Reduction Program (BTRP). Some have been country-specific, others have arisen due, at least in part, to U.S. government or Department of Defense (DOD) policies, and still others are attributable in significant measure to the policies and attitudes of partner governments, ministries, institutions, or key scientists. While some obstacles have been overcome, the challenge for BTRP is to eliminate or reduce remaining obstacles and prevent new ones from arising. To this end, the program should be flexible in adapting to novel concepts and opportunities, particularly to approaches that encourage long-term sustainability of activities initiated through BTRP.

This chapter describes a variety of obstacles and suggests approaches to reduce obstacles. Some suggestions are of sufficient importance that they are subsequently consolidated with related suggestions in other chapters and formulated in Chapter 6 as major recommendations of this report. Other recommendations in this chapter should also be helpful in improving the effectiveness of BTRP.

Political Support for BTRP

During the past decade, DOD and the U.S. Congress have consistently supported strong financial investment in BTRP. Much of the funding has been directed to dismantling facilities designed to produce or test biological agents for weapons and to enhancing security at other facilities where dangerous pathogen strains are located. Recently, large investments have been made in the Threat Agent Detection and Response (TADR) network. DOD and the Congress have enthusiastically supported such activities that put highly visible constraints on production and diversion of pathogen strains while focusing scientific efforts on surveillance activities.

However, the important research engagement component of BTRP has not had long-term support within DOD, particularly with regard to Russia. DOD's mistrust of dual-use activities of former Soviet weapon scientists, hesitancy of the Russian government to make special arrangements for American project monitors to have continuing access to sensitive high-hazard areas, and difficulties in recruiting well-qualified American collaborators willing to spend extended periods of time in Russia have all contributed to a sense of unease within DOD over the potential risks of Russian misuse of research results. This unease has led to bureaucratic delays within DOD in processing and reviewing research applications, with spans of many months and even years passing before BTRP has provided feedback to important Russian and American scientists who have prepared proposals with the encouragement of BTRP.

As will be discussed in Chapter 5, future BTRP efforts should give prompt and steady support to collaborative research throughout the region. DOD should recognize that the insights as to research capabilities as well as the technical benefits from research collaboration are very important. There are considerable risks entailed in not participating

in research engagement activities but instead simply remaining on the sidelines and speculating as to what may be taking place in facilities where research on dangerous pathogens is carried out.

As for Russia, approaches to collaborative research are set forth in Chapter 5. They should circumvent the reluctance of the ministries responsible for defense and health activities to become directly engaged with DOD. Such approaches should recognize that the objectives of cooperation conceived in the 1990s need a new emphasis. Box 4-1 presents an official Russian view in this regard. Sustainability of research groups is of course a key concern. Commercialization programs are an important approach to this end, but other strategies for long-term support of basic research also deserve high priority.

Box 4-1

From Redirection to Sustainability in Russia

“The job of redirecting former weapon scientists to peaceful pursuits is completed, and new cooperative efforts should focus on sustainability and commercialization strategies.”

Russian government spokesman, March 2007.

Support of BTRP research activities by the U.S. scientific, public health, and agriculture communities, and indeed the international communities, is also important. To this end, BTRP needs to demonstrate easily discernible benefits to the advancement of science, to the health of people, and to the availability of agricultural resources. Of course, BTRP should continue to emphasize the benefits in enhancing security in accordance with its legislative mandate. While small segments of the international and American scientific communities have a general awareness of BTRP activities, greater outreach efforts by BTRP to the scientific community within the United States are increasingly important as the program increases the number of countries and international scientists that are included in its activities.

BTRP will only be successful if it has strong and sustained support over many years from partner governments, from their implementing ministries and institutions, and from the scientists in these countries. While most partner governments have been attracted to BTRP, at least in part, by access to a new source of financial support through the program, the economic situation in several of these countries is improving, as discussed in Chapter 1. To remain attractive to these governments, financial aspects should now be accompanied by perceptions that BTRP gives high priority to supporting local scientific, health, and agriculture priorities while enhancing security (see, for example, Box 4-2).

Box 4-2

Neglect of Local Interests

“The Americans do not listen to our suggestions. Therefore, the Russian government is losing interest in cooperative programs.”

Russian project manager, March 2007.

This is not to say that the public health and agriculture authorities in the region are not appreciative of financial support for their activities or that they do not have facilities with a military legacy that need to embrace new research directions. But gaining strong acceptance of cooperative programs should take into account the different perceptions of the likelihood of proliferation originating in the countries of interest and of the threat posed to these countries and to the international community by such acts of proliferation. With regard to most, if not all, countries of interest, the U.S. government is more concerned about this threat than are the partner governments.

Priorities of partner governments within the health and agriculture sectors should be a paramount consideration. These sectors have been burdened with infrastructure, personnel, and financial problems that were exacerbated by the financial crisis during the late 1990s. Preventing proliferation does not rival the priorities associated with the day-to-day economic and social problems that need to be addressed in these sectors. Only a comprehensive approach to engagement that is the theme of this report can address such problems while also advancing U.S. security interests.

That said, full consultations between BTRP and partner governments prior to launching program activities, coupled with a continued willingness of BTRP to adjust preconceived approaches to accommodate local interests, are essential. Designing surveillance systems and establishing research projects that reflect priority interests of both partner governments and BTRP may not be an easy task, but in the long term common priorities will be the key to sustainability. Unfortunately, this reality has not guided the preparation of BTRP’s country science plans, the design of the TADR network, or the content of the Cooperative Biological Research program. All of these activities have been designed largely in Washington and then marketed to partner governments with varying degrees of success in terms of sustainability. Fortunately, during the last year the BTRP leadership has increasingly recognized the critical importance of jointly conceived and implemented programs.

Technical Challenges

Some technical challenges are intertwined with policy issues and others with administrative issues. Among the important technical challenges are the following:

1. An understanding of BTRP’s goals and objectives by current and potential program participants is essential. The relationships between the goal of preventing proliferation and BTRP’s contributions to preventing diseases through research and

surveillance activities that strengthen local capabilities on a broad basis should be clear to participants and other interested parties.

2. The upgrading of facilities essential for modern public health, including surveillance systems and research activities, is at the core of the BTRP program. Large numbers of facilities need attention, and required investments in upgrading will be substantial. The quality of the workforces at the selected facilities should be at a sufficiently high level for the tasks of maintaining and operating the facilities. In this regard, BTRP and the partner ministries might consider selecting several candidate facilities for upgrading and then having a competitive application process prior to selecting each one that is to receive BTRP support. Such a competitive process would help ensure that the quality of the workforce becomes an important consideration. Part of this consultative process should be the matching of personnel training schedules to progress in facility upgrades.

3. A directly related concern is the aging workforces that to date have carried the local burden of implementing BTRP. Soviet reliance on seniority as the criterion for having management responsibilities complicates the transition to a more appropriate approach. Serious problems include inadequate computer skills and lack of familiarity with modern technologies (see, for example, Box 4-3). Also, weak English language skills can inhibit the linking of local research and surveillance activities to international interests.

Box 4-3

Training on Modern Equipment

“Training in laboratory testing and special computer applications is inadequate. Also, more training is needed for operating new equipment.”

Senior Uzbek scientist, March 2007.

BTRP should emphasize training of young and rising specialists who can be brought into the program and who can quickly adapt to modern approaches to biological research, epidemiology, and other important disciplines. While engagement at the senior levels is important, involvement of the “second tier” of specialists who have decades of professional life ahead is no less important. Indeed, greater involvement of local universities and particularly graduate students would also be a healthy development, particularly since many will have dual-use skills that could become a future concern unless they are committed to peaceful and transparent activities. Use of the Field Epidemiology Training Program of the Centers for Disease Control and Prevention or an analogous program for new entrants into the field should be considered.

While BTRP can provide training programs for cadres of specialists, only the partner ministries and institutions can ensure that there will be qualified cadres to train. Providing incentives for highly capable young specialists to enter the workforce—including early access to responsible positions—is a particularly important task. In most research settings, they would have access to relatively old but still serviceable equipment. However, increasing opportunities to work in upgraded facilities and to participate in

international conferences should be important motivators to attract and retain young specialists.

4. The engagement of “former weapon scientists,” often in preference to non-weapon scientists, needs to receive less emphasis. An ever growing number of scientists throughout the world who have never been involved in military-related activities are developing dual-use capabilities. Of course, it is important to continue to engage former weapon scientists who have special skills of concern (see Box 4-4), but the primary criteria in selecting scientists for engagement should be two-fold: their potential dual-use capabilities and/or their contributions in strengthening the scientific, public health, and agriculture infrastructures for addressing infectious diseases in their countries.

Box 4-4

Importance of Weapon Scientists

“Scientists with many years of experience working with the most dangerous pathogens can certainly create greater problems if they were to decide, or were forced, to use this experience elsewhere, say in countries governed by regimes with questionable track records. Their colleagues who worked at ‘open’ institutes usually have only general knowledge of Group A pathogens. Besides, weapon scientists possess specific skill sets and access to dangerous strains of microorganisms. Both could be sources of ‘potential’ threats. But in the case of weapon scientists, it is significantly higher to the point of becoming ‘realistic.’”

Former Soviet bioweapon scientist, November 2004.

5. Once facilities are jointly chosen for upgrading, the ministries should be fully engaged in the technical approaches that are chosen and carried out. To the extent possible, the work that is financed by BTRP should be under the direction of the ministries that control the facilities, with BTRP providing quality control and accounting oversight. The role of American integrating commercial contractors in designing and installing upgrades should be limited whenever possible. The long-term payoff from placing greater responsibility in local hands should be substantial even though delays may be encountered. Local managers are in the best position to ensure that the upgrades are designed and installed in a manner that minimizes complications of maintaining upgraded facilities after BTRP has departed from the scene (see, for example, Box 4-5).

Box 4-5

Need for Greater Role for Local Managers

“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, the centrifuge rotor doesn’t match Eppendorf tubes.”

Kazakhstani manager for BTRP project, March 2007.

At the broader management level, excessive reliance on integrating commercial contractors can alienate partner institutions (see, for example, Box 4-6). BTRP contractors are often perceived as simply an extension of U.S. military interests, whereas well-known U.S. research organizations—governmental and nongovernmental—that are funded by BTRP are usually considered more legitimate participants in global health and agriculture endeavors.

Box 4-6

Problems with 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 project needs 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.”

Georgian senior scientist, March 2007.

6. Metrics are needed for identifying successful approaches in implementing BTRP activities and for guiding future activities. Among the metrics that have been used by BTRP in the past are

- number of weapon scientists involved, including the number trained
- number of sustainable jobs created
- level of matching contributions by cooperating governments or other partners
- follow-on contracts resulting from research projects
- number of publications in internationally recognized journals
- number of patents that have been awarded
- number of research products that have reached the market
- number of companies that have been spawned

These indicators are important but do not go to the essence of the program, namely, “To what extent has the likelihood of outbreaks of endemic and emerging diseases and the associated terrorist aspects been reduced?” A related concern is the timeliness, adequacy, and quality of responses to outbreaks should they occur.

This report has identified many positive changes at the national and facility levels for addressing infectious diseases that are attributed to BTRP and related programs. Developing measures for evaluating the changes (e.g., ease of access to sensitive laboratories, response time in identifying outbreaks) could then provide the foundation for useful metrics.

7. Animal welfare issues have caused delays in BTRP and other U.S.-supported programs. On the other hand, U.S. insistence on meeting appropriate standards of laboratory animal care and use has resulted in significant changes in a number of institutes and has led to international certification of an animal breeding facility in

Russia. BTRP should address animal welfare issues early in its development of research and surveillance programs in each country.

8. Information on a country's pathogen collections is an important requirement in developing country-specific strategies for achieving the greatest risk reduction. But some ministries may not be prepared to part with such information. The information is more likely to be forthcoming if the engagement program is perceived as strengthening the overall research and surveillance systems of the country. In this regard, the BTRP program needs to underscore the local benefits from sound strategic approaches to controlling diseases.

9. The quality of research proposals prepared by BTRP partner institutions needs upgrading. BTRP should continue its practice of providing the institutions with templates, instructions, and training as to the important aspects that should be addressed in proposals. For example, the proper formulation of the hypothesis, the importance of controls, and the calculation of statistical significance need to be underscored. Results of peer reviews of proposals should be carefully considered in detail by the designers of proposals.

10. Partner institutions need to be better informed about protection of intellectual property. They should understand when and why they should seek protection and the procedures for obtaining such protection. Some U.S. government programs, such as those of the Department of Energy, have specialized modules for technology transfer that could be helpful.

Administrative Problems

1. Visas will continue to be a problem when dealing with some countries. At present, visas for Americans traveling to Uzbekistan are uncertain. On occasion, there are time delays for visa issuance by other countries. Also, visa applications for technical specialists traveling to the United States are receiving greater scrutiny than in years past. Sometimes early consultations by BTRP with the Visa Office of the Department of State and/or relevant consulates may help shorten the time line for visa decisions. But BTRP will simply have to recognize this problem and instruct BTRP participants to apply for visas well in advance of planned activities.

2. As discussed in Chapter 3, implementation of BTRP projects has been plagued by the long DOD chain of command that has been established for guiding the process. At present, policy formulation is approved by senior policy officials within DOD, who then instruct the CTR policy office. That office in turn tasks DTRA to implement specific activities. DTRA has several levels of responsible officials, and they in turn must fill in details of the tasks that are being assigned. BTRP then normally turns the tasks over to integrating commercial contractors that typically employ subcontractors. Finally, the tasks come to rest with specialists who are responsible for on-the-ground activities. And these specialists often change positions. The lengthy separation between the policy officials who designed the tasks in the first instance and the implementers has caused difficult program situations.

Instructions and decisions from senior DOD officials are often delayed as they go through the lengthy internal process. Instructions are sometimes not clear at the working level given the changes in circumstances on the ground from the time the task was

originally formulated until the time that implementation instructions are in hand. Often the partners in the countries of interest suggest modifications in the instructions. If requests for modifications go back up the chain, further delays and confusion enter the system. The DOD decision process also can cause program disruption as collaborating scientists become impatient and decide to turn their attention to other requests for their services from within the country or abroad that do not involve such delays. Shortening this chain of command within DOD and BTRP would improve the situation.

As one example of delays, in 2005 BTRP informed the National Academies that at least 30 months were required to process a research proposal received by BTRP from an institution in the former Soviet Union. Such a delay hardly engenders a sense of urgency in combating the threat of bioterrorism. It raises false expectations as to prompt consideration of proposals among researchers, including important scientists who may have other funding options and therefore may not be included in BTRP. The lengthy process is in sharp contrast to the experience in 1997 of the National Academies in managing eight pilot projects for BTRP, which took an average of three months to move from proposal submission to signature of project agreements. BTRP has been shortening its time line in recent months, and this effort should be strongly encouraged.

3. Enhancing physical security of dangerous pathogens, a focus of BTRP to date, will inevitably be complicated in order to comply with safety and security requirements of both the U.S. and partner governments. The merging of Soviet-era and Western security and safety concepts further complicates mutual understanding of procedures. BTRP needs to continue addressing this problem through consultations and training programs. But it also needs to recognize that misunderstandings are inevitable and not attempt to design a fault-proof system that emphasizes delays and excessive redundancies.

4. One of the most important challenges for BTRP is to have sufficient staff with both technical and area expertise that can design and effectively manage programs in collaboration with foreign partners. At present, BTRP staff has limited technical expertise, particularly in public health and veterinary medicine. Also, it has limited foreign language capability. Too much of the technical responsibility for the program has been turned over to contractors who are simply too far removed from the center of policy and technical decision-making. This has led to unnecessary confusion over the definition of tasks, and often the authorities of contractors have been far from clear.

A related concern is the inadequate cultural sensitivity of specialists sent abroad under BTRP. In order to improve this sensitivity, BTRP should have a program of staff training and training for contractors and American collaborators that emphasizes the unique challenges of operating in the former Soviet Union or in other areas where BTRP becomes active.

Recommendation to Improve Efficiency and Effectiveness

Against this background, the committee offers the following recommendation:

To improve program management, DOD/DTRA should ensure availability of adequate internal technical staffing for BTRP and should recognize that while there is a need for integrating commercial contractors for construction projects, assistance in management of research projects and related training programs can be more appropriately provided by government, academic, or nonprofit organizations.

Strengthened internal BTRP staff capabilities are essential to reduce the outsourcing of contacts with important foreign participants and of technical judgments to integrating contractors and to improve the efficiency of the entire management system. DOD and DTRA have not assigned sufficient personnel with adequate technical capabilities to develop, manage, and evaluate a program that currently involves about 600 contractor and other personnel and requires constant judgments to assess scientific uncertainties. The current BTRP staff at DTRA of 17, including 4 with scientific backgrounds, needs augmentation, particularly at the senior levels.

Commercial contractors are essential to ensure that complicated construction activities are carried out as planned, that construction funds are properly managed, and that quality control in designing and constructing facilities is maintained. Also, they have capabilities to deploy personnel abroad quickly. However, with regard to support of research projects after laboratory upgrades are completed, there is little need for relatively expensive commercial contractors to be involved. Other government departments such as the Department of Health and Human Services and nonprofit organizations such as the U.S. Civilian Research & Development Foundation have stronger scientific reputations and considerable experience in providing technical advice and establishing well-accepted mechanisms for transferring funding to partner institutions and to specialists for salaries, laboratory supplies, and research equipment in the former Soviet Union. Also, a number of research components of DOD are highly respected internationally for their scientific expertise, in contrast to integrating contractors, who do not have comparable scientific credentials. These scientific organizations can help BTRP call on American academics who successfully manage competitive research programs for assistance in familiarizing counterparts in partner countries with modern research management techniques. Subcontracting tasks for scientific support to academic or research organizations through commercial integrating contractors has been one way that BTRP has attempted to avoid negative reactions to contractor involvement in research activities, but this approach has been cumbersome and widely viewed as excessively expensive.

5

Future of the Biological Threat Reduction Program

The Department of Defense (DOD) estimates expenditures of about \$200 million annually for the next five to ten years for the Biological Threat Reduction Program (BTRP), a major increase over current expenditure levels.¹ BTRP plans to have significant activities under way in all of the countries of the former Soviet Union except Russia, Belarus, and the Baltic states in the next several years. Reflecting steady budgetary growth, the President's request to Congress for Fiscal Year (FY) 2008 included \$144 million for BTRP.² However, the Senate Armed Services Committee has recommended increasing this level to \$194 million with an additional \$10 million provided for activities beyond the former Soviet Union (FSU).³

Many details of these projections are not publicly available. However, it is clear that the projections do not include funds for further work on Infrastructure Elimination. This program component is scheduled to be financed to completion with FY 2007 funds, as discussed in Chapter 2.

Based on available information, an estimated 90 percent of the funds currently being considered by DOD for the future are to support biosecurity/biosafety and Threat Agent Detection and Response (TADR) activities. The remainder is for the Cooperative Biological Research (CBR) component of BTRP. Of course, DOD may at any time request reprogramming authority from the Congress within the overall Cooperative Threat Reduction program if priorities and opportunities change.⁴

The committee strongly supports this long-term DOD commitment to preventing the proliferation of biological weapons. As discussed throughout this report, the national security payoffs from a robust and far reaching program in this field are considerable.

While BTRP has already made many contributions in promoting U.S. security interests, BTRP and related U.S. programs have touched only a small portion of the challenges of preventing proliferation of biological weapons. The security of many institutions in the FSU and in other areas of the world with biological assets of potential interest to terrorist groups is clearly inadequate. A large number of facilities need urgent upgrading to improve security and to strengthen research and service capabilities. Many talented scientists need additional support to encourage them to concentrate their efforts on public health and agriculture problems. Enhancing facility security and supporting underutilized scientific workforces could help prevent serious adverse impacts on

¹ Project staff discussions with DOD and Defense Threat Reduction Agency (DTRA) officials, June 11, 2007. On June 8, 2007, DTRA announced its intention to select several integrating contractors for the program with total expenditures up to \$4 billion during the next ten years. DOD and DTRA officials consider this estimate somewhat high to cover currently unanticipated requirements.

² U.S. Department of Defense. 2007. Cooperative threat reduction annual report to Congress: Fiscal Year 2008. Cooperative Threat Reduction Program, p. 41.

³ Senate Report 110-77, National Defense Authorization Act for Fiscal Year 2008. Available on-line at <http://origin.www.gpoaccess.gov/serialset/creports/>. Accessed June 14, 2007.

⁴ U.S. Department of Defense. 2007. Cooperative threat reduction annual report to Congress Fiscal Year 2008. Cooperative Threat Reduction Program, p. 41.

geographically dispersed U.S. interests should there be aggressive efforts by adversaries to carry out threats of bioterrorism.

The projected funding levels will enable the U.S. government, acting through BTRP as well as other programs, to continue its global leadership in addressing the dual-use dilemma associated with advancements in biological science and biotechnology. Such advancements are intertwined with important public health, agriculture, and scientific issues. Also, BTRP has repeatedly demonstrated that it not only can accomplish specific objectives in the U.S. government's efforts to prevent the proliferation of biological weapons but can also encourage partner governments and other international governments to expand their support of programs that complement BTRP. BTRP is by far the largest U.S. government biological nonproliferation program, and it is the only program that is growing. Thus, it should play an even more important role in reducing the likelihood of bioterrorism in an important geographical region. In general the committee supports the program priorities selected by BTRP for future years. However, this chapter suggests several modified approaches in the development and implementation of BTRP, with special emphasis on new models to improve the effectiveness of research collaboration

Program Activities for FY 2008

DOD has announced that BTRP plans to use the funds requested for FY 2008 for the following activities:

- **Russia:** Support planned cooperative research projects to improve vaccines and to identify better antiviral medications for smallpox. About \$5.2 million has been allocated for this purpose. However, Russian policies that are unacceptable to DOD and lack of BTRP access to locations believed to be sites for repositories of dangerous pathogens limit the program, and no funding will be sought for FY 2009 and beyond other than for the possible continuation of smallpox-related research.
- **Georgia:** Continue construction of a Central Reference Laboratory (CRL), which will secure all dangerous pathogens in the country and will provide a capability to characterize pathogens and validate diagnoses. Within the CRL, the pathogen repositories (one for human and one for veterinary pathogens) and an accompanying small suite of laboratory space will be built to Biosafety Level 3 (BSL-3) standards.
- **Uzbekistan:** Continue construction of epidemiological monitoring stations and provide training for personnel to respond to and rapidly diagnose disease outbreaks. Collaborative research projects will continue to be developed and implemented.
- **Kazakhstan:** If tax issues can be resolved, initiate work on a CRL, continue to construct/renovate epidemiological monitoring stations, and provide training for personnel to respond to and rapidly diagnose disease outbreaks. Collaborative research projects will continue to be developed and implemented.
- **Azerbaijan:** Construct/renovate four epidemiological monitoring stations and provide training for personnel to respond to and rapidly diagnose disease outbreaks. Continue to develop and implement cooperative research projects.
- **Ukraine:** Construct/renovate five epidemiological monitoring stations. Continue to provide diagnostics and epidemiological equipment and training to respond

to and rapidly diagnose disease outbreaks. Collaborative research projects will continue to be developed and implemented.⁵

Modifying the Orientation of BTRP

BTRP was developed in Washington as an assistance program for states that were on an economic decline following the splintering of the Soviet Union into 15 newly independent nations. While a highly directed program based on the near-term security interests of the United States and tightly managed by American commercial contractors was appropriate during the 1990s, greater attention should now be given to having a program that serves the interests of the partner governments more broadly, as well as serving longer-term U.S. interests. This orientation will help (1) encourage cooperation of partner governments, institutions, and specialists, (2) enlist colleagues in common efforts that will continue for many years to help ensure that dual-use technologies are directed to peaceful pursuits, and (3) set the stage for sustainability of programs initiated through BTRP that should be maintained over the long term by partner institutions. To this end, the committee emphasizes the following:

BTRP should be transformed from a Washington-directed program of assistance to a genuinely collaborative program of partnerships with governments of the states of the former Soviet Union, built on strong relationships between important scientific, public health, and agriculture institutions and between specialists in these states and their counterparts in the United States. Should BTRP expand into other geographical areas, collaboration rather than assistance should be a guiding principle whenever possible.

In short, establishing the long-term viability of partnerships at many levels is as important as deriving the products of individual projects. A critical early step in this regard is for BTRP to fully engage partner governments, institutions, and specialists in the selection and design of proposed cooperative activities from the outset. Greater attention should be given to balancing the priorities of partners and of BTRP. BTRP should be flexible so that BTRP activities can be effectively integrated with partner priorities, especially if they are to address major public health goals of both countries. Also, the likelihood of sustainability by partners of activities initiated through BTRP should be considered before projects are undertaken.

Greater attention should also be given to the activities of local and multinational companies that may have interests in collaboration with BTRP. Joint programs should be considered, with partner governments encouraged to provide tax and other incentives to promote such collaboration when they serve the governments' interests. Involvement of

⁵ Benkert, J.A. 2007. Statement for the record by Joseph A. Benkert, principal deputy assistant secretary of defense for global security affairs, to the Senate Committee on Armed Services, Subcommittee on Emerging Threats and Capabilities, April 11, 2007, p. 8-9. Available on-line at <http://armed-services.senate.gov/statemnt/2007/April/Benkert%2004-11-07.pdf>. Accessed June 14, 2007. Since the date when this presentation was made, progress has been made in resolving tax issues in Kazakhstan, according to comments made by BTRP officials to project staff on June 11, 2007.

the private sector would be a clear signal of the moving of the program from an assistance activity to a program based on shared financial as well as scientific interests.

Establishment of BSL-3 Laboratory Capabilities

Returning to the proposed plans for the next few years, which are still in an early formative stage, DOD intends to support construction of CRLs with BSL-3 capabilities throughout the region. About \$250 million is earmarked for this activity. In addition to the CRL currently under construction in Georgia and the CRL planned for Kazakhstan, additional CRLs are planned as follows:

- **Uzbekistan:** BTRP will design and construct a CRL.
- **Ukraine:** BTRP will design and construct a CRL.
- **Azerbaijan:** The partner government will assume responsibility for financing a CRL, with technical assistance provided by BTRP as needed.
- **Kyrgyzstan:** It is anticipated that the Canadian government and the European Union will assume responsibility for financing a CRL, with consideration given to standardization of design and compatibility of systems throughout the region.

The cost of constructing and equipping each CRL is estimated at \$60 million. Maintenance and operating costs will probably be at least \$5 million annually.

BTRP plans to assume responsibility for supporting maintenance and operation of the CRLs that it constructs for five-year “warranty” periods. Continued financing after the end of the five-year period has not yet been adequately addressed. A number of preliminary suggestions have been made including the linking of CRLs with existing or planned field stations of the Centers for Disease Control and Prevention (CDC) or with overseas U.S. Army or Navy medical research units. These connections would both enhance the prestige of the CRLs, which should strengthen the ability of the CRLs to raise funds, and provide the CRLs with direct access to technical and perhaps limited financial support.

With regard to Georgia, the prime minister has requested that DOD and the U.S. Department of Health and Human Services (DHHS) become partners with his government to develop and sustain a CRL near Tbilisi. Presumably, DOD and DHHS would remain permanently involved after termination of BTRP's presence and would provide some level of financial support. One approach would be to use the model of the five existing DOD overseas laboratories. The committee is unaware of a DHHS response to this request as of July 15, 2007.

The CRLs that are being planned have many important attributes—providing a basis for integrating research on different species, linking diagnostics and epidemiology, consolidating and securing strains, and establishing a strong base for cooperative research and for applications of research results. The design that has been developed for the CRLs is state-of-the-art. The CRLs should help move the scientific workforces of the countries where they are established into an era of modern technology. However, the committee has reservations about inclusion of BSL-3 laboratory capabilities in the CRLs.

As noted in Chapter 2, the committee is concerned by the costs of the investments in BSL-3 laboratory capabilities and the associated life-cycle costs. Achieving and

sustaining a BSL-3 capability would account for a large percentage of the construction and operating costs of the CRLs as currently planned. The frequency of use of BSL-3 capabilities may not be sufficiently high to warrant the costs of placing such capabilities in each country. Regional approaches might be more appropriate. In any event, BTRP should document the likely demand for use of BSL-3 laboratories in the region and the potential funding sources that would support such use in the long term. This information would provide an improved basis for determining where such facilities should be located.

Also, the committee is concerned that a CRL with BSL-3 laboratory capability could fall into the hands of an irresponsible government that might emerge within one of the countries in the future. In principle, the facility could become a significant instrument in supporting nefarious activities that ironically promote rather than constrain proliferation of biological weapons. Of course, it could be argued that a determined adversary could carry out dangerous activities in less safe facilities, and therefore there is little risk that the BSL-3 capability will increase the likelihood of hostile activities. However, an adversary having uninhibited access to a BSL-3 laboratory would introduce considerable instability into the region and would certainly raise the perceived biothreat level.

The committee therefore recommends that the U.S. government consider retaining indefinitely partial ownership of any CRL with BSL-3 capability that is established with BTRP support. Such retention of ownership has important implications, as follows:

- The U.S. government will be committed to ensuring that the CRL will operate for the indefinite future and to this end will be obligated to find financial support when needed.
- Thus, the U.S. government will take great care in carrying out the necessary feasibility assessments in advance of construction to document the need for a BSL-3 capability that will serve U.S. as well as local interests, thereby reducing the likelihood that enhanced capabilities will become “white elephants” that are not adequately used.
- As a part owner, the U.S. government should be in a good position to ensure that the BSL-3 capability is not misused even if there are political changes in the country and will be able to advocate precautions against misuse at facilities built by others throughout the region.

There may be alternatives to U.S. ownership such as long-term intergovernmental agreements. However, when financial responsibilities are involved, there is a high level of interest in the future of the facilities that is difficult to match. Whatever the approach that is to be adopted, a detailed blueprint that integrates activities within and across countries in this important area is needed.

Expanding the CBR Program

With the exception of Russia, the number of cooperative research projects in each of the countries where BTRP is currently active is scheduled to increase, according to BTRP plans. But the increase will be modest since the bulk of BTRP funding is to be invested in facility modifications. Some ongoing research projects will probably be extended while new projects are initiated. In general, these projects are to be designed to

support the TADR system, focusing research efforts on those disease agents and syndromes that are relevant to the TADR network.

DOD seems to underestimate the important contributions of well-conceived collaborative research projects to preventing the proliferation of biological weapons, particularly following the BTRP-financed upgrading of research facilities. The percentage of BTRP funds devoted to CBR should be significantly increased. It is the human dimension of a nation's infrastructure, reflected in large measure in its research capabilities, that is the critical determinant in a nation's effort to control dual-use assets while also translating the contributions of BTRP investments into products that will improve health and agriculture systems.

As discussed in Chapter 1, international engagement among researchers working in science, health, and agriculture is central to the global effort to reduce the likelihood of terrorism—whether promoted by facility insiders or initiated by outsiders. Research is a critical component of the approach to preventing proliferation of biological weapons advocated throughout this report. To this end,

BTRP should give greater emphasis to a comprehensive, multifaceted approach to international engagement for achieving biosecurity, public health, and agriculture objectives. The approach should include development of countermeasures to bioterrorism, enhanced facility security, collaborative surveillance activities, expanded cooperative research, development of common biosafety procedures, adoption of good laboratory practices and good manufacturing practices, development of human resources, and related activities.

BTRP seems to recognize the importance of this principle, but needs to increase the support of human resource development to ensure an appropriate balance among the many elements of the comprehensive approach. At the same time, within the interagency process, BTRP should continue to play a key role in U.S. efforts directed to containment of highly dangerous pathogens and associated activities. But BTRP, in cooperation with other U.S. government departments and agencies, also needs to be a strong advocate for and active participant in addressing broader science, health, agriculture, and biosecurity issues.

However, the United States cannot on its own transform the narrow global focus on physical security for enhancing biosecurity to a more comprehensive approach throughout the world. If BTRP makes significant progress in a variety of fields such as good laboratory and good manufacturing approaches, enhanced disease surveillance, and development of common biosafety procedures, its activities should become models for emulation by others—both its immediate partner organizations and other national and international organizations. In this regard, the G-8 Global Partnership can provide an excellent forum for dissemination of BTRP experience.

A critically important aspect of BTRP's research activities is the participation of well-qualified American collaborators who have strong professional interests in the success of projects that are financed. BTRP has expended considerable resources to this end, but the results have been spotty. While a few excellent American collaborators are currently involved in BTRP projects, some projects have had little more than token

collaborators (see, for example, Box 5-1). Collaborators who are U.S. government employees can sometimes devote significant time to collaborative projects if they are of mainstream interest to the American collaborators. But too often, such collaboration is simply an additional assignment of marginal interest to the American scientists. Also, American academics who have been recruited have usually taken on the assignment of collaborators as an added duty, or as a temporary diversion from their primary research interests, rather than as a mainstream activity within their research programs.

Box 5-1

Importance of Collaborators

“American collaborators need to spend extended time in our laboratories.”

Georgian senior scientist, March 2007.

• • •

“High quality American collaborators are very important.”

Russian senior scientist, March 2007.

BTRP increasingly recognizes the importance of strong and committed collaborators and that adequate financial support must be provided to collaborators. As indicated by the new projects identified in Box 5-2, collaborators are now being drawn from a variety of DOD facilities and academic institutions.

Box 5-2

CBR Projects Being Developed as of June 15, 2007

- Mapping Especially Dangerous Pathogens in Azerbaijan (\$150,000). U.S. collaborating organizations: Walter Reed Army Institute of Research (WRAIR) and California State University, Fullerton.
- Clinical, Epidemiologic, and Laboratory-Based Assessment of Brucellosis in Azerbaijan (\$750,000). U.S. collaborating organizations: U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), WRAIR, and Louisiana State University (LSU).
- Clinical, Epidemiologic, and Laboratory-Based Assessment of Brucellosis in Georgia (\$750,000). U.S. collaborating organizations: USAMRIID, WRAIR, and LSU.
- Active Surveillance of Especially Dangerous Pathogens in the Southern Caucasus Region (Georgia) (\$750,000). U.S. collaborating organizations: Armed Forces Institute of Pathology (AFIP) and the Naval Medical Research Center (NMRC).
- Genetic Peculiarities of Strains of Specially Dangerous Zoonotic Pathogens in Kazakhstan (\$750,000). U.S. collaborating organizations: AFIP and NMRC.

The following suggestions are offered to improve the availability and quality of American collaborators:

- For the non-Russian countries where local researchers have had very limited contact with American colleagues, BTRP should adopt the model used by the U.S. Department of Agriculture, and to some extent by the Department of Health and Human Services, which is discussed in Chapter 3. A potential investigator from the region should spend several weeks with a potential American collaborator determining whether they have common interests in specific types of research activities. Only then should BTRP encourage the development of a cooperative research project by the two collaborators. This approach varies from the initial BTRP practice of BTRP staff and contractors developing the research concepts in considerable detail and then trying to find appropriate investigators in the region and collaborators in the United States.

- BTRP should ensure that American collaborators as well as local researchers have access to sufficient funds to enable them to pursue related parallel research efforts. In many cases, a special BTRP funding stream to support American collaborators will be necessary.

- In addition to the matchmaking by BTRP for foreign scientists who do not have contacts in the United States, BTRP should have periodic grant competitions whereby local scientists prepare proposals, in cooperation with potential American collaborators, in response to solicitations on topics of special interest to BTRP. As discussed below, this approach is particularly attractive for Russia. An important aspect of such solicitations could be opportunities at upgraded facilities in the region to jointly investigate pathogen strains that are unique to the region, thereby reducing the need to ship strains across international borders.

The short-term payoffs from investments in research are difficult to measure. But in the longer term they may be the most significant activities that BTRP undertakes in some countries. They should help detect misuse of pathogens and enhance capabilities to respond promptly to incidents resulting from misuse. They should set a standard of ethical approaches to research that contributes to the development of a culture of personal responsibility for biosafety and biosecurity.

The Special Case of Russia

DOD should work through existing scientific networks and establish new models as appropriate to reinvigorate BTRP in Russia by supporting cost-shared collaborative research projects, scientific conferences, and other scientific activities that promote both Russian and U.S. national security interests through engagement of outstanding established and young scientists in the two countries.

Russia, with its vast ecological diversity and a large well-trained scientific workforce, should be a leader in global efforts to prevent, detect, and respond to disease outbreaks whether naturally occurring or deliberately induced. The nation's resources—technologies, materials, and expertise—for addressing dangerous pathogens are vast and should be harnessed for peaceful purposes. Despite the oil windfall, many biological facilities remain in outmoded conditions, and highly talented specialists remain in difficult financial conditions. As the largest U.S. program with relevant experience, BTRP should have a strong outreach program to Russia.

For a number of years, BTRP has played a significant role, within the interagency context, in redirecting important components of the former Biopreparat defense-oriented complex, which was located primarily in Russia, toward the mainstream of national and international non-defense biological research activities. Almost all BTRP activities in Russia are now coming to conclusion. But opportunities for continued scientific engagement that would benefit international science and global security are many fold.

There is considerable interest in Russia in re-establishing cooperation, although important senior health and defense officials do not favor cooperation with elements of DOD. For example, the Federal Biological Medical Agency expressed interest to the committee in 2007, and its specialists then proposed the following agenda of activities:

- Translation of the results of research projects carried out under BTRP into health care practice
- Financial support of projects to develop drugs for protection from dangerous infections
- Collaborative research to create a joint system of biological safety control

Also, a number of prominent Russian specialists have told committee members on numerous occasions that resumption of BTRP cooperation is overdue.

Against this background of benefits to the United States and strong latent interest in Russia, BTRP should reinvigorate its earlier cooperative biological research and related programs, which have almost disappeared in Russia due to a policy change within DOD in the early 2000s that led to termination of funding of new projects. BTRP may have some difficulty persuading potential Russian partners to prepare research proposals for BTRP consideration given the history of DOD's loss of interest in dozens of sound proposals prepared at the request of BTRP. But prompt implementation of a few major research projects should improve receptivity to participation in BTRP.

While DOD has had difficulties in dealing with the Russian government, the country's biological assets within dozens of facilities are too important not to include Russia in future BTRP activities. There are well-established mechanisms for engaging important Russian institutions and specialists in cooperative activities that circumvent the need for formal agreements between DOD and recalcitrant Russian ministries and agencies. Also, a number of approaches to engagement no longer require BTRP's commercial contractors, thereby reducing the need for logistics teams based in Russia.

DOD is reluctant to engage Russia for administrative reasons—lack of an appropriate executive agent and difficulty in working through the International Science and Technology Center. Also, DOD wants Russia to formally request “assistance.” But national security opportunities clearly trump such administrative problems, and it is time that BTRP began to capitalize in a major way on investments it has already made in Russia.

The emphasis should be on jointly funded high-impact research activities of mutual interest. Priority should be given to sustaining research groups with strong scientific capabilities that have emerged as the result of past investments and on commercialization of research products as discussed in Chapter 2. In this way, BTRP can capitalize on its past investments in research in Russia, recognizing that Russia now has stronger technical capabilities than a decade ago and that the Russian need for financial

assistance has diminished. At the same time, effective commercialization activities will not be easy to achieve, as indicated in Box 5-3.

Box 5-3

Protecting Intellectual Property

“In Russia, copyright protection virtually does not work. In rare instances when researchers receive a worthwhile reward for a new drug, it is not a result of a legal mandate or requirement. It is the result of a personal agreement (not legally documented in any way) with the manager (owner) of the manufacturing company or as a result of the inventor’s leverage to control the production flow (in particular, when the inventor can terminate the production at his own volition).”

Russian bioresearch manager, November 2004.

SOURCE: National Research Council. 2006. *Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security*. Washington, D.C.: National Academies Press, p. 26.

As a related step in reviving and retaining Russian and American interest in cooperative research, BTRP should consider supporting periodic international scientific conferences in Russia on infectious diseases of public health importance to both countries, including naturally occurring and intentionally released pathogens. In association with these conferences, workshops could be held on directly related topics including good laboratory practices, biosafety, and biosecurity. Such conferences could provide important windows into activities in Russia. As a reciprocal gesture, DOD might support attendance by Russian specialists at selected microbiology and virology conferences in the United States. Together, these conference venues could stimulate development of joint research activities using funding from a variety of sources.

A new approach involving joint programs between consortia of laboratories in the two countries should also be considered. Such a mechanism, built around common scientific themes, could reduce administrative burdens while engaging larger numbers of participants than in the past. Russia, with its large number of strong institutes, is a good place to initiate such a program.

Beyond the Former Soviet Union

BTRP has no current plans to carry out activities beyond the boundaries of the FSU. At the same time, there is growing concern over the inadequate security conditions in biological facilities in South Asia and other regions as discussed in Chapter 1 and as reflected in the Congressional action concerning limited funding in FY 2008 for BTRP activities beyond the FSU. BTRP should be in a position to respond promptly to a requirement for deployment in new regions if appropriate.

Cutting across all activities and all geographic regions is the expanding role of information technology (IT). As an educational tool, the backbone of surveillance networks, and the facilitator of international partnerships, the IT capabilities of partner institutions will be a critical determinant as to the effectiveness of national, regional, and

global efforts to contain the spread of infectious diseases. BTRP has recognized the importance of IT in the TADR network and should continue to emphasize IT applications in all aspects of the program.

6

Recommendations

Major Recommendations

Six key recommendations included in previous chapters concerning future Biological Threat Reduction Program (BTRP) activities in preventing the proliferation of biological weapons are set forth below. These recommendations build on past BTRP investments and reflect lessons learned during the development and implementation of BTRP. Adoption of these recommendations by the White House and the Department of Defense (DOD) would improve the efficiency of the program and significantly increase the positive impacts of BTRP on national security during the next phase of the program.

The U.S. government should provide strong and sustained support for BTRP and related programs. Past U.S. government investments in BTRP have provided substantial benefits to national security; however, the task of preventing proliferation of biological weapons has just begun. There are many opportunities for future contributions by BTRP, the largest U.S. program for preventing proliferation of biological weapons (see Chapter 2, page 31).

The White House should exert strong leadership to ensure integration of BTRP with related biological threat reduction activities supported by the U.S. government. Other U.S. government departments have unique capabilities and have international partners with similar interests; therefore, they have comparative advantages that should complement the strengths of BTRP in pursuing different types of biological engagement. The interests of many departments are sufficiently important and diverse to warrant coordination at the highest levels. (see Chapter 3, page 54).

BTRP should be transformed from a Washington-directed program of assistance to a genuinely collaborative program of partnerships with governments of the states of the former Soviet Union, built on strong relationships between important scientific, public health, and agriculture institutions and specialists in these states and counterparts in the United States. Should BTRP expand into other geographical areas, collaboration rather than assistance should be a guiding principle whenever possible. Development of true partnerships is essential to maximize the benefits to the United States and partner countries from program activities and to set the stage for sustaining program activities initiated through BTRP. Partnerships help ensure transparency and encourage colleagues to assume responsibility for introducing and maintaining appropriate biosecurity procedures (see Chapter 5, page 69).

BTRP should give greater emphasis to a comprehensive, multifaceted approach to international engagement for achieving biosecurity, public health, and agriculture objectives. The approach should include development of countermeasures to bioterrorism, enhanced facility security, collaborative surveillance activities, expanded cooperative research, development of common biosafety procedures, adoption of good laboratory practices and good manufacturing practices, development of human resources, and related activities. Short-term biosecurity payoffs will result from enhanced physical security systems. However, investments in the human resources infrastructure will be even more important not only in enhancing capabilities to respond promptly to and diagnose the nature of

outbreaks, but also in spreading a culture of responsible behavior by researchers throughout the world. The involvement of key U.S. facilities and personnel in BTRP programs is a unique opportunity to achieve multiplier effects through other programs (see Chapter 5, page 72).

DOD should work through existing scientific networks and establish new models as appropriate to reinvigorate BTRP in Russia by supporting cost-shared collaborative research projects, scientific conferences, and other scientific activities that promote both Russian and U.S. national security interests through engagement of outstanding established and young scientists in the two countries. To this end, a competitive grants program funded by BTRP that initially emphasizes collaborative projects sited in Russia and then expands to other countries should be considered.

The biological assets of Russia, a country spanning a large portion of the earth's land mass, are too important not to include them in future BTRP activities, using well-established mechanisms for engagement that circumvent the need for formal agreements with recalcitrant Russian ministries. The benefits of engaging Russian scientists have been repeatedly demonstrated through BTRP and related programs and the challenge is to regain lost program momentum by using a variety of approaches to scientific engagement that are acceptable in Russia (see Chapter 5, page 74).

To improve program management, DOD/DTRA should ensure availability of adequate internal technical staffing for BTRP and should recognize that while there is a need for commercial integrating contractors for construction projects, assistance in management of research projects and related training programs can be more appropriately provided by government, academic, or nonprofit organizations. Strengthened internal BTRP staff capabilities are essential to reduce the outsourcing to commercial contractors of contacts with important foreign participants and of key technical judgments about program directions and program results. Excessive outsourcing of activities to contractors has led to misunderstandings and has raised concerns within the United States and abroad over costs, quality, and U.S. motivations for BTRP (see Chapter 4, page 64 through 65).

Additional Priority Recommendations

The following six issues are directly related to the major recommendations set forth above, and they warrant priority attention for BTRP programming (page number is cited with each):

1. *Collaborative development of a country science plan for each country where BTRP has activities.* The plan should provide a shared vision of the goals of the program and a framework for activities that reflect priority interests of partner governments as well as achievement of BTRP objectives (page 40).

2. *Joint strategic planning for proposed national central reference laboratories (CRLs), which may cost \$60 million each to build and equip.* The laboratories should provide services of importance for improvement of public health and agriculture that are not only cost effective but also outweigh the possibility that the facilities might be misused due to unanticipated political developments in the region (page 40).

3. *An early region-wide evaluation of the health and agriculture benefits of the Threat Agent Detection and Response (TADR) network that is being established initially in Georgia to help ensure that similar BTRP investments in other countries are well targeted and result in discernible benefits that will encourage future local investments.* Of special importance is the eventual integration of the TADR network with existing national and regional surveillance networks within the participating countries (page 40).

4. *Joint programs to ensure that important pathogen strains that can be obtained within the region are available at local facilities to international investigators.* This availability will reduce the need for controversial transfers of such strains to the United States that raise questions over BTRP objectives (pages 40 through 41).

5. *Inclusion in the authorizing legislation for BTRP of an explicit provision that helps ensure that BTRP will engage other U.S. government departments with specialized expertise and experience in BTRP activities as appropriate and provide them with the financial resources to this end when necessary* (page 41).

6. *A competitive research grants program funded by BTRP that initially emphasizes projects sited in Russia and then expands to other countries of interest.* The emphasis should be on high impact research activities jointly funded with foreign partners (pages 74 through 75).

Other Recommendations

The previous chapters identify a large number of other activities that deserve greater support by BTRP, other departments and agencies, and foreign partners in the future. They are very briefly summarized as follows (page number is cited with each):

Security Upgrades at Facilities (Physical Systems and Personnel)

- Realistic less-than-perfect physical security systems (page 64)
- Detailed on-the-ground facility assessments (page 34)
- Selection of facilities for upgrades based on both security vulnerabilities and importance in national biological activities (page 23)
- Competition among facilities for selection for BTRP upgrades (page 60)
- Expert assessments of strain consolidation (pages 34 through 35)
- Greater counterpart management responsibilities for facility upgrading (page 61)
- Timely training of personnel for utilization of upgraded facilities (page 36)
- Improving, but not ignoring, previous security training of counterparts (page 34)

TADR

- Expanding the list of disease agents of interest to TADR (page 35)
- Country-by-country studies of TADR benefits (pages 35 through 36)
- Reducing the likelihood of false alarms in the TADR network (page 36)
- Partial U.S. ownership of CRLs (page 71)

Cooperative Research

- Continued focus on applied research programs supported by BTRP (page 40)
- Increased percentage of BTRP research funds for foreign partners (page 38)
- Greater emphasis on supporting non-weapon scientists (page 61)
- Improved quality of research proposals (page 63)
- Linking strong and weak local research groups (page 56)
- Access to information on local pathogen collections (page 63)
- Early attention to animal welfare issues (pages 62 through 63)
- Improved understanding by counterparts of intellectual property rights (page 63)
- Instruction by American academics in research management (page 65)
- BTRP adoption of USDA collaborator model (page 74)
- BTRP financial support of American collaborators (page 74)
- Cooperation between U.S. and Russian consortia of research laboratories (page 76)
- BTRP outreach to U.S. scientific community (page 58)
- Flow of results of nonproliferation research programs to other U.S. programs (page 45)

Interagency Coordination

- National Security Council-led working group on biological security and nonproliferation (pages 53 through 54)
- Annual interagency report of biological nonproliferation programs (page 53)

Assessments and Studies

- Improved use of metrics (page 62)
- More intensive evaluations of BTRP (page 12)
- Adoption of public health “needs assessments” methodology (page 35)
- Assessments of vulnerabilities of potential interest to hostile groups (pages 55 through 56)
- Documentation of achievements of non-proliferation programs (page 45)
- Studies of relevant foreign assistance programs and programs of international organizations (page 12)

Administrative Issues

- Need to augment BTRP staff (page 65)

- Visa delays (page 63)
- Reducing delays and misunderstandings during DOD approval and implementation procedures (pages 63 through 64)

Other

- G-8 global partnership as a forum for dissemination of BTRP experience (page 72)
- Clarification of BTRP objectives for program participants (pages 59 through 60)
- Involvement of younger counterpart scientists and students in BTRP (page 60)
- BTRP cooperation with private companies (pages 69 through 70)
- BTRP support of information technology networks (pages 76 through 77)

A First Step Toward Global Engagement in the Biosciences and Biotechnology

As biotechnology capabilities continue to spread throughout the world, opportunities for misuse of biology that can seriously harm U.S. interests at home and abroad are rapidly growing. Of course, current U.S. government programs for redirecting former weapon scientists in the former Soviet Union to peaceful pursuits and for upgrading the security of facilities in that region and elsewhere which house dangerous pathogen strains are very important. But they are only a beginning. Potential problems associated with the spread of dual-use technologies are so widespread that global engagement which enhances transparency and promotes common interests in preventing diseases on a broad basis is essential.

To this end, BTRP can and should play a central role in supporting development of international networks of institutions and specialists with common interests in biological research, public health, agriculture, and biosecurity. They are an essential mechanism in building trust among governments engaged in activities with dual-use dimensions and in providing insights as to intentions of colleagues at the facility level.

In short, U.S. security interests can be served in many ways by a robust and broadly based BTRP approach.

Appendix A

National Research Council

Committee on Prevention of Proliferation of Biological Weapons

Dr. David R. Franz, Chair

David R. Franz is vice president of the Chemical and Biological Defense Division of the Midwest Research Institute. He served in the U.S. Army Medical Research and Materiel Command for 23 of his 27 years on active military duty. Dr. Franz has served as both deputy commander and then commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and as deputy commander of the U.S. Army Medical Research and Materiel Command. Prior to joining the Command, he served as group veterinarian for the 10th Special Forces Group (Airborne). Dr. Franz served as chief inspector on three United Nations Special Commission biological warfare inspection missions to Iraq, and as technical advisor on long-term monitoring. He served as a member of the first two US/UK teams that visited Russia in support of the Trilateral Joint Statement on Biological Weapons and as a member of the Trilateral Experts Committee for biological weapons negotiations. He also serves as chair of the NRC Committee to Review Proposals from Former Soviet Biological Weapons Institutes, co-chair of the NRC Committee on Protecting Occupants of DOD Buildings from Chemical or Biological Release, and a member of the Committee on International Security and Arms Control of the National Academies.

Dr. Gail H. Cassell

Gail H. Cassell is currently vice president for scientific affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company in Indianapolis. She is the former Charles H. McCauley Professor and chairman of the Department of Microbiology at the University of Alabama School of Medicine and Dentistry at Birmingham. She obtained her B.S. from the University of Alabama at Birmingham and was selected as its 2003 Distinguished Alumnus.

She is a past president of the American Society for Microbiology. She was a member of the National Institutes of Health Director's Advisory Committee and a member of the Advisory Council of the National Institute of Allergy and Infectious Diseases. She was named to the original Board of Scientific Councilors of the Center for Infectious Diseases, Centers for Disease Control and Prevention, and served as chair of the board. She recently served a three-year term on the Advisory Board of the Director of the Centers for Disease Control and Prevention and is a member of the Secretary of Health and Human Services Advisory Council on Public Health Preparedness. Currently she is a member of the Science Board of the Food and Drug Administration. 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. She has served on several editorial boards of scientific journals and has authored over 250

articles and book chapters. Dr. Cassell has received national and international awards and an honorary degree for her research in infectious diseases. She is a member of the Institute of Medicine (IOM) of the National Academies and is currently serving on the IOM Council.

Dr. Cassell has been intimately involved in establishment of science policy and legislation related to biomedical research and public health. For nine years she was chairman of the Public and Scientific Affairs Board of the American Society for Microbiology, has served as an advisor on infectious diseases and indirect costs of research to the White House Office of Science and Technology Policy, and has been an invited participant in numerous Congressional hearings and briefings related to infectious diseases, anti-microbial resistance, and biomedical research. She has served two terms on the Liaison Committee on Medical Education, the accrediting body for U.S. medical schools. She has just completed a term on the Leadership Council of the School of Public Health of Harvard University. Currently she is a member of the Executive Committee of the Board of Visitors of Columbia University School of Medicine and is a member of the Board of Directors of the Burroughs Wellcome Fund, the Executive Committee of the Board of Research!America, and the Advisory Council of the School of Nursing of Johns Hopkins University.

Dr. Timothy Endy

Timothy Endy, associate professor of medicine at the State University of New York, Upstate Medical University, received his master's degree in public health from the University of Michigan in 1982 and his MD in 1986 from the Uniformed Services University. He performed his internship and residency in internal medicine and a fellowship in infectious diseases at the Walter Reed Army Medical Center from 1986-1995, subsequently serving as a specialist in virology and emerging diseases in the United States Army Military Component in Bangkok, Thailand, from 1996-2001. Upon his return to the United States, Dr. Endy served in the Department of Virology at the U.S. Army Medical Research Institute of Infectious Diseases. From July 2003 until his retirement at the rank of colonel in 2006, Dr. Endy served as the 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.

Dr. James W. LeDuc

James W. LeDuc is director of the Program on Global Health, Institute for Human Infections and Immunity, University of Texas Medical Branch Galveston. Prior to assuming this post in November 2006, Dr. LeDuc was director of the Division of Viral and Rickettsial Diseases at the Centers for Disease Control and Prevention, where he coordinated research activities, prevention initiatives, and outbreak investigations for pathogens that cause viral hemorrhagic fevers, influenza and other respiratory infections, childhood viral diseases, and newly emerging diseases such as SARS. He served as the associate director for global health from 1996 to 2000 in the Office of the Director, National Center for Infectious Diseases, and was a medical officer in charge of arboviruses and viral hemorrhagic fevers at the World Health Organization in Geneva, Switzerland, from 1992 to 1996. He also held leadership positions during a 23-year career as a

U.S. Army officer in the Medical Research and Materiel Command, with assignments in Brazil, Panama, and in the United States, including the Walter Reed Army Medical Center and the U.S. Army Medical Research Institute of Infectious Diseases. He is a fellow of the American College of Epidemiology and has received numerous awards for his work in epidemiology. Dr. LeDuc currently serves on the NRC Committee to Review Proposals from Former Soviet Biological Weapons Institutes and has been a member of three previous NRC committees.

Dr. Russ Zajtchuk

Russ Zajtchuk, a national expert in telemedicine, is currently president of Chicago Hospitals International. For more than 27 years, Dr. Zajtchuk served in various positions in the U.S. Army, most recently as commanding general of the Army Medical Research and Materiel Command at Fort Detrick, MD, where he led development of a sophisticated telecommunications infrastructure to speed diagnostics, lab analyses, and consulting expertise worldwide. Zajtchuk is a cardiovascular surgeon who was professor and chairman of the division of cardiothoracic surgery at the Uniformed Services University of the Health Sciences. He also served as assistant surgeon general for research and development for the Department of the Army, and as chief operating officer for the Department of Defense telemedicine test-bed. Dr. Zajtchuk currently serves on the NRC Committee to Review Proposals from Former Soviet Biological Weapons Institutes and the NRC Committee on Counterterrorism Challenges for Russia and the United States and previously served on the NRC Committee on Future Contributions of the Biosciences to Public Health, Agriculture, Basic Research, Counter-terrorism, and Non-Proliferation Activities in Russia.

Appendix B

Extracts from Recent National Research Council Reports

Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security (2005)

This report sets forth four key themes, or pillars, for countering infectious diseases in Russia. They represent the committee's view of priority areas for development over time.

Four Pillars for Countering Infectious Diseases

Pillar One: Improving Surveillance and Response

- Establish two model State Sanitary Epidemiological Surveillance Centers for surveillance, diagnosis, analysis, and communication of information concerning infectious disease episodes.
- Integrate Russia's anti-plague network fully into the national public health surveillance system and then into global systems.

Pillar Two: Meeting Pathogen Research Challenges

- Concentrate financial support at carefully selected research groups that are, or have the potential to become, centers of scientific excellence.
- Upgrade laboratory facilities and equipment for appropriate infectious disease-related research at selected laboratories throughout the country.

Pillar Three: The Promise of Biotechnology

- Develop a business environment that encourages investment in biotechnology activities in Russia.
- Promote investment in biotechnology niches that are well suited for activities based in Russia.

Pillar Four: The Human Resource Base

- Encourage postdoctoral scientists to remain in Russia as practicing scientists through mentoring programs that prepare them for positions of leadership in various fields that support the control of infectious diseases.
- Continuously expand the professional competence of specialists in fields related to infectious disease, particularly enhancing their ability to address multidisciplinary challenges through advanced training programs.

Modifying the Approach to Bilateral Cooperation

- Establish a bilateral U.S.-Russian intergovernmental commission on the prevention and control of infectious diseases.
- Complete the integration of former Soviet biodefense facilities that are no longer involved in defense activities into the civilian research and production infrastructure of the country.
- Focus U.S. and other Western programs on establishing true partnerships in Russia.



Letter Report on the Threat Agent Detection and Response (TADR) System Database (2006)

Challenges

1. The data collection and processing technology is complex.
2. Three sets of reporting requirements should be integrated into a single system.
3. Stable funding will be difficult to ensure.
4. Recruitment, training, and retention of personnel capable of operating the TADR network will be a constant concern.
5. Governments are already apprehensive over the possibility of U.S. control of all data.
6. Full compliance in providing “all” required data to the General Data Repository (GDR) will be difficult.
7. The selection of a location or locations for the GDR in the United States is critical.
8. Review of large quantities of raw data transmitted to the GDR in the United States—starting from the initial report of a disease occurrence by a clinician through laboratory analyses of both suspected pathogens and human and animal tissue samples—would probably result in many false alarms.
9. Effective integration of human and animal disease surveillance, reference diagnostics, and reporting activities will be difficult, both in the host countries and in the United States.

Significant Conclusions

Given the foregoing observations, we offer the following conclusions on three key aspects of the TADR network prior to turning to specific recommendations.

1. The TADR network is well designed to support the U.S. government’s strategy for strengthening Biological Weapons Convention (BWC) compliance while also supporting the mission of the Department of Defense (DOD) more broadly.
2. Sustainability of the TADR network after the Defense Threat Reduction Agency (DTRA) completes its participation in the program is critical.
3. An essential element of sustainability is the broadening of the focus of the network from the 16 agents, classes of agents, and diseases of primary interest to DOD for proliferation reasons.

Recommendations

1. A single GDR should be located at the Centers for Disease Control and Prevention (CDC).
2. An important recipient of data from CDC should be the Centers for Epidemiology and Animal Health of the Veterinary Services of the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) in Fort Collins, Colorado.
3. A U.S. government organization should not be the primary entity for sending information from the TADR network to international organizations.
4. Although the TADR network is currently being installed in several countries, DTRA should select one country as a site for evaluation of a country-wide network as soon as possible.
5. A feasible mechanism for addressing these questions would be a conference to be held 12 to 18 months from now, when the TADR network should be sufficiently well established in at least one country to permit evaluation.

Appendix C

Relevant Reports by the National Academies

- Globalization, Biosecurity, and the Future of the Life Sciences*. Development, Security, and Cooperation, Board on Global Health, 2006
- Overcoming Challenges to Develop Countermeasures Against Aerosolized Bioterrorism Agents: Appropriate Use of Animal Models*. Board on Life Sciences, Institute for Laboratory Animal Research, 2006.
- An International Perspective on Advancing Technologies and Strategies for Managing Dual-Use Risks: A Report of a Workshop*. Board on Global Health, Development, Security, and Cooperation, 2005.
- Biotechnology Research in an Age of Terrorism*. Development, Security, and Cooperation, 2004.
- Learning from SARS: Preparing for the Next Disease Outbreak: Workshop Summary*. Board on Global Health, Institute of Medicine, 2004.
- Seeking Security: Pathogens, Open Access, and Genome Databases*, Board on Life Sciences, 2004.
- Countering Agricultural Bioterrorism*, Board on Life Sciences, Board on Agriculture and Natural Resources, 2003.
- Microbial Threats to Health: Emergence, Detection, and Response*, Board on Global Health, Institute of Medicine, 2003.
- The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment: Workshop Summary*, Board on Global Health, Institute of Medicine, 2003.
- Biological Threats and Terrorism: Assessing the Science and Response Capabilities*, Institute of Medicine, 2002.
- Assessment of Future Scientific Needs for Live Variola Virus*, Institute of Medicine, 1999.
- America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests*, Institute of Medicine, 1997.

Controlling Dangerous Pathogens: A Blueprint for U.S.-Russian Cooperation, A Report to the Cooperative Threat Reduction Program of the U.S. Department of Defense, National Research Council, 1997.

Emerging Infections: Microbial Threats to Health, Institute of Medicine, 1992.

Appendix D

Relevant Recent Reports by the U.S. Government Accountability Office¹

Cooperative Threat Reduction: DOD Has Improved Its Management and Internal Controls, but Challenges Remain (GAO-05-329, June 2005)

Weapons of Mass Destruction: Nonproliferation Programs Need Better Integration (GAO-05-157, January 2005)

Weapons of Mass Destruction: Observations on U.S. Threat Reduction and Nonproliferation Programs in Russia. Statement of Joseph A. Christoff, Director, International Affairs and Trade (GAO-03-526T, March 2003)

Weapons of Mass Destruction: Additional Russian Cooperation Needed to Facilitate U.S. Efforts to Improve Security at Russian Sites (GAO-03-482, March 2003)

Weapons of Mass Destruction: State Department Oversight of Science Centers Program (GAO-01-582, May 2001)

Biological Weapons: Effort to Reduce Former Soviet Threat Offers Benefits, Poses New Risks (GAO/NSIAD-00-138, April 2000)

¹ Reports available on line at <http://www.gao.gov>.

Appendix E

Other Reports of Interest

Reports of the Department of Defense

- U.S. Department of Defense. 2006. Georgia Country Science Plan. Defense Threat Reduction Agency, Biological Threat Reduction Program (December).
- U.S. Department of Defense. 2006. Kazakhstan Country Science Plan. Defense Threat Reduction Agency, Biological Threat Reduction Program (December).
- U.S. Department of Defense. 2006. Uzbekistan Country Science Plan. Defense Threat Reduction Agency, Biological Threat Reduction Program (December).
- U.S. Department of Defense. 2002. Cooperative Threat Reduction Annual Report to Congress FY 2002. Cooperative Threat Reduction Program.
- U.S. Department of Defense. 2003. Cooperative Threat Reduction Annual Report to Congress FY 2003. Cooperative Threat Reduction Program.
- U.S. Department of Defense. 2004. Cooperative Threat Reduction Annual Report to Congress FY 2004. Cooperative Threat Reduction Program.
- U.S. Department of Defense. 2005. Cooperative Threat Reduction Annual Report to Congress FY 2005. Cooperative Threat Reduction Program.
- U.S. Department of Defense. 2006. Cooperative Threat Reduction Annual Report to Congress FY 2006. Cooperative Threat Reduction Program.
- U.S. Department of Defense. 2007. Cooperative Threat Reduction Annual Report to Congress FY 2007. Cooperative Threat Reduction Program.

Other U.S. Government Reports

- Centers for Disease Control and Prevention (CDC). Undated. CDC Requirements for Electronic Integrated Disease Surveillance System (EIDSS), Communications & Information Technology (C&IT) Integrated Product Team (IPT)
- U.S. Department of Agriculture. 2004. Proceedings from the USDA-ARS Former Soviet Union (FSU) Scientific Cooperation Workshop, May 4-5, 2004. Office of International Research Programs.

U.S. Department of Health and Human Services. 2007. Strategy for Fiscal Years 2007 and 2008 for the Biotechnology Engagement Program. Office of Europe and Eurasia, Office of Health Programs, Office of the Secretary.

U.S. Department of State. 2006. Biotechnology Russia 2006. Bio Industry Initiative.

U.S. Department of State. 2006. Biotechnology Ukraine 2006. Bio Industry Initiative and Science and Technology Center in Ukraine.

Other Reports

Franz, D. and Hamlet, M. 2004. Trip report regarding their visit to former Russian weapons labs, May 2004.

Williams, I. and Luongo, K. 2007 Analysis of the Department of Energy's fiscal year 2008 International Nonproliferation Budget Request. Partnership for Global Security (February).

Appendix F

Research Projects Supported under the Cooperative Biological Research Program (1999-present)

	Title	Budget	Investigators	Former Soviet Union institute/ location
Russia: Active Projects				
ISTC #1638	Combinatorial Antibody Libraries to Orthopoxviruses	\$118,646.00	Alexander Ilyichev	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #1987	Conservation of Genetic Material and Study of Genomic Structure of Different Variola Virus Strains	\$668,456.00	Sergei Shchelkunov	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #1989	Search for Antivirals for Treating and Prevention of Orthopoxviral Infections Including Smallpox	\$716,687.00	Evgeny Belanov	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #2129	Magnetometric Immunosensor for Multi-pathogen Continuous Monitoring	\$496,906	Peter Sveshnikov	Research Center of Molecular Diagnostics and Therapy, Moscow
Total		\$2,000,695.00		
Russia: Completed Projects				
ISTC #884	Genome of Monkeypox virus	\$362,880	Sergei Shchelkunov	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #919	Investigation of the immunological effectiveness of delivery <i>in vivo</i> of the Brucella main outer membrane protein by the Anthrax Toxin components	\$108,016.00	Anatoly Noskov	State Research Center for Applied Microbiology, Obolensk

ISTC #1176	Development of Methods for Therapy of Chronic Melioidosis with Burkholderia Specific Immunogens	\$1,059,785.00	Igor Kalachev	State Research Center for Applied Microbiology, Obolensk
ISTC #1197	Study of the Role of <i>Yersinia pestis</i> Lipopolysaccharides (LPS) Structural Organization in the Development of Immune Preparations	\$943,408.00	Andrei Anisimov	State Research Center for Applied Microbiology, Obolensk
ISTC #1198	Experimental Study of Antiviral Activity of Glycyrrhizic Acid Derivatives against Marburg and Ebola Viruses	\$525,365.00	Andrey Pokrovsky	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #1487	A Sampler for the Detection and Express Identification of Airborne Microorganisms	\$680,000.00	Alexander Tolchinsky	Research Center for Toxicology and Hygienic Regulations of Biopreparations, Serpukhov
ISTC #1215	Monitoring of Anthrax Infection	\$455,000	Nikolai Staritsyn	State Research Center for Applied Microbiology, Obolensk
ISTC #1233	Development of Immunofiltration and Immunoenzyme Express Diagnostic Test-Kits for the Determination of Infectious Diseases	\$972,354.00	Peter Sveshnikov	Research Center of Molecular Diagnostics and Therapy, Moscow
ISTC #1291	Study of the Genomic Structure of Crimean-Congo Hemorrhagic Fever Virus Isolates Circulating in the Southern Regions of NIS Countries	\$604,645.00	Vladimir Petrov	State Research Center for Virology and Biotechnology (Vector), Koltsovo
ISTC #1515	Development of Liposomal Forms of Specific Immunoglobulins A for Urgent Prophylaxis and Treatment of Highly Dangerous Infections	\$678,251.00	Alexander Ischenko	State Research Institute of Highly Pure Biopreparations, St. Petersburg

ISTC #1813	Design of Experimental Aerosol DNA-Vaccine Preparation against Hantaviral Infection	\$599,000.00	Felix Filatov	Research Center for Toxicology and Hygienic Regulations of Biopreparations, Serpukhov
		\$6,988,704.00		
		\$8,989,399.00		
Non-Russia				
Georgia: Active Projects				
GG-1	Ecology, Genetic Clustering, and Virulence of Yersinia Pestis Strains Isolated for Natural Foci of Plague in Georgia	\$850,796.00	Lela Bakanidze	National Center for Disease Control, Tbilisi
GG-13	Isolation, Distribution, and Biodiversity of Selected Bacteriophages and Their Bacteriophages from Aquatic Environments in Georgia	\$673,614.00	Marina Tediashvili	Eliava Institute for Bacteriophage, Microbiology and Virology, Tbilisi
Georgia: Projects Under Development				
GG-17	Clinical, Epidemiologic and Laboratory Based Assessment of Brucellosis in Georgia	\$750,000	Marine Nikolaishvili	Laboratory of the Ministry of Agriculture, Tbilisi; National Center for Disease Control, Tbilisi
GG-18	Active Surveillance of Especially Dangerous Pathogens in the Southern Caucasus Region	\$750,000	Lela Bakanidze	National Center for Disease Control, Tbilisi
		\$3,024,410		
Kazakhstan: Active Projects				
KZ-1	Ecological and Socio-Economic Factors of Anthrax Foci Activity and Improvement of its Diagnosis and Prophylaxis in Kazakhstan	\$599,556.40	Alim Aikimbayev	Kazakh Scientific Center for Quarantine and Zoonotic Diseases, Almaty

KZ-2	Ecology of Brucella biotypes within Southern Kazakhstan	\$1,500,900.00	Stanislav Kazakov	Republic Sanitary Epidemiological Station, Almaty
KZ-4	Epidemiology of Crimean-Congo Hemorrhagic Fever and Hemorrhagic Fever with Renal Syndrome in the Republic of Kazakhstan	\$618,917.28	Bolat Ospanov	Kazakh Scientific Center for Quarantine and Zoonotic Diseases, Almaty
Kazakhstan: Projects Approved				
KZ-16	Research on a New Highly Immunogenic Strain from Francisella Tularensis, Subspecies Mediaasiatica, a Candidate for Human Vaccine	\$550,000.00	Alim Aikimbayev	Kazakh Scientific Center for Quarantine and Zoonotic Diseases, Almaty
KZ-27	Epizootological Monitoring and Biological Characterization of the Avian Influenza Virus	\$1,084,000	Zhailaubay Kydyrbayev	The Republic National Governmental Enterprise "Research Institute for Biological Safety Problems" Otar
Kazakhstan: Projects Under Development				
KZ-28	Genetic Peculiarities of Strains of Especially Dangerous Zoonotic Pathogens	\$750,000	Tleuli I. Tugambaev	M. Aikimbaev's Kazakh Science Center for Quarantine and Zoonotic Diseases, Almaty; National Center of Monitoring, Reference, Laboratory Diagnosing and Methodology in Veterinary Medicine, Astana
		\$4,019,374		
Uzbekistan: Active Projects				
UZ-1	Epizootological, Epidemiological Monitoring in the Republic of Uzbekistan	\$1,278,143.02	Aminjon Nematov	Uzbek Center for Prevention and Quarantine of the Most Hazardous Infections, Tashkent
UZ-2	Viral Diagnostics in Uzbekistan	\$951,221.03	Saida Alakbarova	Institute of Virology, Tashkent

UZ-4	Epidemiological Surveillance of Human and Animal Brucellosis in the Republic of Uzbekistan	\$786,082.88	Ulugbek Imomaliev	Republican Institute of Epidemiology, Microbiology and Infectious Diseases, Tashkent
Uzbekistan: Approved				
UZ-10	Ecological and Virological Study of Arbovirus Infections in the South Aral Region of Uzbekistan	\$805,118.00	Nematullo Komilov	Research Institute of Virology, Ministry of Health, Republic of Uzbekistan, Tashkent
Uzbekistan: Projects Under Development				
UZ-VOZ	A Comprehensive Epizootological Study of Vozrozhdenie Island in the Aral Sea	\$600,000.00	Aminjon Nematov	Uzbek Center for Prevention and Quarantine of the Most Hazardous Infections, Tashkent
		\$4,420,564.93		
Azerbaijan: Active Projects				
AJ-1				
Azerbaijan: Projects Under Development				
AJ-2	Clinical, Epidemiologic, and Laboratory Based Assessment of Brucellosis in Azerbaijan	\$750,000	Shair Gurbanov	Republican Antiplague Station, Baku
AJ-3	Mapping Especially Dangerous Pathogens in Azerbaijan	\$150,000	Faig H. Mamedzadeh	Republican Antiplague Station, Baku
Total Azerbaijan:		\$900,000		
Total Non-Russia:		\$12,364,348.61		
CBR Program Grand Total:		\$21,353,747.61		

Appendix G

Agenda

**Committee on the Prevention of Proliferation of Biological Weapons
Preliminary Committee Meeting
Keck Center, Room 204, 500 Fifth Street, NW, Washington, D.C.
February 7, 2007**

9:00-12:00. Very brief overviews of programs, lessons learned, and suggestions for the future

- Andrew Weber, Adviser, Cooperative Threat Reduction, Department of Defense
- Jason Rao, Director, BioIndustry Initiative, Department of State
- Indongesit Essiet-Gibson, BTEP Government Program Manager, Department of Health and Human Services
- Melanie Peterson, International Affairs Specialist, Office of International Research Programs, U.S. Department of Agriculture
- Peter Green, GIPP Operations, National Nuclear Security Administration, Department of Energy
- Albes Gaona, International Affairs Specialist, Environmental Protection Agency

12:00-1:00 General discussion of Department/Agency experiences

1:00-2:00 Lunch

2:00-3:30. Other presentations on lessons learned and suggestions for the future

- Linda Trocki, Project Manager, BTRP, Bechtel
- Greg Mann/Walter McVey, Project Managers, Joint University Partnership, Penn State/New Mexico University
- Leonard Specter, Deputy Director (Washington, DC), Monterey Institute of International Studies
- Richard Bohne, Business Development Manager, Raytheon Technical Services Company
- Chris Robinson, Director, Nonproliferation Programs, U.S. Civilian Research & Development Foundation (CRDF)
- Jennifer Runyon, Assistant Director for Operations and Membership, International Council for the Life Sciences, Nuclear Threat Initiative

3:30-4:00 General discussion of experiences of presenters

Appendix H

Foreign Colleagues Who Participated in Discussions of BTRP in Garmisch, Germany (April 2007)

Azerbaijan

Abdullayev, Rakif; Republic Anti-Plague Station
Abdullayev, Rahib; Republic Veterinary Service
Aghamaliyeva, Aytan; Azerbaijan Medical University, Ministry of Health
Aslanov, Elman; Republic Veterinary Laboratory
Gurbanov, Shair; Republic Anti-Plague Station
Ismayilova, Rita; Republic Anti-Plague Station
Jahanov, Musa; Republic Anti-Plague Station
Mammadii, Fuad; Republic Anti-Plague Station
Mammazada, Faig; Republic Anti-Plague Station
Orujov, Abuzar; Republic Veterinary Laboratory
Sansyzbay, Abylay; Research Institute of Veterinary Medicine
Seyidov, Agil; Ministry of Defense
Seyidova, Esmiralda; Republic Anti-Plague Station

Georgia

Adamia, Revaz; Eliava Institute of Bacteriophage, Microbiology, and Virology
Bakanidze, Lela; National Center for Disease Control
Chkeidze, Gvantsa; Ministry of Agriculture
Didebulidze, Aklexander; Ministry of Education
Ghvinjilia, Marina; Laboratory of the Ministry of Agriculture
Imnadze, Paata, National Center for Disease Control
Janelidze, Nino; Eliava Institute
Jaoshvili, George; Center for Monitoring and Prognosis
Jugeli, Levan; Ministry of Labor, Health, and Social Affairs
Kokashvili, Tamar; Eliava Institute
Kutateladze, Mzia; Eliava Institute
Maglakelidze, Jambul; Laboratory of Ministry of Agriculture
Metopishvili, Elza; Ministry of Defense
Onashvili, Tinatin; Laboratory of Ministry of Agriculture
Solomonias, Revaz; Institute of Physiology
Tediashvili, Marina; Eliava Institute
Trapaidze, Nino; National Center for Disease Control
Tsanava, Shota; National Center for Disease Control
Tsertsvadze, Nikoloz; National Center for Disease Control

Kazakhstan

Aikimbayev, Alim; M. Aikimbayev Scientific Center for Quarantine and Zoonotic Diseases
Atshabar, Bakyt; M. Aikimbayev Center
Davletbekova, Taty; Research Institute for Biological Safety Problems
Grushina, Tamara; M. Aikimbayev Center
Izvekov, Igor, M. Aikimbayev Center
Kazakov, Stanislav; Republic Sanitary Epidemiology Station
Kunitsa, Tatyana; M. Aikimbayev Center
Kydyrbayev, Zhailaubay; Research Institute for Biological Safety Problems
Lukhnova, Larissa; M. Aikimbayev Center
Maikanov, Nurbek; M. Aikimbayev Center
Mamadaliyev, Seidigapbar; Research Institute for Biological Safety Problems
Mikhalev, Alexandr; Research Institute of Veterinary Medicine
Mizanbayeva, Sulushash; Republic Sanitary Epidemiology Station
Neizer, Valery; Republic Sanitary Epidemiology Station
Ospanov, Bolat; M. Aikimbayev Center
Pazylov, Yerlan; M. Aikimbayev Center
Sultanov, Akhmetzhan; Veterinary Department of Ministry of Agriculture
Tassynov, Talgat; Research Institute for Biological Safety Problems
Temiraliyeva, Gulnara; M. Aikimbayev Center
Temirgaliyeva, Aigul; Ministry of Health
Ten, Viktor; Research Institute of Veterinary Medicine
Troitskiy, Yevgeniy; Research Institute for Biological Safety Problems
Tursunkolov, Shakhaidar; National Center of Monitoring, Reference, Laboratory Diagnosis, and Methodology in Veterinary Medicine (NVC)
Yedygenov, Alet; National Center in Veterinary Medicine (NVC)
Yespembetov, Bolat; National Center in Veterinary Medicine (NVC)

Russia

Cherkasov, Vladimir; Research Center of Molecular Diagnostics and Therapy
Sveshnikov, Peter; Research Center of Molecular Diagnostics and Therapy

Ukraine

Abramov, Artur; Central State Laboratory of Veterinary Medicine of Ministry of Agriculture
Khaytovych, Oleksandr; Crimea Anti-Plague Station
Kutsan, Oleksandr; Institute of Experimental and Clinical Veterinary Medicine
Lozynskyy, Ihor; Lviv State Research Institute of Epidemiology and Hygiene
Mogilevskyy, Lev; Mechnikov Anti-Plague Research Institute
Nekrasova, Lyubov; Central Sanitary Epidemiology Station

Svyta, Viktor; Central Sanitary Epidemiology Station
Tarasyuk, Oleksandra; Lviv State Research Institute of Epidemiology and Hygiene
Ushkalov, Valeriy; State Scientific-Control Institute of Biotechnology and Strains of
Micro-organisms
Volyansky, Andriy; Mechnikov Anti-Plague Research Institute

Uzbekistan

Ismatova, Rano; Veterinary Research Institute
Kadirov, Akbar; Institute of Virology
Kalashnikova, Tatyana; CDC CAR
Khalilov, Mansur; Center for Prevention and Quarantine of Most Hazardous Infections
Komilov, Nematulla; Institute of Virology
Nematov, Aminjon; Center for Prevention and Quarantine
Yaraev, Rushan; Veterinary Research Institute

