

Biological Proliferation and Terrorism

Only a thin wall of terrorist ignorance and inexperience now protects us.
—Former Secretary of the Navy Richard Danzig

Biological science and technology today transcend borders. These fields engage a vast and expanding array of actors in the government, private, and commercial sectors, and they are advancing at a remarkable pace. The more that sophisticated capabilities, including genetic engineering and gene synthesis, spread around the globe, the greater the potential that terrorists will use them to develop biological weapons. The challenge for U.S. policymakers is to prevent that potential from becoming a reality by keeping dangerous pathogens—and the equipment, technology, and know-how needed to weaponize them—out of the hands of criminals, terrorists, and proliferant states.

The Commission believes that much more can be done to prevent biological weapons (BW) proliferation and terrorism—even as we recognize it is unrealistic to think that we can completely eliminate the possibility of misuse. Accordingly, we recommend a number of initiatives to enhance efforts at prevention, in addition to existing programs by the Department of Health and Human Services and the Department of Homeland Security to mitigate the consequences of a biological weapons attack.

Consistent with its legislative mandate, this Commission has focused on assessing and making recommendations on how to improve measures for the prevention of biological proliferation and terrorism. Nevertheless, countering the threat of BW proliferation and terrorism will require concerted action across a policy continuum that extends from prevention to consequence management. Prevention alone is not sufficient, and a robust system for public health preparedness and

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response is vital to the nation's security. In order to deter biological attacks, we need to demonstrate—through effective preparedness measures and public exercises—that we are capable of blunting the impact of an attack and thus thwarting the terrorists' objectives.

To date, the U.S. government has invested most of its nonproliferation efforts and diplomatic capital in preventing nuclear terrorism. The Commission believes that it should make the more likely threat—bioterrorism—a higher priority. Only by elevating the priority of the biological weapons threat will it be possible to bring about substantial improvements in global biosecurity. To this end, the new administration should urgently develop a comprehensive approach to the prevention of biological proliferation and terrorism.

Domestic Findings and Recommendation

Securing Dangerous Pathogens

A major hurdle for terrorists seeking biological weapons is the difficulty of acquiring disease-causing microbes (chiefly bacteria and viruses) and toxins (poisonous substances produced by living creatures) that can be harnessed to incapacitate or kill humans, livestock, or crops. Although dangerous pathogens such as the anthrax bacterium can be isolated from natural sources, it would generally be easier for terrorists to steal or divert well-characterized “hot” strains from a research laboratory or culture collection.

To reduce the likelihood of theft or diversion, in 1996 Congress created the Select Agent Program, which established a list of pathogens and toxins of bioterrorism concern. The initial regulations required the reporting of all transfers of these “select agents” to other laboratories and mandated that the facilities involved in the transfers be registered with the Department of Health and Human Services (HHS) or the Department of Agriculture (USDA).

In 2002, in response to the anthrax letter attacks of autumn 2001, Congress expanded the list of select agents and added a requirement that all U.S. laboratories that possess or transfer select agents must register with one of the two departments. In addition, all such laboratories must implement enhanced security measures including physical access controls and the FBI vetting of all scientists, technicians, and laboratory officials before they are allowed to work with select agents. Biodefense

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researchers at U.S. Army laboratories must submit to a more stringent vetting process that includes a background investigation and a security clearance. Nevertheless, in August 2008, the Department of Justice identified Bruce E. Ivins, a U.S. Army researcher, as the sole perpetrator of the 2001 anthrax letter attacks, a development that has raised questions about the adequacy of current personnel vetting procedures.

Since the 2001 terrorist attacks on the United States, the Departments of Defense, Health and Human Services, Homeland Security, and other agencies have spent or allocated nearly \$50 billion for civilian biodefense. This huge influx of funding has been accompanied by the design and construction of numerous federal, state, and private high-containment laboratories (at Biosafety Level 3), as well as maximum-containment laboratories (at Biosafety Level 4), that work with the most dangerous pathogens. For example, the number of Biosafety Level 4 (BSL-4) labs is expected to triple from 5 in 2001 to 15 in 2012. This rapid expansion of laboratory capacity has been justified by the need for research on measures to counter both deliberate acts of bioterrorism and the global spread of emerging infectious diseases of natural origin, such as SARS (severe acute respiratory syndrome) and avian influenza.

At the same time, the dramatic increase in the number of high-containment labs in the absence of a comprehensive regulatory framework has raised safety, security, and terrorism concerns. At present, some 400 research facilities in the United States are authorized to store and handle select agents, and nearly 15,000 individuals have been approved to work with them. The rapid growth in the number of facilities and people handling select agents has increased the risk of laboratory accidents or intentional misuse by insiders. Moreover, no single entity in the executive branch is responsible for overseeing and managing the risks associated with all the high-containment (BSL-3) laboratories operated by the U.S. government, industry, or academia.

Promoting a Biosecurity Culture

The government and the private sector must urgently address both *biosafety* concerns (preventing the accidental infection of laboratory workers and the release into the environment of dangerous pathogens) and *biosecurity* concerns (preventing the theft or diversion of dangerous pathogens for nefarious purposes).

The nuclear age began with a mushroom cloud—and all those who

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worked in the nuclear industry in any capacity, military or civilian, instantly understood that they must work and live under a clear and undeniable security mandate. But the life sciences community has never experienced a comparable iconic event to focus their attention on security. Instead, most biologists view their research as an absolute good that promotes human health and prosperity, and they jealously guard their independence. There is understandable tension between the biology community and the government with regard to regulatory and oversight efforts, such as the Select Agent Rules. Although the recent assertion that a U.S. Army scientist was responsible for the anthrax letter attacks has created some awareness of the need for greater security, much still remains to be accomplished.

The choice is stark. The life sciences community can wait until a catastrophic biological attack occurs before it steps up to its security responsibilities. Or it can act proactively in its own enlightened self-interest, aware that the reaction of the political system to a major bioterrorist event would likely be extreme and even draconian, resulting in significant harm to the scientific enterprise.

Because science is a global activity, any biosecurity regime must ultimately be international in nature. As a first step, it is necessary for the United States to put its own house in order and lead the rest of the world by providing the highest standards of biosafety and biosecurity. The U.S. goal must be to keep dual-use materials, technology, and expertise out of the hands of terrorists and proliferators.

The U.S. government has sought to foster the development of a “culture of security awareness” within the life sciences community to prevent the misuse of biology for warfare or terrorism. However, scientists in academia and industry generally view the Select Agent Program as an unnecessary burden rather than as an important means of preventing bioterrorism. To help change this attitude, federal agencies have launched a number of outreach and education efforts.

In 2005, the FBI established the Science and Technology Outreach Program (since renamed the Biological Sciences Outreach Program) to increase its dialogue with the academic, biotechnology, and public health communities and thereby gain their aid in thwarting bioterrorists. That same year, the Bureau established the National Security Higher Education Advisory Board, which consists of about 20 presidents of major U.S. research universities. The advisory board aims

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to promote communication between the U.S. government and academic leaders on issues related to homeland security, law enforcement, and visa and immigration policies.

Meanwhile, in 2004, the Department of Health and Human Services created the National Science Advisory Board for Biosecurity to consider how to minimize the risk that advances in bioscience and biotechnology could be misused to threaten public health and national security. This committee is developing guidelines to improve the oversight of biological research.

Microbial Forensics

Microbial forensics is a new science that involves the use of molecular tools, such as DNA sequencing and isotopic analysis, to analyze a microbial pathogen or toxin. Such techniques can help determine the source of a particular strain of pathogen, thereby providing useful investigative leads. When combined with more traditional techniques, such as the analysis of hair, fibers, and fingerprints, microbial forensics can narrow the range of suspects in a bioterror attack. The FBI investigation into the anthrax-tainted letters of autumn 2001 provided a strong impetus for the rapid development of this new field. Analysis of subtle variations in the DNA sequences of different anthrax bacterial strains ultimately made it possible to pinpoint the source of the material used in the 2001 attacks to a single flask at the U.S. Army's biodefense research center at Fort Detrick, in Maryland.

A number of U.S. government agencies are currently involved in microbial forensics. In partnership with the FBI, the Department of Homeland Security's Science and Technology Directorate operates the National Bioforensic Analysis Center, which President George W. Bush designated in 2004 as the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials from biocrime and bioterror investigations.

RECOMMENDATION 1: The United States should undertake a series of mutually reinforcing domestic measures to prevent bioterrorism: (1) conduct a comprehensive review of the domestic program to secure dangerous pathogens, (2) develop a national strategy for advancing bioforensic capabilities, (3) tighten government oversight of high-containment laborato-

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ries, (4) promote a culture of security awareness in the life sciences community, and (5) enhance the nation's capabilities for rapid response to prevent biological attacks from inflicting mass casualties.

The Commission believes there are a number of specific actions that the United States should undertake to implement this recommendation.

ACTION: The Department of Health and Human Services should lead an interagency review of the domestic program to secure dangerous pathogens.

Congress passed legislation in 2002 strengthening the Select Agent Program, which had been established to secure dangerous pathogens used in research laboratories. But since the tightened regulations have gone into effect, the U.S. government has not conducted an internal review of the program's effectiveness in improving biological security and its impact on legitimate scientific research. A representative of a leading professional association in the life sciences expressed to the Commission the concerns of some of its members, who feel that the Select Agent Program is impeding collaboration with foreign scientists and blocking transfers of endemic pathogens from developing countries for study in U.S. laboratories. Although the Centers for Disease Control and Prevention (CDC) recently commissioned the Homeland Security Institute to review some aspects of the Select Agent Program, this effort is too narrow in scope and does not include the full set of stakeholders.

The Commission believes that an interagency review of the implementation of the Select Agent Program is long overdue. Issues or concerns emerging from such a review should be addressed during the first year of the new administration. The review should explore ways of implementing the Select Agent Program so that it continues to prevent the misuse of dangerous pathogens without hampering vital domestic research and international collaboration.

ACTION: The Department of Homeland Security should take the lead in developing a national strategy for advancing microbial forensics capabilities.

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Microbial forensics, a set of genetic and physical techniques for analyzing a biological or toxin agent that has been acquired by a proliferant state or terrorist group, can clarify where a breach in laboratory security has occurred. It can also help identify the perpetrators of a biological weapons attack and support their criminal prosecution. For deterrence, defense, and law enforcement purposes, the U.S. government is currently making a concerted effort to increase the likelihood that biological materials that have been obtained illicitly or used in an attack can be traced back to their source and perhaps linked to a terrorist organization or its state sponsor.

The Commission supports these efforts but believes they are not sufficient. By the end of 2009, the U.S. government must develop a national strategy for acquiring a state-of-the-art capability for microbial forensics. Such a national strategy should (1) facilitate the development and maintenance of a comprehensive library of pathogen reference strains; (2) establish a government-wide set of standard procedures for collecting, processing, and analyzing samples to improve consistency and quality, and identify both a lead agency to direct this effort and the roles and responsibilities of support agencies; and (3) fund basic research to support the further development of microbial forensic techniques.

ACTION: The Department of Health and Human Services, in coordination with the Department of Homeland Security, should lead an interagency effort to tighten government oversight of high-containment laboratories.

Despite the inherent safety and security risks associated with high-containment laboratories, such facilities in the United States are not specifically regulated; they become subject to federal oversight only if they are government-funded or possess pathogens and toxins on the Select Agent List. Thus many BSL-3 laboratories that work with dangerous but unlisted pathogens, such as the SARS virus, operate outside of federal regulation and indeed even federal knowledge of their existence. Moreover, the number of scientists working with dangerous pathogens is increasing—and many are working with them for the first time. These changes have led to a higher incidence of accidents and laboratory-acquired infections and to new biosecurity concerns.

The problems have been exacerbated by the unbridled growth in the

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number of high-containment laboratories since 2001, which has occurred without effective and coordinated federal oversight. In October 2007, the Government Accountability Office underscored this deficiency, reporting that “no single federal agency has the mission and, therefore, is accountable for tracking the number of all BSL-3 and BSL-4 labs within the United States. . . . Therefore, no agency is responsible for determining the aggregate risks associated with the expansion of these labs.”

The Commission believes that safety and security considerations warrant direct federal oversight of all high-containment laboratories. We recommend that the next administration take appropriate action to (1) determine present and future requirements for research on bio-defense threats and emerging infectious diseases, and plan future expansion to minimize the associated safety and security risks; (2) require federal registration of all BSL-3 and BSL-4 facilities (whether or not they work with select agents), identify a lead federal agency to oversee and enforce the registration process, and create a government-wide database of all high-containment labs in the United States; (3) implement a common set of safety and security requirements for all high-containment labs; and (4) mandate standard biosafety and biosecurity training for all personnel who work in high-containment labs, and fund the development of educational materials for that purpose.

The new administration should act immediately to complete its assessment of national requirements for high-containment laboratories and take the action necessary to establish federal oversight of all BSL-3 and BSL-4 laboratories in the United States. The government should also consider centralizing the regulatory functions for biosafety and biosecurity by developing a new oversight mechanism for high-containment laboratories that combines the existing CDC/USDA Select Agent Program and the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules.

ACTION: The Department of Health and Human Services and Congress should promote a culture of security awareness in the life sciences community.

Members of the life sciences community—universities, medical and veterinary schools, nongovernmental biomedical research insti-

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tutes, trade associations, and biotechnology and pharmaceutical companies—must foster a bottom-up effort to sensitize researchers to biosecurity issues and concerns. Scientists should understand the ethical imperative to “do no harm,” strive to anticipate the potential consequences of their research, and design and conduct experiments in a way that minimizes safety and security risks.

At present, no clear procedures, structures, or support systems exist for addressing the problem of dual-use research in the life sciences. The next administration should create a domestic review and oversight system for such research. The Commission also calls on the leaders of the life sciences community, both inside and outside of government, to speak out clearly and frequently about the professional responsibility of scientists to prevent the misuse of biology for hostile purposes. Congress should hold hearings to discuss the problem and should foster practical solutions for addressing it.

Several other bottom-up steps are also warranted. The currently separate concepts of biosafety and biosecurity should be combined into a unified conceptual framework of *laboratory risk management*. This framework should be integrated into a program of mandatory education and training for scientists and technicians in the life sciences field, whether they are working in the academy or in industry. Such training should begin with advanced college and graduate students and extend to career scientists. The U.S. government should also fund the development of educational materials and reference manuals on biosafety and biosecurity issues. At the same time, the responsibilities of laboratory biosafety officers should be expanded to include laboratory security and oversight of select agents, and all biosafety officers should be tested and certified by a competent government authority.

Finally, whistleblower mechanisms should be established within the professional life sciences community so that scientists can report—without risk of retaliation—their concerns about safety and security, including suspicious or aberrant behavior on the part of colleagues. For example, a help line might be established under the auspices of a nongovernmental or professional organization that would receive reports from scientists about suspicious activities and then initiate investigative action when appropriate.

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ACTION: The Department of Health and Human Services, in coordination with the Department of Homeland Security, should take steps to enhance the nation's capacity for rapid response to prevent an anthrax attack from inflicting mass casualties.

Since 2001, the U.S. government has taken important steps to prepare a national response to a bioterrorist attack involving anthrax bacterial spores, the most likely near-term biological threat to the United States. Because the risk of bioterrorists' using anthrax is real and the timeline for responding to an attack is extremely unforgiving, the United States must make a concerted effort to improve its capabilities in this area. Although our mandate is to examine preventive measures, the Commission believes that a substantially greater effort is needed to develop and make operational a response plan that can counter an anthrax attack effectively. This plan would also help deter such an attack by significantly reducing its probability of success. Establishing an effective system to respond to an anthrax attack would also improve the nation's ability to manage other public health disasters, be they natural or man-made.

Inhalational anthrax can be prevented in exposed individuals if effective oral antibiotics are administered during the first 48 hours after infection—before the onset of acute symptoms, when the disease becomes highly lethal and difficult to treat. Although the Department of Health and Human Services has maintained a national stockpile of medical countermeasures since 1999, distributing these items during a national emergency remains a major challenge. In the case of inhalational anthrax, the 48-hour window imposes an extremely demanding timeline for executing an effective medical response: the U.S. government must detect an aerosol attack soon after it occurs, immediately set the response plan in motion, and distribute stockpiled antibiotics to the affected states, which in turn must dispense them to the local population—all within two days.

In October 2008, Health and Human Services Secretary Michael Leavitt announced that his department is working with the U.S. Postal Service to assist state and local authorities in addressing the distribution problem. In the event of an anthrax attack, mail carriers, escorted by police officers, would quickly deliver a short-term supply

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of antibiotics from the national stockpile to all residences in the affected area, giving state and local public health authorities enough time to set up dispensing centers for longer-term (60-day) antibiotic treatment. We have not had time to review this new initiative but are inclined to doubt that it fully satisfies this vital need. The United States still does not have and must quickly develop a fully comprehensive and tested system for the rapid delivery of lifesaving medical countermeasures against anthrax and other bioterrorist threats.

As a first step in addressing these issues, the Bush administration submitted a fiscal year 2009 budget amendment request asking Congress for an additional \$969 million to fund the development and manufacture of medical countermeasures, innovative approaches to distribution and decontamination, and upgrades to the BioWatch network of air samplers designed to permit early detection of a bioterrorist attack. These urgent funding requirements should be taken up early in the next Congress. In addition, the next administration should, as a matter of national priority, fully implement an effective anthrax preparedness strategy.

The Commission believes that an innovative approach will be needed to solve the problem of how to rapidly dispense antibiotics and other medical countermeasures to the exposed population should a large-scale bioterrorist attack occur. Serious consideration should be given to harnessing the existing distribution networks of large retail stores and forging effective public-private partnerships. Furthermore, the dispensing system for medical countermeasures should be exercised and reviewed regularly to demonstrate both to the American public and to our enemies that the U.S. government takes the threat of bioterrorism seriously and is fully prepared to defend the population. “Red-teaming” exercises, in which deliberate attempts are made to disrupt the dispensing system, are also useful for identifying areas of weakness. These exercises should assess the emergency response and treatment capabilities of hospitals as well as the effectiveness of public health networks for gathering and evaluating hospital reports of infectious disease cases.

Another potential gap in U.S. biological defenses is the threat of bioterrorist attacks with strains of anthrax that have been genetically modified to make them resistant to standard antibiotics. Given this potential threat, additional funding is needed for the National Institutes of Health and the private sector to develop new classes of antibiotics, as

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well as antitoxin treatments that can neutralize the deadly toxins released by the anthrax bacterium in an infected individual.

Finally, an effective public information strategy is essential to educate and inform the U.S. population during a bioterrorist attack, so that citizens are able to take effective action to minimize their risk of exposure, prevent the person-to-person spread of contagious agents, and diagnose and treat themselves and their loved ones at home when possible so that hospitals and other treatment centers are not inundated. Such a public information strategy was sorely lacking during the 2001 anthrax letter attacks. The Department of Health and Human Services and Department of Homeland Security, in cooperation with state and local health departments and emergency responders, should prepare specific messages that can be disseminated after a bioterrorist attack to facilitate citizens' self-protection and self-decontamination.

International Findings and Recommendation

Biological Weapons Convention

The cornerstone of international efforts to prevent biological weapons proliferation and terrorism is the 1972 Biological Weapons Convention (BWC). This treaty bans the development, production, and acquisition of biological and toxin weapons and the delivery systems specifically designed for their dispersal. The BWC forbids member states (now numbering more than 160) from assisting other governments, non-state entities, or individuals in obtaining biological weapons. In addition, the convention requires each state party to take "any necessary measures to prohibit and prevent" the activities banned by the treaty on its territory and other areas under its jurisdiction and control. This provision has been interpreted as obligating each member state to adopt domestic legislation imposing criminal sanctions on its citizens for developing or producing biological weapons, and to secure dangerous pathogens from unauthorized access or theft. Although the negotiation of the BWC was a major achievement of arms control, the treaty has been marred by serious violations and a lack of universal membership.

Unlike many other arms control treaties, the BWC does not contain any formal verification mechanisms, nor does it establish an international implementing organization. The treaty was negotiated at the height of the Cold War, when the Soviet Union refused in principle to

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accept any on-site arms control measures, leaving bilateral consultations or an investigation by the United Nations Security Council as the only avenues for addressing concerns about noncompliance. In fact, violations of the BWC are extraordinarily difficult to verify. Because biological activities, materials, and equipment can be used for good as well as harm, compliance ultimately depends on the underlying intent, which may be peaceful or offensive. Yet evidence for the intent to use biology as a weapon is hard to discern: nefarious purposes can easily be concealed within a host of legitimate activities, such as pharmaceutical development, vaccine production, and general life sciences research.

Despite these serious verification challenges, the perceived weakness of the Biological Weapons Convention prompted many countries in the early 1990s to call for the negotiation of a legally binding verification regime to supplement the convention. The U.S. government under President George H. W. Bush opposed this proposal, arguing that because biotechnology is essentially dual-use, effective verification of the convention by an international regime was impossible. In 1994, however, the Clinton administration sidestepped the verification issue and decided to support the negotiation of a protocol to the BWC as a means of promoting greater transparency and of deterring noncompliance.

International negotiations began in Geneva in 1995, but major disagreements soon emerged. Russia, still suspected of harboring an illicit biological weapons program and apparently seeking to limit the prohibitions of the BWC, insisted that key terms in the convention be defined narrowly. Iran, China, Pakistan, India, and other members of the Non-Aligned Movement demanded that the protocol end all national export controls, on the grounds that such controls “discriminated” against developing countries. Finally, the European Union and others pressed for intrusive inspections that went much further than U.S. proposals for greater transparency, raising both national security and commercial concerns that sensitive information might be compromised.

In mid-2001, after more than six years of talks and the introduction of a compromise text by the chairman of the negotiating forum, the United States withdrew its support for the draft Biological Weapons Convention Protocol, prompting widespread international criticism. The United States concluded that the confidence-building transparency sought by the protocol could be achieved only at the unacceptable cost of (1) creating the false perception that the convention was

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verifiable by an international organization, (2) acquiescing to an international inspection regime that could jeopardize sensitive U.S. information, and (3) accepting Russian and Non-Aligned Movement demands that would have seriously undermined international biological weapons nonproliferation efforts and the convention itself. These concerns remain valid today, when the continuing global spread of dual-use biological materials, equipment, and facilities has only made verifying compliance to the BWC more difficult.

In 2002, at the convention's fifth review conference, the member states agreed to suspend the protocol negotiations indefinitely. Instead, they adopted a U.S. proposal to hold a series of annual expert and political meetings between the review conferences held every five years. Launched in 2003, these annual meetings have focused on the prevention of bioterrorism by addressing such topics as domestic legislation implementing the BWC, pathogen and laboratory security, infectious disease detection and response, scientific codes of conduct, and investigations of alleged use of biological weapons. The annual meetings have proven useful for increasing international awareness of biological security issues, and the Sixth Review Conference in 2006 renewed the intersessional work program until the next review conference in 2011.

Biological Threat Reduction

Cooperative threat reduction (CTR) is a series of U.S. government programs that were originally designed to secure and dismantle WMD stockpiles from the former Soviet Union (FSU). U.S. biological CTR efforts in Russia and the former Soviet republics have focused on three objectives: (1) dismantling former biological weapons production facilities, (2) improving the security of collections of dangerous pathogens, and (3) engaging former biological weapons scientists and redirecting them into peaceful areas of research. In recent years, the United States has sharply cut back its biological CTR programs in Russia because of bureaucratic and political difficulties in dealing with the Russian government, which has refused U.S. requests for greater transparency at former biological weapons facilities controlled by the Ministry of Defense.

The U.S. government is also pursuing biosecurity cooperation and engagement outside the former Soviet Union. The Biosecurity Engagement Program, launched in 2006 by the State Department, seeks to promote pathogen security and collaborative bioscience research in

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critical regions of the world. The objective of the program is to promote legitimate bioscience research in select countries while addressing their dangerous blend of bioterrorism threats, emerging infectious diseases, poorly secured collections of dangerous pathogens, and rapidly expanding biotechnology industries. Initially it is focusing on countries in South Asia, Southeast Asia, and the Middle East that have indigenous terrorist groups interested in acquiring biological weapons. Pilot efforts in Indonesia and the Philippines include conducting risk assessments; developing country-level strategies for bilateral engagement on laboratory biosafety, pathogen security, and the monitoring of outbreaks of infectious disease; and developing a grants assistance program to promote research collaboration between U.S. and local institutions. This effort must be expanded to additional regions.

Global Monitoring of Infectious Disease Outbreaks

Crucial to mounting a defense against biological weapons development and attack is the early detection and reporting of outbreaks of infectious disease, a capability known as *disease surveillance*. Today, a number of surveillance networks provide early warning of outbreaks throughout the world. Although these networks are designed primarily to detect naturally occurring infections such as SARS, Ebola, West Nile virus, and avian influenza, they could also detect deliberate attacks using biological weapons.

The World Health Organization (WHO) is the focal point of international disease surveillance efforts. The WHO's International Health Regulations (IHR) require participating states to notify the WHO of a potential "public health emergency of international concern" so that an epidemic can be contained before it spreads across borders. The regulations also require WHO member states to meet specified benchmarks for national disease surveillance and response capabilities. In addition, an operations center at WHO Headquarters is responsible for integrating the outbreak reports it receives from member states into the Global Outbreak Alert and Response Network and dispatching response teams from approximately 150 partner organizations around the globe with the goal of containing disease outbreaks close to where they originate. Disease surveillance and reporting remains a difficult and demanding task, however, and outbreak information is not always provided by WHO member states on a timely basis.

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Today's international surveillance networks are not comprehensive in their coverage, and belated detection of an outbreak hinders a swift response. Reporting delays may result from political or bureaucratic hurdles as well as the lengthy laboratory analyses needed to confirm a disease diagnosis. Another problem is that many infectious diseases are zoonotic—that is, they infect both animals and people. In such natural infections as West Nile virus and avian influenza, wild birds are sentinel species: they typically become infected before humans and provide early warning of an impending epidemic. Similar sentinels may exist for zoonotic diseases that pose bioterrorism concerns, including anthrax, tularemia, plague, Q fever, Venezuelan equine encephalitis, rabies, and viral hemorrhagic fevers. Yet surveillance systems for animal diseases are significantly less developed than those for human diseases, and WHO and the World Organization for Animal Health (OIE) have not fully integrated their respective disease surveillance networks.

RECOMMENDATION 2: The United States should undertake a series of mutually reinforcing measures at the international level to prevent biological weapons proliferation and terrorism: (1) press for an international conference of countries with major biotechnology industries to promote biosecurity, (2) conduct a global assessment of biosecurity risks, (3) strengthen global disease surveillance networks, and (4) propose a new action plan for achieving universal adherence to and effective national implementation of the Biological Weapons Convention, for adoption at the next review conference in 2011.

Ensuring that the life sciences evolve safely and securely will require both top-down oversight by national governments and bottom-up leadership from all the life sciences communities—professional, academic, and industry. National regulation and international cooperation are necessary elements of a global biosecurity framework, and can help countries meet their obligations under UN Security Council Resolution 1540 to prevent terrorist groups from acquiring access to biological weapons and the materials and equipment needed to produce them. Ultimately, however, governments can only point the way—those working in the life sciences must commit to the journey.

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ACTION: The Department of State and Department of Health and Human Services should press for an international conference of countries with major biotechnology industries to discuss the norms and safeguards necessary to keep dangerous pathogens out of the hands of terrorists and to ensure that the global revolution in the life sciences unfolds safely and securely.

With a view to achieving broad international involvement in and support for biosecurity, the Commission believes that the United States should press for the establishment of an international conference of countries, bringing together Western industrialized states that possess advanced capabilities in the life sciences (e.g., Canada, France, Germany, Japan, Switzerland, the United Kingdom, and the United States) and emerging biotech powers (e.g., Brazil, China, India, Malaysia, Singapore, South Africa, South Korea, and Russia) to develop a road map for ensuring that the revolution in biology unfolds safely and securely.

The purpose of such a biotech powers conference should be to identify key principles of biosecurity, to harmonize national regulatory frameworks for dangerous pathogens and dual-use research of concern, and to promote international biosecurity cooperation. Furthermore, the conference would consider bottom-up approaches for raising the awareness of life scientists in academic institutions and commercial enterprises about the security dimensions of their work, with a view to creating a transnational “culture of security awareness.” Once consensus on a biosecurity road map has been reached, it could serve as the basis for broader regional and international engagement and consensus building of the kind required to devise an effective global framework.

ACTION: The Department of State should lead a global assessment of biological threats and engage in targeted biological threat prevention programs in additional countries.

The Commission recommends that the Department of State lead a comprehensive effort to prevent the emergence of new biological threats, as well as reduce existing threats. This initiative, which might be termed the Cooperative Bio-Threat Prevention Program, would involve the following steps: (1) conduct a global assessment of pathogen

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security, (2) develop a prioritized list of countries where poorly secured collections of dangerous pathogens are at risk of theft or diversion, and (3) devise a comprehensive strategy for assisting these countries to upgrade the security of their laboratories and their culture collections. Supporting this type of global approach to biological threat prevention, which should be integrated with efforts to improve the public health infrastructure in the affected countries, will require increased funding.

ACTION: The Department of Health and Human Services (primarily through the Centers for Disease Control and Prevention) should work to strengthen global disease surveillance networks.

Global networks for infectious disease surveillance can provide an “extended defense perimeter” for the United States by making it possible to detect and contain outbreaks of contagious diseases, whether natural or human-caused, before they reach U.S. shores. Such networks can also help defend U.S. military bases, embassies, and other American interests abroad against such outbreaks.

The Commission believes that more can and should be done, both domestically and internationally, to enhance the health security of the U.S. population by improving infectious disease surveillance and reporting capabilities. The gaps between the medical, public health, veterinary, and wildlife health communities must be closed to create integrated reporting systems for disease outbreaks in humans and animals, as well as effective response capabilities. Internationally, the United States should assist the World Organization for Animal Health (OIE) to improve its capabilities for monitoring outbreaks of zoonotic diseases, and should facilitate the integration of data and analyses between the WHO and the OIE.

Complementing the efforts of international organizations, the United States should continue to foster the development of other global surveillance networks. The Global Disease Surveillance System, sponsored by the Centers for Disease Control and Prevention, has significant promise and should be further developed and expanded to ensure worldwide coverage. In addition, the United States should offer bilateral assistance to those developing countries at greatest risk of epidemics, helping them to establish surveillance networks for detecting

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and reporting both human and animal disease outbreaks prior to a confirmed laboratory diagnosis. In order to promote these and other biosecurity efforts, the Department of Health and Human Services should strengthen the capabilities of its Office of the Secretary, better positioning it to lead international engagement programs. Finally, the department should encourage disease surveillance programs undertaken by nongovernmental organizations.

ACTION: The United States should reaffirm the critical importance of the 1972 Biological Weapons Convention to international peace and security by proposing a new action plan for achieving universal adherence and effective national implementation, to be adopted at the next review conference in 2011.

The 1972 Biological Weapons Convention constitutes a standard of international conduct that should be universally supported. It outlaws biological weapons, bars parties to it from providing assistance to anyone seeking such weapons, and obligates them to take “any necessary measures to prohibit and prevent” anyone on their territory from acquiring biological weapons. The collapse of the BWC Protocol negotiations in 2001 left the Convention without a clear direction for future efforts, a political vacuum that has been only partially filled by annual intersessional meetings.

Some countries have continued to press for a resumption of the protocol negotiations. As recently as late 2007, Iran, Pakistan, India, and Russia advocated resuming the talks, and the new U.S. administration may come under renewed international pressure in early 2009 to return to the negotiating table.

The Commission believes that the U.S. decision in 2001 to withdraw from the BWC Protocol negotiations was fundamentally sound and that the next administration should reject any efforts to restart them. History has shown that it is extraordinarily difficult to verify compliance with the BWC because virtually all biological materials, equipment, and facilities are dual-use. This verification problem has been compounded by the spread of advanced biotechnology around the world. The well-intentioned effort by the United States during the 1995–2001 protocol negotiations to promote confidence-building “transparency” was undone both by the unrealistic view of European

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and other allies that compliance with the BWC could be verified by an international organization and by the determination of Iran, Russia, and others to exploit the protocol to undermine international nonproliferation efforts and the convention itself.

But U.S. policy on biological weapons cannot rest solely on opposition to the BWC Protocol. It is essential that the United States lead the international community and promote a new approach for strengthening national implementation of the BWC. To signal the political importance that the United States attaches to preventing biological weapons proliferation and terrorism, the new administration should consider sending a senior-level official to address the Seventh BWC Review Conference in 2011.

During the two years leading up to the Seventh Review Conference, the United States should work with its allies and other parties to develop new initiatives aimed at achieving universal adherence to the BWC and promoting effective national implementation, especially with respect to the prevention of bioterrorism. The United States should also seek broad political support for an expanded intersessional work program that focuses on (1) building the capacities of BWC member states in key areas of bioterrorism prevention such as laboratory security, disease surveillance (including new diagnostic laboratories), and the oversight of research in the life sciences with a high potential for misuse for hostile purposes and (2) improving the practical training of experts from BWC member states in technical aspects of biosafety, biosecurity, and disease surveillance.

Finally, the United States should support an appropriate increase in the size and stature of the BWC Implementation Support Unit, currently a small staff based at the United Nations Office in Geneva, so that it can function as an effective facilitator and coordinator for an expanded set of BWC activities and initiatives.