THE HENRY L. STIMSON CENTER

Compliance Through Science: US Pharmaceutical Industry Experts on a Strengthened Bioweapons Nonproliferation Regime

A Collaborative Research Report of Experts from the US Pharmaceutical and Biotechnology Industries

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Preface and Acknowledgements

This report materialized through a collaboration of several individuals, namely ten top-notch experts from the US pharmaceutical and biotechnology industries and the staff of the Stimson Center's Chemical and Biological Weapons Nonproliferation Project. The industry experts graciously accepted the Stimson Center's invitation to examine the proposals that the US government advanced in the fall of 2001 to substitute for a legally binding, multilateral monitoring protocol to the Biological and Toxin Weapons Convention (BWC). Recognizing that some of the brightest scientific minds in the countries reside within the US private sector and appreciating fully the significant impact that experts from the US chemical industry had in shaping the Chemical Weapons Convention, the Stimson Center sought to tap this expertise to sanity check the approach that the US government has advocated to strengthen the international regime against germ weapons.

The project is indebted to the industry participants who voluntarily detoured from their busy schedules to attend meetings and review the draft report. The industry experts who can be acknowledged by name are, in alphabetical order, Dr. Robert Goldberg, a thirty-year veteran of US industry and the National Cancer Institute; Dr. Robert Hamilton; senior scientist and group leader at a large US biotechnology firm; Dr. Jennie Hunter-Cevera, who brought extensive industry experience to her current position as president of the University of Maryland Biotechnology Institute; Mr. Douglas Jaeger, recently retired after thirty-five years with a major US pharmaceutical company: Dr. Robert Maigetter, vice president of operations at Immunomedics, Inc.; Dr. George Pierce, formerly a manager of technology development and engineering for Cytech Industries, now a professor in Georgia State University's Department of Applied and Environmental Microbiology; Dr. James Poupard, director of strategic microbiology in the Research and Development division of GlaxoSmithKline; and, Dr. Eric Utt, health and safety manager at a large US pharmaceutical company. Three other participants have chosen to be identified only by their relevant experience and credentials so that they could avert any potential negative fallout from expressing their views on these matters. Their request for anonymity in no way diminishes the project's gratitude for their thoughtful contributions.

In-house, Ms. Claudine McCarthy, an indefatigable and uncannily sharp research associate, carried a particularly heavy burden, poring over the meeting transcripts to draft large segments of the report. Mr. Clayton Nall, a project research assistant, organized the meetings and lent a hand with various research tasks. The project's intern for the summer of 2001, Mr. Ted Wittenstein, also pitched in with research and some writing assistance. Several Stimson staff members helped to review and proof the draft report.

Of course, the meetings would not have been held, nor the report produced, without the financial assistance of the Nuclear Threat Initiative, which awarded the project a grant to solicit the industry's technical expertise on how the international biological weapons nonproliferation regime might be strengthened. The project is grateful for the Nuclear Threat Initiative's generosity, as well as for the

support that it has long enjoyed from the Carnegie Corporation of New York, the Ploughshares Fund, and Mrs. Margaret Spanel. The grants that underpin the project represent a trust in the project's ability to devise and pursue the implementation of pragmatic methods to reduce the twin threats posed by biological and chemical weapons. That trust is deeply valued.

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List of Abbreviations

APHIS	Animal and Plant Health Inspection Service
ASM	American Society for Microbiology
BL	biosafety level (followed by number)
BWC	Biological and Toxin Weapons Convention
CBI	confidential business information
CDC	Centers for Disease Control and Prevention
CBM	confidence-building measure
CFR	Code of Federal Regulations
CWC	Chemical Weapons Convention
DNA	deoxyribonucleic acid
EWARN	early warning and response network
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
GOARN	Global Outbreak Alert and Response Network
GPHIN	Global Public Health Intelligence Network
HEPA	high efficiency particulate arresting (filter)
HHS	US Department of Health and Human Services
HVAC	heating, ventilating, and air conditioning
IACUC	Institutional Animal Care and Use Committee
IEEE	Institute of Electrical and Electronic Engineers
MD	medical doctor
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
PHRMA	Pharmaceutical Research and Manufacturers of America
SOP	standard operating procedure
UN	United Nations
UNSCOM	United Nations Special Commission on Iraq
USAMRIID	US Army Medical Research Institute of Infectious Diseases
USDA	US Department of Agriculture
VEREX	Ad Hoc Group of Verification Experts
WHO	World Health Organization

Executive Summary

Biological weapons have long been recognized as abhorrent, which is why 145 nations have joined a 1972 treaty that bans the development, production, stockpiling, and transfer of germ weapons. Even at the time the Biological and Toxin Weapons Convention (BWC) became international law, it was understood to be more of a normative than an enforceable agreement. True to treaties of the 1970s, the BWC included no provisions to monitor the compliance of member countries with its prohibitions against using diseases as weapons to harm man, livestock, and plants.

The absence of monitoring provisions meant, for example, that no inspectors ever investigated suspicions that the Soviet Union was violating the BWC. Public allegations to that effect dated back to a 1979 outbreak of anthrax caused by an accident at a biological weapons production facility in a town then known as Sverdlovsk. In 1994, the BWC's membership finally chartered negotiations to craft a monitoring protocol. However, in December 2001, after rejecting a draft protocol and introducing a series of proposals intended to serve as alternatives to a legally binding, multilateral accord, the US government called for an end to negotiations. Chapter 1 of this report summarizes the somewhat troubled history of the BWC and efforts to strengthen this treaty.

In the remainder of this report, a group of experts from the US pharmaceutical and biotechnology industries assesses the suitability of the US government's alternative proposals, providing technical counsel that reshapes and improves them. This group jointly has over 280 years of experience in various types of industry facilities, with specialties ranging from drug research and development to process scale-up and manufacture of medicines. Each expert is well versed in various government regulations, compliance requirements, and inspections as they pertain to biotechnology facilities. Each is also a veteran of countless encounters with the internal scientific entities that govern activities in university settings and at industrial facilities. Their recommendations, summarized in Chapter 5 of this report, draw upon this deep well of experience.

The industry experts agreed with the US government's July 2001 decision to reject the draft BWC monitoring protocol, despite the fact that this text included several of the monitoring techniques that the experts argued would be useful for inspectors. Their main rationale was that no matter how good the inspection techniques, the inspectors would not have a fighting chance if they were too few in number, lacking in essential skills, and not deployed on site for a sufficient amount of time to accomplish their jobs. The draft protocol was deficient in all of these respects.

The US government made two types of proposals to supplant a formal BWC monitoring protocol. The first type centered on traditional monitoring that would deploy inspectors to certain locations to ascertain whether a prohibited activity had occurred. In the second category are proposals aimed at having individual nations strengthen laws, practices, and capabilities related to the handling of dangerous

pathogens, the conduct of research, the ability to detect disease outbreaks, and the prosecution of individuals engaged in offensive bioweapons activities.

US PROPOSALS TO MONITOR BWC COMPLIANCE

First, the US government proposed that the authority to investigate suspicious outbreaks of disease or allegations of biological weapons use remain with the United Nations Secretary General. The second US proposal would have member governments try to resolve compliance concerns via a bilateral consultation process wherein one option would be to open sites of concern voluntarily to inspection. US industry experts deemed this pair of proposals at best ineffectual and at worst, possibly damaging to US industry and national security interests since neither appears structured for meaningful monitoring results.

Industry experts could find little merit in leaving the capability to investigate suspicious disease outbreaks in the hands of the very body that failed to do anything to explore the root causes of the Sverdlovsk outbreak or any of the other charges of BWC violations voiced over the last quarter century. In addition, the group observed that this US proposal made no mention of a right to investigate allegations that a facility was covertly developing, testing, manufacturing, or storing biological weapons. If a challenge inspection system is not geared to pursue violators aggressively, then it does not serve US security interests.

The group questioned the value of a voluntary visit knowing that a violator could easily clean up evidence of foul play before issuing an invitation to inspectors. Moreover, the industry experts noted that a government might insist that an industry facility host such an inspection for political reasons. Such circumstances would be doubly objectionable since the "volunteered" industrial site would have to endure an inspection with negligible monitoring value.

As Chapter 2 explains in more detail, the industry experts expressed a conviction that it is incumbent on any investigation or monitoring activity to be able to discern the difference between a facility engaged in legitimate research and manufacturing activities and one involved in illegal biological weapons activities. The group affirmed the conclusions of a May 2001 Stimson Center report, entitled *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol*. Briefly, in that report, a different group of industry experts outlined monitoring strategies and techniques (e.g., site tours, interviews, document reviews) that inspectors could use to detect and sort out inconsistencies with a facility's stated purpose, ultimately differentiating between violators and compliant facilities.

Accordingly, the industry experts agreed to write detailed plans to guide the conduct of trial inspections to test the feasibility of their proposed monitoring strategies and techniques at two principal kinds of industry facilities, manufacturing plants and research and development sites. This group of industry experts expects their trial inspection plans to help lay the foundation for the US government and industry to meet the requirements of Public Law 106-113. This 1999 congressional mandate, which both

the Clinton and Bush administrations have ignored to date, stipulates that the Executive Branch complete a cost-benefit analysis after holding trial inspections at various US government, academic, and industry sites. Similar to clinical trials that fully ascertain the benefits and risks of candidate drugs, the group concurred that securing field research data on BWC monitoring techniques and strategies is essential to the utility of any attempt to construct a monitoring protocol.

US PROPOSALS FOR ACTION BY INDIVIDUAL STATES

In addition, the Bush administration introduced several initiatives asking BWC members to take individual action to:

- strengthen disease surveillance;
- stiffen the security of dangerous pathogens;
- establish oversight of genetic engineering research;
- enhance biosafety;
- develop and adopt code(s) of conduct for professionals working with dangerous pathogens; and,
- pass legislation criminalizing offensive biological weapons activities and adjust or create bilateral extradition agreements to enable prosecution of biocriminals.

All of these proposals, according to the industry experts, suffer from the same handicap, namely the failure to articulate an international standard that governments would be expected to meet. Absent identification of and agreement on such standards, governments will have little to compel them to take action. Many governments will enact measures that fall short of worthwhile standards either unintentionally, because they cannot decipher the existing discrepant regulatory concepts, or intentionally, because they seek to perpetuate illicit activities. The let-each-government-do-as-it-pleases approach would further foster an uneven patchwork of domestic laws and practices that might have little near-term value and could prove difficult to harmonize in the future. All of these outcomes are unsatisfactory.

Disease Surveillance, Criminalization, and Code of Ethics

The industry specialists applauded the suggestion that BWC member governments individually support the World Health Organization's disease surveillance and outbreak response capabilities. Likewise, the group thought the Office of International Epizoonotics and the Food and Agricultural Organization, which work to contain outbreaks of animal and plant diseases, certainly deserved the backing of the international community. The industry specialists agreed that countries should enact laws penalizing individuals for developing, producing, and using biological weapons. However, worrying that the US proposal might result in the creation of safe havens for bioterrorists in countries that brush off this

proposal or pass weak laws, the industry group advised instead adopting an international criminalization treaty.

A scientific ethics code serves mainly to reassure the public that scientists are applying their skills responsibly. Accordingly, the industry experts viewed the US government's proposal to have BWC members establish a professional code of ethics for those working with dangerous pathogens as posing the most minimal of impediments to individuals attempting to acquire an offensive bioweapons capability. Noting that governments have either compelled scientists or appealed to their sense of patriotic duty to get them to work on weapons programs in the past, the group's most positive assessment of this proposal was that it would do no harm. Were ethical codes in place, some industry experts argued that scientists *might* be emboldened to blow the whistle on a covert weapons program. Chapter 3 of this report provides a more in-depth discussion of the group's reaction to this trio of proposals.

Biosafety, Biosecurity, and Research Oversight

As Chapter 4 discusses, the industry experts were particularly concerned that the US proposals for biosafety, biosecurity, and research oversight would result in individual governments taking fragmented, if not superficial, action. They did not consider allowing governments to set their own arbitrary standards to be a constructive step forward. Therefore, the industry experts recommended that states adopt mandatory practices in each of these areas. The industry group cited as models for uniform standards the pertinent regulations issued by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH).

Establishing select lists of pathogens, including toxins that are dangerous to humans, animals, and plants, would facilitate the implementation of biosafety, biosecurity, and research oversight standards. For example, the CDC employs a select list to govern transfer of some human pathogens. Risk-stratified lists of human, animal, and plant pathogens need to be agreed upon to help anchor the standards. Such lists could change over time, but it would be counterproductive if too many agents were inappropriately categorized as high risk.

With regard to biosafety, the industry experts stated that the United States needs to get its own house in better order. Government-funded organizations in the United States must follow the CDC/NIH biosafety guidelines, but for other institutions adherence is optional. CDC/NIH biosafety standards should be made mandatory for all US facilities, and these or substantially equivalent standards should be in place globally. As is the case in the United States, the standards should be relaxed for clinical laboratories, which conduct primary diagnostic procedures on a large volume of samples at biosafety level 2, although some samples warrant biosafety level 3 precautions.

Sound reasons exist for establishing universal biosecurity standards. Biosecurity regulations currently vary in strength—some incorporate oversight and penalties for noncompliance, others do not. Other biosecurity regulations apply only to very limited areas of activity (e.g., shipping). The industry experts identified as an appropriate model for a minimum global standard the US access, transfer, and chain-of-custody regulations for select pathogens and toxins, or their equivalent.

Access and transfer restrictions alone are insufficient in that they do not even begin to account for the dangerous pathogens and toxins that are already present in organizations worldwide. Therefore, the industry group recommended a companion biosecurity measure: a "house cleaning" activity. Around the world, academic and research institutions, industry facilities, culture collections, and other facilities should be required to conduct a thorough inventory of the strains that they possess; declare to the appropriate authorities those delineated on the select agent lists of dangerous human, animal, and plant pathogens; and, in consultation with authorities, dispose of them, as appropriate.

Another aspect of biosecurity that the US proposals do not address is that of physical security. As these enhanced standards are instituted, it may be easier for terrorists or governments aspiring to a biological weapons capability to identify those facilities handling select-list agents. Accordingly, these facilities may themselves become targets for foul play. Therefore, in the not too distant future, the industry group suggested undertaking a clearer articulation of physical security requirements.

The industry experts recognized that the effective implementation of any standards hinges on training, which should be conveyed first in universities and colleges and regularly reinforced in the workplace. Lamentably, the industry experts observed, US institutions of higher learning have placed less and less emphasis on basic training in biosafety and research practices in recent decades. If higher standards are to become a reality, all pertinent entities have to embrace the best practice of continual training, from the time one becomes a student until one retires.

The second foundation of implementing tougher standards begins at the level of the individual organizations that are working with dangerous pathogens or conducting research with genetically modified organisms. At universities, research institutes, industrial and government facilities, the appropriate infrastructure must be put in place to oversee these activities. For example, designated individual(s) at a facility would be responsible for proper training of personnel; review of research proposals involving genetically modified organisms; and evaluation of the sufficiency of risk assessments and containment for proposed projects. National regulations should require the creation of a governing infrastructure along the lines of the one laid out in the NIH Guidelines for Research Involving Recombinant DNA Molecules, where it does not already exist.

Next, the only way to ensure that standards are being uniformly applied nationwide is for countries to establish a national capacity to oversee facilities working with dangerous pathogens and engaged in research involving genetically modified organisms. This regulatory body would:

- receive declarations about pertinent activities and capabilities from academic, research, industry, and government organizations;
- certify biosafety and biosecurity practices at these facilities;
- review, approve, and track all projects involving genetically modified organisms; and,
- enforce research oversight, biosafety, and access, transfer, and clean house regulations.

The industry group strongly urged that noncompliance penalties (e.g., loss of job, loss of government grants, suspension of licenses) be an integral part of agreed international standards. Absent the articulation and enforcement of considerable penalties for noncompliance, some individuals or organizations would make only a minimal effort to abide by the regulations.

The culminating step in the implementation of global biosafety, biosecurity, and research oversight standards would be to create an international body to coordinate, promote, and administer these activities, including the updating of standards, as appropriate.

Singly, research oversight, biosafety, and biosecurity enhancement measures will not go far in thwarting nations or terrorists from engaging in wayward research, experiencing leaks at covert weapons facilities, or gaining access to dangerous pathogens. Collectively, however, global adoption of the CDC/NIH guidelines or their equivalent would raise the bar, hampering the ability of aspiring proliferators to achieve an offensive weapons capability.

The industry group also underscored that biosecurity, biosafety, and research oversight standards also constitute safe, sound practices for those working with select-list pathogens. Finally, should a formal BWC inspection process ever be instituted, the improved standards would aid the efforts of inspectors in differentiating between legitimate research and commercial enterprises and illicit weapons activities.

Chapter 1
Introduction

Biological weapons issues featured prominently in the security news of 2001. In the United States, the anthrax letters that killed five people and sickened seventeen captured the bulk of the attention.[1] Even as those events transpired, however, important developments in the six-year international effort to strengthen the Biological and Toxin Weapons Convention (BWC) were unfolding on the international stage.

While 145 countries have ratified this 1972 treaty banning the development, testing, production, storage, and use of germ and toxin weapons, it lacks legally binding verification measures.[2] The Ad Hoc Group, a committee open to all BWC member states, set out in 1995 to fill this void by creating a BWC monitoring protocol. Negotiations produced a draft text in March 2001, which many states believed would be formally approved at the BWC's Fifth Review Conference in the fall of 2001. Instead, the United States rejected the draft protocol in July and at the Review Conference called for the elimination of the Ad Hoc Group.[3] Discarding the idea of a legally binding, multilateral accord, the Bush administration advanced two alternative proposals that would involve inspections, with the remainder of the initiatives focused on steps that BWC member states could take individually to strengthen the biological weapons nonproliferation regime.[4]

The Henry L. Stimson Center has assembled two groups of experts from the US pharmaceutical and biotechnology industries to weigh various proposals aimed at reinforcing the BWC's prohibitions. The first group of industry experts met in 2000; the second convened in 2002.[5] The Stimson Center asked

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[1] On the anthrax letters sent to US media and political figures, Ann Gerhart and David Montgomery, "Cipro Nation; As Anthrax Scare Spreads, A Who's Who Nation of Pill Takers," *Washington Post*, 24 October 2001; John Lancaster and Justin Blum, "District Postal Worker Seriously Ill; As Capitol Reopens, Anthrax Case Revives Concern About Spores' Potency," *Washington Post*, 22 October 2001; Steve Fainaru and Joby Warrick, "Deadly Anthrax Strain Leaves a Muddy Trail," *Washington Post*, 25 November 2001.

[2] Note that while the BWC includes a provision to refer matters to the United Nations Security Council, it is otherwise devoid of on-site inspection tools. A list of countries that have joined the BWC can be found at http://www.stimson.org/cbw/?SN=CB2001121271.

[3] Undersecretary of State for Arms Control John Bolton stunned the conference by proposing to disband the Ad Hoc Group just minutes before the group was to conclude its work. Alexander G. Higgins, "Talks On Germ-Warfare Ban Suspended For One Year After U.S. Proposal Shocks Delegates," Associated Press, 7 December 2001. Off the record, some European delegates referred to the action as "treacherous" or "sabotage." Seth Brugger, "BWC Conference Suspended After Controversial End," *Arms Control Today*, January/February 2002. Available at http://www.armscontrol.org/act/2002_01-02/bwcjanfeb02.asp.

[4] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001, 1. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

[5] The first industry group met on 29-30 June and 23-24 August 2000. The second industry group met on 18-19 June and 9-10 August 2002.

the first group of experts to bring their more than 200 years of cumulative experience to bear in examining the technical feasibility of monitoring the BWC. Their counsel, presented in a May 2001 Stimson Center report entitled *House of Cards: the Pivotal Importance of a Technically Sound Monitoring Protocol*, was in line with the Bush administration's subsequent decision to turn down a weak agreement. However, this group of experts fashioned inspection strategies and techniques that they believed would enable inspectors to distinguish reliably whether a facility was in compliance with the BWC's prohibitions. Therefore, they recommended that the US government move forward with field trials to explore thoroughly the feasibility of various monitoring methods, thereby informing further negotiations.[6]

The second group of industry expert picked up where the first one left off by considering the alternative proposals that the Bush administration advanced to replace a formal BWC monitoring protocol. This report captures the second industry group's discussions and recommendations. This chapter sets the context for their review of the US alternative proposals by first explaining the rather fitful history of international efforts to combat the spread and use of biological weapons, beginning with the BWC's entry into force. Next, the chapter presents an overview of the US proposals offered as alternatives to a formal monitoring protocol. The first chapter ends with a discussion of the methodology underlying this publication.

THE INTERNATIONAL REGIME AGAINST BIOLOGICAL WEAPONS

The 1925 Geneva Protocol banned the use of biological, toxin, and chemical weapons, but nearly a half-century passed before the international community developed a more comprehensive prohibition against the production and possession of germ weapons. Opened for signature on 10 April 1972, the BWC contains a sweeping prohibition against germ weapons. The linchpin of this treaty is Article I, which mandates:

> [E]ach State Party. . .undertakes never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes; (2) weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[7]

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[6] Technical experts from the US pharmaceutical industry, research institutions, and universities stated that the draft protocol incorporated many of the appropriate monitoring tools (e.g., visual observation, review of records, interviews), but argued that the draft protocol's provisions did not allow inspectors sufficient manpower and time to be able to unravel the complexities that would undoubtedly be encountered in the field. They recommended that the Bush administration conduct technical research and the field trials required by Public Law 106-113. *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol* (Washington, DC: Henry L. Stimson Center, May 2001).

[7] Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons, Article I. Hereinafter referred to as the Biological and Toxin Weapons Convention.

In addition, the BWC enjoins participating states not to transfer any of those agents, toxins, weapons, equipment, or means of delivery to any recipient for non-peaceful purposes and not to otherwise abet the proliferation or acquisition of biological agents or weapons. The BWC also requires states that possess biological weapons to destroy them within nine months of the treaty's activation.[8]

As noted earlier, this accord lacks what many see as a fundamental component of any arms control treaty—the means to verify compliance or to detect noncompliance. This absence of cooperative verification provisions is typical of arms control treaties negotiated during the Cold War. The BWC was crafted in the early 1970s, a time when the type of highly intrusive on-site inspections needed for effective verification were widely viewed as politically unacceptable, infeasible, or unnecessary. Moreover, the negotiators were not pressed to include verification measures in the BWC because at that time policy makers viewed biological weapons as lacking military utility. That perception has changed significantly over the last twenty-five years due to violations of the BWC and to advances in biotechnology.[9] In an example of the former, the USSR, one of the BWC's co-depositaries, maintained a significant covert biological weapons program for decades.[10]

The BWC does allow participating states to raise compliance "complaints" with the United Nations (UN) Security Council and requires an accused state to cooperate with efforts to ascertain the validity of a complaint. The Security Council would initiate any non-compliance investigation.[11] The limiting drawback of this approach is that any permanent member of the Security Council can veto the launch of an investigation.

In addition to blatant indications that some states were not adhering to their obligations under the BWC, the field of biotechnology underwent something of a technical revolution in the latter part of the twentieth century. Technical advances amplified the potential military utility of biological weapons. For example, genetic engineering has made it possible to alter some biological agents so that they are resistant to environmental stresses and not susceptible to vaccines or antibiotics.[12] Thus, experts began to worry

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[8] Biological and Toxin Weapons Convention, Articles II, III, and IV.

[9] Jonathan B. Tucker, "Strengthening the Biological Weapons Convention," *Arms Control Today* 25, no. 3 (April 1995): 9.

[10] For an insider's account of this program, see Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999). More briefly, see Milton Leitenberg, "The Conversion of Biological Warfare Research and Development Facilities to Peaceful Uses," in Erhard Geissler and John P. Woodall, eds., *Control of Dual-Threat Agents: The Vaccines for Peace Programme*, Stockholm International Peace Research Institute Chemical and Biological Warfare Studies 15 (London: Oxford University Press, 1994), 77–105; Anthony Rimmington, "From Military to Industrial Complex? The Conversion of Biological Weapons Facilities in the Russian Federation," *Contemporary Security Policy* 17, no. 1 (April 1996): 80–112.

[11] Biological and Toxin Weapons Convention, Article VI.

[12] US Congress, Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction* (Washington, DC: Government Printing Office, December 1993), 114–5. The USSR, for example, made several of its bioagents resistant to multiple antibiotics. Alibek, *Biohazard*, 155–6, 160, 167, 261, 281.

that advancements in biotechnology, microbiology, genetic engineering, and related scientific disciplines would make circumvention of the BWC's prohibitions easier to accomplish and more difficult to catch.

Given these circumstances, the BWC's members decided that the treaty needed to be strengthened with a legally binding verification protocol. The feasibility of strengthening the BWC and the appropriate means of doing so are, however, strongly debated within the international community. Briefly, proponents of creating a verification protocol argue that it would increase the cost and difficulty of a clandestine weapons program, enhance confidence among compliant states, provide a legal framework for challenge inspections, and ultimately decrease the number of sites of proliferation concern. They cite the 1993 Chemical Weapons Convention (CWC) as a model of a verifiable arms control agreement. Critics, on the other hand, argue that the BWC cannot be effectively verified. They point to obstacles such as the dual-use nature of biological production facilities, the likelihood that a verification protocol would generate false confidence in compliance, and the possibility that inspections would expose facilities to foreign espionage. Opponents to a verification protocol also note that the BWC has a loophole because it does not directly prohibit research with biological agents.[13]

The Onset of Efforts to Strengthen the BWC

The BWC requires all member states to participate in review conferences to be held at five-year intervals. The objective of these meetings is to undertake an article-by-article review of the BWC's operation, ascertaining whether the purposes of the treaty's preamble and main articles are being achieved. Each such review should "take into account any new scientific and technological developments relevant to the" BWC.[14] The culmination of each review conference is a final declaration that "can also serve as a basis for further strengthening of the Convention."[15]

The First Review Conference was held in March 1980. As the meeting unfolded, participating countries raised concerns about verification and compliance, but a majority finally agreed that the existing international procedures for consultation and cooperation would be adequate to resolve any problems that might arise concerning the BWC. In the Final Declaration, the participants thus reaffirmed their support

[13] For a variety of opinions about the ability to verify the BWC, see S.J. Lundin, ed., *Views on Possible Verification Measures for the Biological Weapons Convention*, Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 12 (London: Oxford University Press, 1991); Joseph Finder, "Biological Warfare, Genetic Engineering, and the Treaty That Failed," *Washington Quarterly* 9, no. 2 (Spring 1986): 5–14; Douglas J. Feith, "Biological Weapons and the Limits of Arms Control," *National Interest* (Winter 1986/87): 80–4; and Federation of American Scientists, "Progress in Identifying Effective and Acceptable Measures for a Compliance Protocol for the Biological Weapons Convention," Working Group on Biological and Toxin Weapons Verification, Working Paper (Washington, DC: May 1993).

[14] Biological and Toxin Weapons Convention, Article XII.

[15] United Nations, *Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Declaration,* Document BWC/CONF.III/23, Part II, 1991, 10.

for the treaty and found that Article I of the BWC "had proved sufficiently comprehensive to cover recent scientific and technological developments relevant to the Convention."[16]

The Second Review Conference took place in September 1986 amid a surge in concern about the "adequacy of the Convention in light of advances in genetic engineering and biotechnology…and allegations of breaches of the Convention."[17] The BWC's members were faced with the challenge of restoring confidence in the treaty's viability. This gathering coincided with the growing recognition of the value of confidence-building measures (CBMs), which encompass a variety of measures that states can undertake to promote openness in military matters and to build a climate of trust among nations.[18] The BWC's members sought to incorporate these mechanisms into the treaty regime. In the Final Declaration, the participants agreed to implement data exchanges concerning biological activities permitted under the treaty. An ad hoc meeting of scientific and technical experts therefore assembled in the spring of 1987 to design procedures for annual data exchanges among the BWC's members.[19] Beginning that year, states were asked to voluntarily submit pertinent data to the UN. Among the data to be declared annually was information on outbreaks of infectious diseases, the publication of scientific research results, and biological research laboratories that specialize in permitted protective, prophylactic, and other peaceful biological activities that are directly related to the BWC.[20]

Not long after these CBMs were instituted, members of the BWC arrived at a consensus that their non-legally binding nature was insufficient to produce meaningful results. The agreed CBMs did not authorize the UN to demand that states make declarations, and states that failed to submit data did not incur any penalty. Whether they were suspected of having covert biological weapons programs or not, most countries simply neglected to provide the information requested in the CBMs. For example, during the initial ten years after the CBMs were agreed upon, only fifty-two nations provided data at least once,

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[16] Aida Luisa Levin, "Historical Outline," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, Erhard Geissler, ed., Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 10 (London: Oxford University Press, 1990), 8. For more on the early years of the BWC, see also Nicholas A. Sims, *The Diplomacy of Biological Disarmament: Vicissitudes of a Treaty in Force, 1975–85* (London: MacMillan Press, 1988); and Barend ter Haar, *The Future of Biological Weapons* (New York: Praeger, 1991), 1–53.

[17] Levin, "Historical Outline," 9.

[18] For more on the origin, art, and practice of CBMs in a variety of contexts, see Johan Jorgen Holst and Karen Melander, "European Security and Confidence Building Measures," in *Arms Control and Military Force*, Christoph Bertram, ed. (London: International Institute for Strategic Studies, 1980): 223–31; Richard E. Darilek, "The Future of Conventional Arms Control in Europe—A Tale of Two Cities: Stockholm, Vienna," *Survival* 29, no. 1 (January/February 1987): 5–19; and Michael Krepon, ed., *A Handbook of Confidence-building Measures for Regional Security* (Washington, DC: Henry L. Stimson Center, January 1995).

[19] US Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, DC: Government Printing Office, 1990), 132.

[20] Erhard Geissler, "Agreed Measures and Proposals to Strengthen the Convention," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, 44–7.

and only eleven participated every year.[21] Prior to the Third Review Conference in September 1991, most countries thus recognized the inadequacy of relying solely upon voluntary CBMs for enhancing confidence in compliance with the BWC.

In addition, other developments contributed to widening concerns about the BWC's weakness. A number of reports alleged that as many as ten countries possessed or were in the process of acquiring biological weapons.[22] Moreover, after the 1991 Gulf War, the UN Special Commission on Iraq uncovered evidence that Iraq, a signatory of the BWC, had a biological weapons program. The extent of this program—encompassing weaponization of several agents and deployment of germ-filled missiles and other munitions during the war—is still being investigated.[23] The situation in Iraq again highlighted the lack of an independent inspectorate to monitor the BWC's prohibitions. Aside from the difficulty of dealing with the proliferation of biological weapons at the state level, one 1991 report maintained that "an increased risk now exists that the acquisition and use of biological weapons is being contemplated not only by nations but by subnational groups."[24] Later underscoring this point, the Japanese cult Aum Shinrikyo, infamous for its use of poison gas in a March 1995 terrorist attack in Tokyo, also endeavored but failed to develop a biological weapons capability.[25]

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[21] Another notable problem is that the international community did not set aside resources to analyze the data. Marie Chevrier, "Doubts About Confidence: The Potential and Limits of Confidence-Building Measures for the Biological Weapons Convention," in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, January 1998), 5–6.

[22] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 9; US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington, DC: Government Printing Office, August 1993), 14–5, 63–6; Testimony of James Woolsey, US Congress, Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 103d Cong., 1st sess., S. Hrg. 103–208 (Washington, DC: Government Printing Office, 24 February 1993), 8–18; Office of the Secretary of Defense, *Proliferation: Threat and Response* (Washington, DC: Government Printing Office, November 1997).

[23] UN Security Council, "Note by the Secretary-General," Document S/1997/774, 6 October 1997. See also, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: US Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997. UN inspections in Iraq were aborted in 1998, when Iraq insisted that the Special Commission leave the country. Barbara Crossette, "Iraqis Break Off All Cooperation with Inspectors," *New York Times*, 6 August 1998. In December 1999, a new inspection agency called UNMOVIC—the United Nations Monitoring, Verification and Inspection Commission—was created. "Security Council Establishes New Monitoring Commission for Iraq," UN Press Release SC/6775, 17 December 1999. However, as of this printing UNMOVIC inspectors had yet to set foot in Iraq.

[24] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 7. For a more comprehensive look at attempts to use biological agents for terrorist purposes, see Jonathan B. Tucker, "Historical Trends Related to Bioterrorism: An Empirical Analysis," *Emerging Infectious Diseases* 5, no. 4 (July/August 1999): 498–504; W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century*, Working Paper, Center for Counterproliferation Research (Washington, DC: National Defense University, July 1999).

[25] Many press reports have erroneously credited the cult with the successful dissemination of anthrax and botulinum toxin. Aum's attempts to develop a biological weapons program were extensive, but ultimately unsuccessful. See Amy E. Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the US Response* (Washington, DC: Henry L. Stimson Center, October 2000), 72–111.

Thus, the 1991 Review Conference authorized a group of governmental experts to identify and examine potential BWC verification measures from a scientific and technical standpoint. This Ad Hoc Group of Verification Experts, known as VEREX, examined and evaluated twenty-one measures that ranged from off-site surveillance of publications to on-site monitoring and inspections. VEREX evaluated each proposed verification measure according to the amount of data it could or could not provide; its ability to differentiate between activities that are prohibited and permitted under the BWC; its capability to clarify ambiguities concerning compliance; its requirements for manpower, technology, equipment, or other material; its implications for the protection of confidential business information and for the development of permitted research and scientific activities; and its financial, legal, organizational, and safety ramifications.[26] In all, VEREX met four times from March 1992 to September 1993. In its final report, VEREX concluded that no single approach could adequately monitor the BWC. Rather, VEREX recommended a combination of means—including off-site and on-site measures—to make the BWC a more effective instrument. Off-site measures included national declarations of biological weapons defense programs, vaccines, and facilities handling specific organisms and toxins; on-site measures included short-notice inspections and information visits to declared facilities.[27]

In April 1992, Russian President Boris Yeltsin conceded that the Soviet Union had violated the BWC and issued a decree outlawing the continuation of the biological weapons program.[28] Acknowledging international concern, Moscow decided to work with the BWC's two other co-depositary nations to try to establish some confidence that Russia was no longer operating an offensive program. A trilateral process, formally initiated in September 1992, involved visits to military and non-military facilities of possible compliance concern.[29] US and British officials visited several Russian facilities and vice versa, but the trilateral process gradually lost momentum and did not completely alleviate remaining compliance concerns about Russia's biological facilities.[30] Although collaborative research grant

[26] US Arms Control and Disarmament Agency, "Fact Sheet: The Biological Weapons Convention," Office of Public Affairs (Washington, DC: 18 August 1993): 1–2.

[27] United Nations, *Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Report*, Document BWC/SPCONF/1, 19–30 September 1994, 14–5.

[28] R. Jeffrey Smith, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992; J. Dahlburg, "Russia Admits It Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992; "Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons," Moscow, 11 April 1992.

[29] Among other steps taken to end the offensive program, Russia stated that it had cut personnel in the program by fifty percent and reduced research funding by 30 percent. US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," Press Release, Office of Public Affairs (Washington, DC: 14 September 1992). See also, "Proprietary Agreement: Procedures for Respecting Proprietary Information During Visits to Non-Military Biological Sites Pursuant to Paragraph 4(A) of the Joint US/UK/Russian Statement on Biological Weapons," Moscow, 12 May 1993.

[30] R. Jeffrey Smith, "US Wary of Russian Germ Arms; Despite Assurances from Yeltsin, Effort May Be Continuing," *Washington Post*, 8 April 1994; R. Jeffrey Smith, "US to Press Moscow on Alleged Arms Violations," *Washington Post*, 9 May 1994; US Arms Control and Disarmament Agency, *Threat Control Through Arms Control: 1994 Report to Congress,*

programs have brought numerous scientists and other visitors to many of the institutes involved in the former Soviet biowarfare program, no outsiders have ever been to the four military facilities at the core of this program.[31]

In September 1994, a Special Conference of BWC members convened in Geneva to discuss the findings of VEREX. This Special Conference called for the formation of the Ad Hoc Group to draft verification measures to be incorporated into a legally binding protocol to the BWC. The Ad Hoc Group was also to address the creation of measures to investigate the alleged use of biological weapons, as well as the following issues:

- The definition of terms and objective criteria (e.g., lists of biological warfare agents and possible threshold quantities);
- The possible incorporation of existing and additional enhanced CBMs into the verification regime;
- The development of a system of measures to promote compliance with the BWC; and,
- The delineation of a program for technical cooperation in the field of biotechnology for peaceful purposes.[32]

The Ad Hoc Group, which is open to all states parties to the BWC, began negotiations in 1995. Twenty-two rounds of negotiations were held through March 2001, with well over sixty member countries participating and additional countries observing. Upon completion, the Ad Hoc Group is to present its draft text to a Special Conference of the BWC's members and then to the UN General Assembly for approval. Once these two bodies endorse a completed monitoring protocol, it must then be ratified by all of the BWC's members, taking effect for each participating state as it completes the ratification process.

Hope that a monitoring protocol could be fashioned was drawn from the 1993 Chemical Weapons Convention, which contained intricate monitoring procedures to oversee the destruction of chemical weapons arsenals and production facilities, as well as to safeguard against covert weapons programs.[33]

(Washington, DC: US Arms Control and Disarmament Agency, 13 July 1995): 70; US Department of Defense, *Proliferation: Threat and Response*, 46.

[31] The four military sites are Sergiyev Posad, Kirov, Yekaterinburg, and Strizhi. For more on the collaborative research grant programs that are helping to transform the weapons institutes to peaceful, commercial research centers, see Amy E. Smithson, *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes* (Washington, DC: Henry L. Stimson Center, December 1999).

[32] United Nations, *Special Conference of the States*, Document BWC/SPCONF/1, 10.

[33] The CWC's articles consume forty-six pages, while the annexes detailing how to implement the treaty run over 140 pages. Underpinning the obligations that states take to destroy chemical weapons capabilities and forsake future weapons production, the CWC's verification annex specifies the inspection methods and procedures to be employed during routine inspections of chemical weapons defense, storage, production, and destruction facilities as well as at a variety of industrial facilities. Challenge inspection procedures are also spelled out in this annex, as are the safeguards that host facilities can employ to protect sensitive data unrelated to the treaty compliance. A separate annex lays out procedures to be used to protect

Monitoring the BWC would prove a tougher challenge, however, because nature is the source of the microorganisms that are the basis of biological weapons, and diseases must be studied if cures are to be found. Moreover, technical advances have given scientists the ability to engineer new disease strains and clean an entire manufacturing facility's fermenters and pipelines within minutes, capabilities that a government set on cheating could use to great advantage. The BWC protocol negotiators, in other words, would need to stretch the horizons of monitoring technologies and strategies if they were to succeed in creating a meaningful and feasible protocol.

Late in 1996, the Fourth Review Conference was held. An Iranian proposal to amend Article I by adding a prohibition against the use of biological weapons did not receive widespread support. Instead, seeking to reinforce the broad scope of the BWC's Article I prohibitions, the Final Declaration emphasized that those prohibitions apply to the emerging fields of molecular biology and genome studies. The Final Declaration called for the enactment of national penal legislation to criminalize individuals engaged in biological weapons activities.[34] Although the Final Declaration stated the importance of adherence to the BWC's provisions, it made no specific reference to the Soviet/Russian and Iraqi biological weapons programs, the existence of which by that time was well known.[35] This omission, indicative of the political sensitivity of directly naming BWC violators, was perhaps a harbinger of how challenging it would be to conclude a verification protocol. Despite the difficult nature of this task, however, the Final Declaration mandated that the Ad Hoc Group "intensify its work with a view to completing it as soon as possible before the commencement of the Fifth Review Conference."[36]

In the intervening months, the Ad Hoc Group made incremental progress. In the July 1997 negotiating session, the series of papers that had been produced in previous meetings was presented as a rolling text. This 246-page document consisted of twenty-three articles, seven annexes, and five appendices.[37] Virtually every line of this initial draft protocol was bracketed, indicating a lack of

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confidential information. Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.

[34] This idea is embraced in the US alternative proposals discussed later in this chapter. From the outset of negotiations, the Harvard-Sussex project has advocated this concept. For more details, see Matthew Meselson, "Averting the Hostile Exploitation of Biotechnology," *CBW Conventions Bulletin* 48 (June 2000): 16–19; "Draft Convention on the Prevention and Punishment of the Crime of Developing, Producing, Acquiring, Stockpiling, Retaining, Transferring or Using Biological or Chemical Weapons," *CBW Conventions Bulletin* 42 (December 1998): 2–5.

[35] For more, see Malcolm R. Dando and Graham S. Pearson, "The Fourth Review Conference of the Biological and Toxin Weapons Convention: Issues, Outcomes, and Unfinished Business," *Politics and the Life Sciences* 16, no. 1 (March 1997): 105–26.

[36] United Nations, *Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Declaration*, Document BWC/CONF.IV/9, 25 November–6 December 1996.

[37] United Nations, *Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, Document BWC/AD Hoc Group/38, 6 October 1997.

agreement on the proposed measure or language. Gradually, however, the negotiators seemed to find compromise language. Activities began shifting in 1998 as the negotiators began submitting fewer working papers and focusing more keenly on working with the wording already in the rolling text. The amount of bracketed language decreased by mid-2000,[38] but the remaining brackets were in intensely disputed sections of the draft protocol.

Finally, in March 2001, Ad Hoc Group Chairman Tibor Toth introduced compromise language in what is known as the chairman's text. The tabling of such a text usually signals the onset of a negotiating endgame, and a draft protocol was to be concluded by the Fifth Review Conference.[39] Some participating governments and outside observers depicted the Review Conference as a window of opportunity not to be missed to launch the draft protocol toward its opening for signature.[40]

This outcome was put in doubt long before the Review Conference. In July 2001, the United States announced it would not support the chairman's text. This decision was the product of an interagency review that had unanimously concluded that while the verification mechanisms outlined in the draft protocol would do little to uncover treaty violations, they could potentially compromise national security and US industry interests.[41] A senior State Department official said of the draft protocol, "On a cost-benefit analysis, [the protocol] has zero benefits."[42]

At the Fifth Review Conference, the United States did not retreat from this position. Rather, US representatives unveiled a series of proposals, described in the next section. The Review Conference was then thrown into disarray with the unexpected, last minute US proposal to curtail the Ad Hoc Group

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[38] Graham S. Pearson, "Progress in Geneva: Strengthening the Biological and Toxin Weapons Convention," *CBW Conventions Bulletin* 51 (June 2000): 33–8.

[39] A chairman's text for the Chemical Weapons Convention was tabled in March 1992, setting off a furious pace of negotiations over the summer and conclusion of the text by August 1992.

[40] Richard Norton-Taylor, "Britain Urges New Bio-Weapons Deal," *Guardian (London)*, 27 March 2000; Address by H E Leslie Luck, Ambassador and Permanent Representative to the United Nations and the Conference on Disarmament during the 19th Session of the BWC Ad Hoc Group, Geneva, Switzerland, 27 March 2000; "Political Decisions Needed Soon on Germ-Warfare Treaty: Chairman," *Associated Press*, 31 March 2000; "European Union Moves to Break Logjam on Anti-Germ Warfare Treaty," *Associated Press*, 29 June 1999. As one analyst noted, "Taken as a whole, it is evident that such outstanding issues are indeed soluble in such a way that different states-parties' concerns can be met while still achieving the goal of a protocol that strengthens the convention. It is simply a display of political will that is needed to go the final distance, and the window of opportunity for completion is indeed now." Graham Pearson, "The Protocol to the Biological Weapons Convention Is Within Reach," *Arms Control Today* (June 2000). Available at: http://www.armscontrol.org/ACT/june00/bwcjun.htm.

[41] Michael R. Gordon and Judith Miller, "U.S. Germ Warfare Review Faults Plan on Enforcement," *New York Times*, 20 May 2001, 1; Alexander G. Higgins, "Germ Warfare Group Suspends Negotiations Following U.S. Pullout," Associated Press, 3 August 2001.

[42] Merle D. Kellerhals, Jr., "Proposed Biological Weapons Protocol Unfixable, U.S. Official Says," US Department of State, International Information Programs, 25 July 2001. Available at http://usinfo.state.gov/topical/pol/arms/stories/01072503.htm.

negotiations. The conference went into a full one-year suspension, until November 2002. Indicating little interest in participating in the resumption of the Review Conference, the Bush administration has called for its speedy conclusion.[43]

THE US ALTERNATIVE PROPOSALS

In offering substitute initiatives for a formal BWC monitoring protocol, the Bush administration made two types of proposals. The first type centered on traditional monitoring that would deploy inspectors to ascertain treaty compliance. In a second category of alternative proposals, the US government asks states to take a variety of actions individually.

With regard to inspection procedures, the US government proposed that BWC members ask for clarification and resolution of compliance concerns related to unusual disease outbreaks or allegations of bioweapons use. If a bilateral exchange of information did not settle matters, concerned treaty members could then request the United Nations Secretary General to send an inspection team to the site. While the US proposal centers around BWC members agreeing in advance to cooperate with such inspections, it would also allow the host country to control all access to the site so that national security and business interests could be protected.[44] In addition, the United States suggested that bilateral consultations should be pursued to answer compliance concerns. Such consultations could include information exchanges and other measures, such as the voluntary opening of one or more sites to inspection.[45]

The Bush administration also put forward an assortment of proposals whereby nations would strengthen various domestic laws, practices, and capabilities. The US Government proposed that states individually:

- Criminalize the range of offensive activities that the BWC prohibits, making such actions punishable by imprisonment and/or fines and also bolstering extradition laws;
- Support the World Health Organization's disease surveillance and rapid outbreak response capacity, as well as similar programs conducted by the Office of International Epizootics and the Food and Agricultural Organization, which oversee surveillance of plant and animal diseases;
- Join with scientific organizations to develop and adopt professional conduct codes for scientists with specific admonitions against applying their skills and knowledge for hostile purposes;

[43] At a preparatory meeting in Geneva in early September, US officials threatened to name treaty violators unless the conference was concluded quickly with no further discussion of establishing a monitoring regime. David Ruppe, "BWC: With Threat, U.S. Pressures to End Review Conference Early," *Global Security Newswire*, 6 September 2002.

[44] The Secretary General would file a report in the aftermath of such an inspection. US Department of State, "New Ways to Strengthen the International Regime," 6.

[45] Ibid, 4.

- Enact controls for domestic and international transfers of dangerous pathogens and report any incidents related to work with such microorganisms that could have implications for other states, possibly extending access controls to who could work with dangerous pathogens and where such work could be performed;
- Put strict biosafety procedures in place for work with human, plant, and animal pathogens, patterned on the requisite guidelines of the World Health Organization, the Office of International Epizootics, or equivalent national practices; and,
- Make scientists engaged in genetic engineering research aware of its possible military applications and begin developing guidelines for possible national oversight of genetic engineering research.[46]

Subsequent reaction to the US initiatives has been mixed, with many governments and nongovernmental organizations somewhat distracted by the US insistence that the Ad Hoc Group not be the forum for entertaining these or any other proposals.[47]

METHODOLOGY OF THE REPORT

As previously noted, the Stimson Center's Chemical and Biological Weapons Nonproliferation Project convened a group of individuals with extensive experience in the US pharmaceutical and biotechnology industries to evaluate the soundness of the US alternative proposals. As the resumes contained in the appendix attest, the individuals who gathered around the Stimson conference table are each top experts in their respective fields. Together, they represent over 280 years of experience in a variety of industrial settings.

While the industry participants were not specialized in biological weapons nonproliferation *per se*, they brought significant experience to the table that is pertinent to the design of a monitoring system, biosafety, biosecurity, and the conduct of science. Their industrial specialties ranged from drug research and development to process scale-up and manufacture of medicines. Each expert is well versed in various government regulations and inspections as they pertain to biotechnology. Each is also a veteran of countless encounters with the internal scientific entities that govern research and manufacturing activities in university settings and at industrial facilities.

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[46] Conduct codes could be scratch-built or incorporated into existing codes, such as the one espoused by the American Society of Microbiologists. Nations could work with professional societies and national scientific academies to explore possible research oversight guidelines. Ibid, 3-5, 7.

[47] For the British's government views and a critique of two US analysts, see, respectively, *Strengthening the Biological and Toxin Weapons Convention: Countering the Threat from Biological Weapons* (London: Ministry of Foreign and Commonwealth Affairs, April 2002) and Jonathan B. Tucker and Raymond A. Zilinskas, "Assessing U.S. Proposals to Strengthen the Biological Weapons Convention, *Arms Control Today* 32, no. 3 (April 2002): 10-4.

The Stimson Center's role was that of convener, discussion facilitator, and report drafter. Not only did Stimson opinions not matter one iota, Stimson personnel were explicitly barred from even entering the fray. Otherwise, the main ground rule was that the floor was wide open for the participants to sort through the issues, identifying advantages, drawbacks, and gaps in the Bush Administration's proposals, thereafter developing recommendations to improve the initiatives. Unless indicated otherwise, all recommendations in the report reflect the consensus views of the group.

The remaining chapters of this report were compiled from verbatim transcripts of the meetings. Each of the participants reviewed the draft report. Afterwards, they were given the choice of being identified by name and affiliation or by a general characterization of their skills and work history. Both those who lent their name to the report and those who declined to be identified by name fully agreed that the report accurately reflects the proceedings and their specific views. The experts who decided to remain anonymous cited worries about a possible backlash from their employers or the media. All participants, it should be noted, volunteered their time for this project.

Chapter 2
Evaluating US Proposals to Monitor Compliance with the BWC

In comparison to treaties that limit or ban other types of weapons, the Biological and Toxin Weapons Convention (BWC) is singular in the compliance monitoring challenges that it poses. Inspectors can count tanks and missiles or use detectors to identify nuclear materials and chemical warfare agents definitively.[1] However, discerning the difference between offensive biological weapons activities and legitimate commercial and defense endeavors will be extremely difficult not only because the biowarfare agents themselves have their origins in nature, but because of the dual-purpose aspects of equipment, materials, skills, and activities in facilities scattered worldwide.

In this chapter, experts from the US pharmaceutical and biotechnology industries first evaluate the US government's July 2001 decision to reject the draft BWC monitoring protocol. Then, they critique two of several proposals that the US government introduced in November 2001 to substitute for a legally binding, multilateral monitoring protocol. These two alternatives might be categorized as "traditional" in that they would involve the use of inspectors to help determine whether a BWC violation had occurred. Briefly, one of the proposals would have nations agree in advance to allow the United Nations (UN) Secretary General to dispatch an international team of inspectors to investigate suspicious disease outbreaks and/or alleged biowarfare incidents. A second US proposal would have nations try to resolve compliance ambiguities bilaterally with consultations, data exchanges, and, perhaps, a voluntary visit to a facility of concern. Their viewpoints on these matters are drawn in no small part from prior discussions, captured in the May 2001 Stimson Center report entitled, *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol*.

A DEAL BEST REFUSED

According to experts from the US pharmaceutical and biotechnology industries, the purpose of inspections to monitor the BWC would be two-fold. One principal objective would be to discover if a facility is engaged in illicit weapons activities. In the event that the inspectors did not uncover evidence of violations, unexplained inconsistencies with the facility's stated purpose, or other cause to suspect that something was amiss,[2] they would file a report briefly describing the evidentiary support

[1] To illustrate, the Conventional Forces in Europe Treaty provided for inspectors to keep tabs on the quantities of major conventional armaments (e.g., personnel carriers) in the European theater, and the Intermediate-Range Nuclear Forces Treaty dispatched inspectors to military bases as well as to facilities in Votkinsk, Russia, and Magna, Utah, that produced key stages for Russian and US nuclear missiles. Inspectors for the Nuclear Nonproliferation Treaty and the Chemical Weapons Convention are allowed to employ sensors and sampling that can detect weapons materials. The nuts and bolts of these treaties can be found in US Department of State, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, DC: US Arms Control and Disarmament Agency, 1996).

[2] Examples of behavior that might generate suspicions among inspectors would be refusal of host officials to share requested data and grant access that would help inspectors understand factors at the facility that seemed inconsistent with its stated purpose. Inspectors would note both the inconsistencies and host official's uncooperative behavior in their inspection report.

that the facility was conducting legitimate activities. In short, the second major purpose of inspections was to affirm that compliant facilities were just that, clean.[3] Flowing from these two basic purposes, the industry experts defined effectiveness as the ability of monitoring techniques to help determine whether a facility was either compliant or intentionally violating the BWC.

When they reviewed the investigatory and non-challenge procedures in the draft BWC monitoring protocol,[4] the industry group concluded that what the Ad Hoc Group had crafted would not allow the inspectors to determine what was happening at facilities. Instead of clarifying compliance matters, the inspectors would end up adding to uncertainties by leaving a question mark hanging over legitimate facilities and covert weapons sites alike. The industry experts were so unimpressed with the draft BWC protocol that they gave it a grade of "D."[5]

Accordingly, the industry experts agreed with the Bush administration's decision to reject the draft BWC protocol. US officials listed three main reasons for their decision. First, they stated that the draft protocol would not resolve compliance concerns. Second, they said that the inspections would compromise national security and proprietary business data. Third, they noted that the inspections would pose a burden on sites that were monitored.[6]

The industry specialists took issue with the suggestion that inspections would pose an unacceptable burden and inevitably result in the loss of sensitive business data. Moreover, the industry

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[3] One of the industry experts explained that inspectors would have their hands full figuring out what some companies were doing. For example, some companies are exploring whether highly toxic agents can

> selectively kill cancers. That alone may not concern the inspectors, but this research involves developing high affinity antibodies that can target tumors specifically and don't react with other tissues, then conjugating these antibodies with highly toxic agents that will work at low concentrations to selectively destroy cancers. This work also involves animal facilities for monitoring affects of very low, sub-lethal doses. Given these dual-purpose capacities, this great research might not look straightforward in the eyes of inspectors. Legitimate facilities, though will have reams of documentation, knowledgeable personnel, business relationships, and regulatory agencies that will help inspectors understand that their facility is on the up-and-up.

Dr. Robert Hamilton, 9 August 2002. Dr. Hamilton is a senior scientist and group leader at a large US biotechnology firm, holds a PhD in microbiology and cell biology, and has over twenty-five years of experience in research and industry.

[4] Note that the industry experts did not review the rolling text of the BWC monitoring provisions until after they had developed their own monitoring strategies and tactics. They assessed the following iteration of the rolling text: United Nations, Draft Composite Text: Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, BWC/Ad Hoc Group/CRP.8, 30 March 2001. The monitoring provisions of this version of the rolling text were essentially the same as the composite text that the US rejected in July 2001.

[5] "D," rather than "F" was the worst grade that the group could have conferred. As Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, explained during a 23 August 2000 meeting of experts, "Sometimes an 'F' shows a little innovation."

[6] "The draft Protocol will not improve our ability to verify BWC compliance. It will not enhance our confidence in compliance and will do little to deter those countries seeking to develop biological weapons. In our assessment, the draft Protocol would put national security and confidential business information at risk." Ambassador Donald A. Mahley, "Statement by the United States to the Ad Hoc Group of Biological Weapons Convention State Parties," Geneva, 25 July 2001. Available online at http://usinfo.state.gov/topical/pol/arms/stories/01072501.

experts asserted that it would be worthwhile for commercial facilities to undergo inspection if monitoring could differentiate between cheating and legitimate facilities. Better to have strong inspections that would deter the use of industrial sites to camouflage weapons programs and be able to catch violators than to put a flimsy monitoring regime in place, they reasoned. They came to this conclusion after designing their own approach to monitoring, which is delineated in the coming paragraphs. Also, as an industry expert told Ad Hoc Group negotiators, the loss of trade secrets, a viewpoint long expressed by the Pharmaceutical Research and Manufacturers of America, was a "red herring" argument.[7] With each of the inspection procedures that they recommended, industry experts discussed the steps that they would take to avoid revealing valuable proprietary data to inspectors or giving them opportunities to steal it.

AN INDUSTRY APPROACH TO BWC MONITORING

According to the industry experts, no one monitoring tool in and of itself would necessarily get inspectors to the truth about whether a facility was researching or making pharmaceutical products or weapons. To get at this truth, the inspectors would need to concentrate on inconsistencies between the facility's stated purpose and what they found on site. No single incongruity is likely to be sufficient to label a facility "dirty," but an accumulation of them should raise suspicion. They recommended that the inspectors get to the bottom of things by first gathering information about the facility and then, once on site, using visual observation, review of documents, interviews, and, as a last resort, sampling and analysis. The industry experts argued that these methods, described below in turn, would lend clarity and confirm compliance or noncompliance.

Pre-Inspection Activities

Before going on site, the inspectors should obtain certain information from both the facility and from open sources. Data requested from the site itself should include what product(s) a plant is making and in what quantity, as well as a staff listing, including job titles. Among the open source data that could prove useful are annual reports, staff publications in journals, various news items (e.g., unusual disease outbreaks nearby), and patent estate and intellectual property portfolios. Knowing the stated purpose and size of a facility first allows the inspectorate to deploy a team of the appropriate size and skill sets. Such

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[7] Dr. Steve Projan, Director of Antibacterial Research at Wyeth-Ayerst Research, explained that job hopping of scientists from one company to another would be a more likely source of the loss of confidential business data. Presentation accompanying the report release, 6 May 2001, Geneva. According to a position paper on a BWC protocol,

> The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty. However, these elements also entail risks to commercial facilities including the potential loss of proprietary information, risks to commercial reputations, and added regulatory expenses that ultimately affect the cost and availability of medicines and other widely-used products.

Pharmaceutical Research and Manufacturers of America, "Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention," position paper, July 1998. Available at http://srpub.phrma.org/phrma/Jul.98.PhRMA.bwc.html.

data also create a set of expectations among the inspectors concerning containment, waste treatment, and other operational set-ups, which prepares them to discern departures from a normal operation once they are on site.

In addition, inspectors should consult satellite photographs of a facility to get their bearings on the layout and identify areas of interest. Comparison of photos taken just prior to and right after the announcement of an inspection might also reveal signs of unusual activity.

Site Tour

Once on the premises, simply observing what is going on will be crucial. For example, savvy inspectors will notice if a plant that is supposed to be making particular products is not configured and equipped accordingly. Inspectors should make their way around the facility with the floor layout, the architectural diagram, the as-built engineering diagram, and the piping and instrumentational diagram in hand. Such diagrams would allow the inspectors to tell quickly whether the plant layout made sense for its stated purpose, as well as if equipment was missing and pipes were connected in the right sequence, welded appropriately, and headed where they should. Inspectors could locate and account for key pieces of equipment (e.g., autoclaves, spray and freeze driers, aerosolizers), later comparing what they had seen with equipment lists as a double check against hidden items. Finally, these blueprints would let the inspectors know whether their hosts were steering them away from certain areas during the tour or taking them to the places they were supposed to see.

Matters deserving special attention from the inspectors include the isolation of reactors, air-handling systems, water cooling systems, and the like when the product(s) being made did not call for such measures. Post-production and purification capabilities appropriate for the declared product(s) should be present, consistent with a commercial enterprise supposedly concerned about product integrity and quality. Inspectors would want to check whether the containment was markedly out of step for the product(s)—unusually high containment for an animal vaccine plant or oddly low containment for a pharmaceutical for human consumption.

Industry experts counseled inspectors to watch for several things in storage areas, such as unlabelled supplies, unusual supplies, or large inventories of certain supplies (e.g., antibiotics). Stocks of high efficiency particulate arresting (HEPA) filters, gowns, and disinfectant should be in line with the facility's declared activities and operational status. With regard to media, the inspectors should be attuned not just to surplus quantities, but to the presence of media that was out of place, such as specialty media (e.g., oxide beef broth) not called for by the stated product(s).

Inspections of freezers should be done only if circumstances warrant and then with the understanding that sometimes seemingly unusual microorganisms get left behind or forgotten in the depths of freezers. Still, discovering a super virulent strain at a facility claiming to produce vaccine

should raise eyebrows. The level of containment present may provide clues to a facility's intent for questionable strains. Also, plant managers should be able to describe why they had such strains and provide supporting documentation (e.g. grant information).

Inspectors should check to see if design, construction, and operation of the waste handling system fit with what was needed to inactivate and treat the organism(s) and other facility wastes. Inspectors should be wary of a plant that declared it was making nontoxic waste with no biologic activity but still had procedures, equipment, and chemicals in place to treat hazardous wastes. Likewise, it would be odd if liquid waste from all phases of the production process were sent into treatment, particularly from purification and formulation areas.

If present, another area that should receive close scrutiny is the animal facility. The higher the species of animal and the more animals present, the harder the inspectors should look, especially if the animals are being kept isolated in individual, negative air flow chambers. Facility operators' concerns about possible contamination might make access to an animal facility unwelcome. However, inspectors might be able to view certain parts of it remotely, or one or two inspectors might be allowed in some rooms. Documentation (e.g., animal pathology records) might answer some questions, as might information from certification organizations, such as the American Association for the Advancement of Laboratory Animal Care or an equivalent. Should such activities prove inconclusive, a complete tour of this area might be scheduled for a time when there is a break in the testing process.

Finally, viewing the plant's staff performing their daily activities could be telling. Were inspectors to see personnel take stringent precautions while working with nonpathogenic, bacterial agents, it could indicate they are more accustomed to high-level containment work. Another telltale sign of personnel quickly pulled from high-level containment is dermatitis on the hands.[8] In all sectors of the plant, personnel should be executing their tasks and standard operating procedures (SOPs) smoothly. Should the inspectors note awkwardness, personnel might be putting on some type of masquerade.

Checking Paperwork for Clues

When it comes to paperwork, the military and legitimate pharmaceutical companies both document their activities voluminously. Inspectors can take advantage of that fact and use inconsistencies in paperwork to belie a violator. Conversely, a paperwork trail that cross-checks well would buttress giving a legitimate plant a clean bill of health. A genuine manufacturing facility will have a start-to-finish paperwork trail with several types of overlapping records.

At the outset, inspectors can survey the incoming ingredients via documents such as purchasing requisitions, receiving documents, disposition and warehousing records, and the bill of materials, which

[8] Dermatitis is a skin condition that can be caused by wearing protective gloves.

lists every ingredient used to manufacture product(s) at the facility. Inspectors can tell what kinds and amounts of materials the facility is regularly receiving and whether items are being ordered in types and quantities different from what the site needed for its research or manufacturing aims. For example, close scrutiny of amounts of personal protective equipment and other biosafety items consumed would be informative. Detailed paperwork on the media, namely material safety data sheets and the paperwork that certifies the media being used, should also be available in plants operating in many countries.

The operational pace of a facility can be traced through activity, equipment, and cleaning logs. Batch records will show how much product was processed within certain time periods, which inspectors can then check against ingredient inventory levels and the list of products that a facility manufactures at every step. Since normal plants do not operate perfectly, inspectors should see records of deviations from ideal operations, as well as records to investigate what went wrong on such occasions. In a similar vein, inspectors can learn about the tempo of plant operations by looking through the engineering control records for biosafety cabinets, HEPA filters, autoclaves, and decontamination operations as well as the documents about evaluating hazards operations. Moreover, certain equipment will generate pressure and temperature data, which inspectors should review to see that trends correspond to stated activities. Equipment validation and calibration records could indicate if there were attempts to recalibrate equipment before the arrival of the inspection team.

A manufacturing plant will have plenty of SOPs that inspectors can examine to see if they correspond to the plant's stated purpose. Oddities that should make inspectors wonder would be a facility making bacterial vaccines that does not have an SOP for a "kill step" after fermentation or a plant that has emergency response SOPs that do not match the kind of microorganisms declared. SOPs for quality control testing should make sense for the facility's stated product(s).[9]

If something appears out of order, these SOPs should be cross-matched against the list of quality control supplies and raw test data, which constitutes a huge paper trail. The lot release test records would also contain lot numbers that can be put side by side with batch records as well as product specifications. Faking this cross-cutting documentation would be no easy task. Should the inspectors have reason to believe commercial goods are not coming off the line, they can study the product billing, sales, and shipping records.

Inspectors should also closely eye records dealing with a facility's personnel and visitors. A review of the organizational charts would show whether staff ratios in different departments were reasonable for the facility in question. Training records should conform to the facility's stated activities, and personnel turnover rates should be within the expected range for the industry in that country. Likewise, visitor logs should show an expected level of traffic (e.g., maintenance contractors, business

[9] Products using bacteria, for example, should be tested for endotoxins (i.e., lipopolysaccharide) and pyrogens.

partners, regulatory inspectors) for that type of site. An explanation would be requested for military visitors or those who had specialized expertise out of step with a facility's purported line of work.

The beauty of having a wealth of documentation is that inspectors can compare various items against each other. Should the inspectors sense that a plant is really working around the clock instead of fielding just a day shift, they can pull gate records and timesheets. These items can be checked against utility expenditure documents (e.g., energy, water), airflow diagrams, and heating, ventilation and air conditioning maintenance records, among other things. Utility bills and filter changes would need to be in line with the number of shifts the plant says it is running. Inspectors could crosscheck visitor logs with service contracts, and if need be, subsequently interview contract personnel to confirm the nature of their activity on site. Inspectors that believe they have been fed a cover story can request project proposals and reports, service contracts, Institutional Animal Care and Use Committee documents, and records from internal review committees that govern project approval, biosafety, and waste management.

The industry experts noted that while documentation practices differed from country to country, even in countries with more modest regulatory requirements, commercial facility operators should have several paper trails (e.g., laboratory notebooks, construction records, waste treatment documents) for inspectors to examine. Moreover, the group observed that should enhanced biosafety, biosecurity, and research oversight standards be implemented worldwide, as they recommend in Chapter 4, facilities should have even more records that can be made available to inspectors. Given that the truth is often amidst the devilish details of such records, document review can be the tool in the inspectors' kit that clarifies or condemns.

Interviews

Industry experts opted to slate interviews after a site tour and a thorough review of documents because at that point inspectors should have a good idea of what questions to pose to the facility's personnel. Ideally, key people in each division would be made available for interviews. Were all of the key personnel conveniently on vacation or out-of-town "business" when the inspectors arrived, it would be a bad omen. The inspectors should also speak with the rank and file to find out whether they really know their jobs. If inspectors believe something is awry, they should have the worker bees run through their own SOPs, which should be no problem for personnel at a *bona fide* facility.

Sampling and Analysis

A final product sample would be the only type of sample that does not raise the specter of losing extremely valuable business data. Understandably, therefore, the industry experts approached the prospect of other types of sampling with considerable trepidation. Well aware that sampling is a powerful investigative tool that has tremendous potential to reveal proprietary information, the industry experts

proceeded to craft sampling and analysis ground rules that would satisfy the needs of inspectors and host facilities alike.[10]

Industry experts laid down a few governing principles for sampling. First, due to its intrusiveness, sampling should be a last-resort tool, reserved for occasions when inspectors seriously suspect prohibited activity, unless the industry facility volunteered a sample under other circumstances. Second, the inspectors should have the right to request samples, and the host facility the right to refuse that request, offering inspectors alternative ways to answer their concerns. Third, if inspectors found that samples were in order, ideally they would be taken on the first day of inspection by facility staff or a third party with proven sampling skills. Samples might be taken from points along the production process, the waste treatment system, personnel or test animals, and other general surface locations at the facility.[11] Fourth, the sampling techniques would be pre-stated with protocols based on accepted practice for different sample types (e.g., air, water). The sample would be split into blind or double blind sets for the inspectors and the host site and subsequently held in a lock box on site.

If the inspectors were able to conclude their work and resolve their concerns without analysis of the samples, then the host facility would have the right to destroy those items. In the event that the investigation needed to proceed to analysis to resolve ambiguities, the test(s) performed on the sample(s) would have to be pre-validated, with false positive rates specified. Preparing the assays for various samples would be a lengthy process, but the industry group reasoned that running unvalidated assays would not be scientifically credible and might not even catch a violator. Once validated assays were available, the samples would be taken from the dual-key lock box and preferably analyzed on site under the watchful eye of inspectors. Another, less desirable option would be to ship the samples under pre-agreed chain-of-custody procedures to certified third-party laboratories that are routinely tested for competency. In that case, the plant would have the right to have its personnel observe the analytical work from start to finish.

Inspection Formats

Timeframes and inspection teams will be crucial to the success of any inspection regime. The industry experts viewed a notice of at least five days sufficient time for the inspectors to gather and analyze the necessary pre-inspection information. In a challenge inspection setting, host officials should not receive much, if any, advance notice if a modicum of surprise is to be achieved.

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[10] To review their verbatim discussion on this topic, see Box 4.2 of *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol* (Washington, DC: Henry L. Stimson Center, May 2001): 78-84.

[11] Note that a plant that claims to be making vaccines or biopharmaceuticals but does not have multiple sampling access points within its production process should automatically provoke questions from the inspectors. Pharmaceutical and biotechnology manufacturing facilities often retain samples from various points throughout their processes. If facility operators agreed, inspectors might examine such samples to resolve some ambiguities without interfering with the manufacturing process.

To try to assemble all the pieces into a coherent picture of a facility's activities, an inspection team tailored with an appropriate number of inspectors with the right disciplines must be deployed. At a minimum, the team should encompass the following areas of expertise: biochemical engineering; industrial microbiology; materials management; heating, ventilating, and air conditioning operations; infectious disease research; regulatory and quality control operations; and support/process /instrumentation/civil engineering. At least five or six individuals, but ideally six to eight inspectors should comprise a team because additional site-specific functional expertise would probably have to be added.[12] Also, even though the industry group recommended that legal and administrative support staff be on-call at inspectorate headquarters, someone on the team should have a working knowledge of service contracts and other routine legal matters.

In sum, the inspectors will be confronted with a constant stream of seeming contradictions, so a cross-disciplinary team would be essential to unravel the complexities and determine whether a facility was engaged in commercial work or illicit weapons activities. The industry group stressed that the monitoring tools would only be as good as the inspectors. Intentional BWC violations may be difficult to prove definitively, but the industry group had mostly high confidence that the inspection strategies and tactics they recommended would prove successful in the field.[13]

EVALUATING THE US GOVERNMENT'S ALTERNATIVE BWC MONITORING PROPOSALS

As noted briefly above, the US government has advanced two proposals ostensibly to supplant a formal BWC monitoring protocol. First, the US government proposed that the BWC members agree to use the following procedures to investigate suspicious outbreaks of disease or allegations of use. Any BWC member could ask another treaty member to clarify and resolve concerns, requesting, if necessary, an investigation under the terms of the 1925 Geneva Protocol, which prohibits the use of germ weapons. The country receiving such a request would be required to provide an international inspection commissioned by the UN Secretary General timely access to the site of the outbreak. This inspection team would subsequently file a factual report, which the UN Secretary General would distribute. During the inspection, the host state would control "all access within the area of investigation" so that national security and business interests would not be jeopardized.[14]

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[12] Inspectors must be able to understand the native tongue of host officials, so having good interpreters on the inspection team will be essential. Also, since business practices vary from country to country, it will be important that someone on the inspection team understand the local business culture.

[13] See Table 4.2 in *House of Cards*, where the industry experts rated the expected effectiveness of monitoring in a particular functional area (e.g., medical facilities, supplies, downstream processing). In two areas, the group gave a low expected effectiveness rating, followed by a one low to medium rating, two medium ratings, three medium to high ratings, six high ratings, and one rating of very high expected effectiveness. *House of Cards*, 76.

[14] This summary was drawn from US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001, 6. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

In the second US proposal, any BWC member that receives a bilateral request from another treaty member to clarify and resolve compliance should respond "promptly and fully" with explanatory information. If that data exchange is insufficient to dispel compliance ambiguities, the two states concerned can enter into an arrangement to exchange additional data or to conduct visits and other procedures at the site(s) involved.[15] In an abbreviated version of this proposal, the US government characterized it as setting up "a voluntary cooperative mechanism" for addressing compliance concerns.[16] In shorthand, the proposal is described as involving "voluntary visits."

In a word, industry experts deemed both of these proposals toothless. The group observed that the proposal to have states pledge to cooperate with the Secretary General's inspectors would do little more than perpetuate current circumstances. The General Assembly and Security Council have already strengthened the investigatory responsibility that the BWC originally vested with the Security Council by allowing the UN's leader to deploy inspection teams without getting approval to do so from a majority of UN member states. In the 1980s and early 1990s, Iran, Iraq, Mozambique, and Azerbaijan cooperated when the Secretary General sent inspectors to investigate allegations of chemical or toxin weapons use, but other governments denied UN inspectors access.[17] Since Article VI of the BWC already stipulates that member countries should cooperate with UN inspections,[18] a tougher US proposal is needed if BWC members are to be obligated unequivocally and fully to cooperate with future inspections.

The industry group identified three essential ingredients that would set the stage for successful challenge inspections. First, challenge investigations would be as isolated as possible from politics, which would indicate a set-up similar to the provisions of the Chemical Weapons Convention, where a challenge inspection proceeds automatically unless halted by a three-quarters vote of that treaty's governing body.[19] Second, the governing provisions must provide for investigation of facilities suspected

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[15] US Department of State, "New Ways to Strengthen the International Regime," 6.

[16] Ibid, 1.

[17] In each and every instance UN inspectors were deployed, but they were looking into suspicions of chemical weapons use, not germ warfare use or accidental releases. For more detail on these inspections, see Jonathan B. Tucker and Raymond A. Zilinskas, "Assessing U.S. Proposals to Strengthen the Biological Weapons Convention," *Arms Control Today* 32, no. 3 (April 2002): 10-4.

[18] Article VI of the BWC allows member states to complain to the UN Security Council, which may initiate an inspection. Paragraph 2 of this article says: "Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council." Throughout the treaty's early history, the willingness of states to cooperate was not put to the test largely because one of the permanent five Security Council members, each of which carry a veto power, would presumably step forward to defend the interests of a country under suspicion of cheating. For example, the USSR would have vetoed any attempt to investigate the 1979 outbreak of anthrax at Sverdlovsk, which killed at least sixty-eight. Russian President Boris Yeltsin conceded in April 1992 that this outbreak was caused by an accident at an anthrax production facility. Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons, Moscow, 11 April 1992; R. Jeffrey Smithson, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992. In the early 1990s, an authoritative investigation of the Sverdlovsk outbreak was conducted by outside experts. Mathew Meselson, Jeanne Guillemin, et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 266, no. 5188 (18 November 1994): 1202-8.

[19] Within a twelve-hour window before the inspection begins with the landing of the team at the port of entry in the challenged state, the forty-one members of the Executive Council of the Chemical Weapons Convention can vote to halt a challenge inspection if, after hearing the reasons underpinning the challenge, they deem the inspection frivolous or unwarranted.

of conducting prohibited activities, not just suspicious outbreaks of disease or allegations of uses. Third, a sufficient number of appropriately skilled inspectors must be dispatched promptly once a situation meriting challenge inspection is identified. Once there, the inspectors must be allotted sufficient time to sort allegation from fact, employing a panoply of inspection tools.

With regard to the voluntary inspection proposal, the industry experts were stumped as to why it would be tabled in the first place. Any facility that opened its doors for such a visit would have ample time to scour their grounds of evidence of cheating prior to inviting the inspectors. Therefore, the monitoring value of voluntary inspections is questionable, if not negligible because of the emptiness of the exercise. Another negative aspect of this formulation is that a government could decide for political reasons to "volunteer" an industry facility for such an inspection.[20] Since the inspection format could well produce meaningless outcomes, then voluntary inspections could be a costly nuisance to industry. For these reasons, the industry group did not see voluntary visits as a constructive monitoring approach.

CHARTING A COURSE FORWARD

In introducing these two alternative monitoring proposals, the US government publicly reasserted "it is impossible to verify compliance with the BWC."[21] Obviously, experts from the US pharmaceutical and biotechnology industry take issue with that statement. They believe that if multidisciplinary inspection teams are allowed sufficient time on site and empowered to use pre-inspection research and analysis, site tours, document reviews, interviews, and sampling, they can discern legitimate from cheating facilities. Moreover, the industry experts stated that the operators of commercial facilities, well versed in hosting all manner of regulatory inspections, would be able to protect their proprietary business data during such inspections at the same time that they helped the inspectors achieve their aims.

Article IX, paragraph 17, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction*.

[20] This concern arises out of the experience of one US firm during inspections conducted under the September 1992 trilateral agreement between Russia, Great Britain, and the United States. In mid-February 1994, the Russians requested an inspection of a Pfizer, Inc. site in Terre Haute, Indiana, part of which was originally built to produce biowarfare agents. That portion of the plant was mothballed before it became operational. The Russians accused the firm verbally and in writing of possibly violating the BWC because the fermenters in question had not been destroyed, even though corporate officials explained that it was cheaper to padlock that building than destroy the equipment. A week later, the Russians asked to inspect a Pfizer research and development facility in Groton, Connecticut. Pfizer officials wanted to decline the visit, but agreed to it under considerable White House pressure. Russian inspectors made similar allegations of cheating. Later, US government officials described these trilateral visits as voluntary. On the trilateral agreement, see US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," press release, 14 September 1992. On the Pfizer trials, briefly, "Biological Weapons Convention: Chronology 1994," *Arms Control Reporter* 13, no 3 (14 February 1994): 701.B.123-4. Also, US government officials, interviews with Amy E. Smithson, Washington, DC, (30 December 1996, 31 December 1997, 2 January 1998, 6 January 1998); US industry official, Washington, DC, (2 January 1998).

[21] US Department of State, "New Ways to Strengthen the International Regime," 7. This was certainly not the first time that the US government has made such a statement. The administration of George H.W. Bush likewise stated that the BWC was "unverifiable." "The convention is not effectively verifiable and we do not know any way to make it so." Ronald F. Lehman, Arms Control and Disarmament Agency Director, "Address to Third Review Conference of the Biological and Toxin Weapons Convention," Geneva, 10 September 1991. Available at http://www.fas.org/nuke/control/bwc/news/910910-196372.htm.

What remains something of a mystery to US industry experts is why their government has failed to do the requisite research and field-testing to identify once and for all what methods could be used to monitor the BWC. Given the inchoate results of the two US field trials held in the mid-1990s and the existence of a congressional mandate to conduct additional field trials at government, academic, and pharmaceutical sites,[22] the industry group believed that it is incumbent on the US government to forge ahead as swiftly as possible with such field trials. Absent the conduct of such trials, the Bush administration can hardly declare the BWC "unverifiable," particularly since inspectors who spent time at former Soviet and Iraqi sites repeatedly encountered evidence—sometimes blatant, sometimes very subtle—of these nations' bioweapons programs.[23] The industry group stated that US companies and the trade associations representing them—namely the Pharmaceutical Research and Manufacturers of America and Biotechnology Industry Organization—should assist with such field trials.

To encourage the US government and industry to move ahead with field trials, experts from the US pharmaceutical and biotechnology industries agreed to draft plans of work for trial inspections at two types of industry sites, research and development and manufacturing facilities. The purpose of these trial plans is to put inspectors through their paces in a tough and realistic, but controlled environment so that data can be gathered for the type of cost-benefit analysis that should underpin the US position on BWC inspections.[24] Upon completion, this group of industry experts intends to share these trial inspection plans with the US government, industry trade associations, and other interested governments to facilitate the testing of various monitoring strategies, tactics, and technologies.

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[22] The 1999 National Security and Corporate Fairness Under the Biological Weapons Convention Act. This law requires trial investigations and visits at US government facilities, installations, and national laboratories; academic institutions; and vaccine production, pharmaceutical, and biotechnology facilities. Following these trials, the Executive Branch is to report to Congress describing the monitoring results that can be expected and the risks of monitoring to US national security and business interests. See Public Law 106-113. As for the two prior US trials, one was a three-day exercise conducted in late October 1995 at a US facility that was producing anthrax vaccine and making botulinum toxin for medicinal treatments. A second one-day trial was conducted at a trio of research facilities in Albuquerque, New Mexico, on 26 March 1996. At the conclusion of both trials, inspectors could not definitively state that the sites were not covertly engaged in prohibited activities, nor could they prove that such illicit activity was underway. The report from the October 1995 trial was never released publicly, but the second trial is described in a limited distribution report. See *DOE Exercise to Determine the Potential Impact of a Legally Binding BTWC Regime on DOE Sites*, report number PNNL-11015, prepared by Pacific Northwest National Laboratory under Contract DE-AC06-67RLO 1830 (Richland, Wash.: June 1998).

[23] US and British inspectors visited several former Soviet bioweapons facilities under the 1992 Trilateral Agreement. Several veterans of these inspections related anecdotes of their experiences, which included visual observation of blatantly missing or disabled equipment and statements by scientists being interviewed that discussed weapons work. Round table discussions held on 27 April 2000 at the Henry L. Stimson Center, Washington, DC. On the United Nations Special Commission on Iraq inspections that uncovered the details of that country's biological weapons program, see UN Security Council, "Note by the Secretary-General," Document S/1997/774, 6 October 1997. See also, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: US Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997. UN inspections in Iraq were aborted in 1998, when Iraq insisted that the inspectors leave the country. Barbara Crossette, "Iraqis Break Off All Cooperation with Inspectors," *New York Times*, 6 August 1998.

[24] As one industry expert explained, their actions are based on "tried but true scientific method. . . .this is based on the premise of hypothesis and testing. We are putting forth our hypothesis of the best method, think inspections will work, but the hypothesis must by definition pass or fail, when it comes to testing." Dr. Robert Hamilton, senior scientist and group leader at a large US biotechnology firm, 10 August 2002.

Chapter 3
Weighing the US Proposals to Criminalize Offensive Bioweapons Activities, Improve Global Disease Surveillance, and Institute Scientific Codes of Ethics

The Bush administration announced initiatives at the 2001 Biological and Toxin Weapons Convention (BWC) Fifth Review Conference intended to move individual nations to build up their domestic capacities to prosecute biocrimes, to detect and respond quickly to disease outbreaks, and to create professional codes of conduct for scientists working with dangerous pathogens. This chapter treats this set of proposals in turn. After the US government's proposals are briefly recapitulated, the discussion proceeds to a mixture of background information and the points that the representatives of the US pharmaceutical and biotechnology weighed. Each section of this chapter ends with a brief statement from the industry experts that captures their views and recommendations to improve these initiatives.

CRIMINALIZATION OF OFFENSIVE BIOLOGICAL WEAPONS ACTIVITIES

One of several alternatives that the Bush administration proposed to a multilateral, legally binding BWC monitoring protocol was that individual BWC members criminalize offensive biological weapons activities. In tandem, the US government proposed that BWC members enhance bilateral extradition agreements with each other to prevent their citizens from being prosecuted abroad.[1]

The need for criminalization of offensive biological weapons activities arises because the BWC's prohibitions against the production, procurement, and use of biological weapons refer primarily to the actions of states. Only vaguely does the BWC address the issue of individual responsibility.[2] Yet, the threat of biological weapons usage by terrorists requires a coordinated international effort to deter and penalize the actions of individuals. Unifying international standards for criminal misconduct would punish all individuals, regardless of nationality, who attempt to acquire or use these weapons of mass destruction.

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[1] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001, 3-4. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

[2] Article IV of the BWC requires each state to prohibit activities on its territory, "in accordance with its constitutional processes," that are prohibited to states under the Convention. This language implies, though by no means mandates, that states must hold their citizens responsible for violating the BWC's provisions. Matthew Meselson and Julian Robinson, *A Draft Convention to Prohibit Biological and Chemical Weapons Under International Criminal Law*, The Harvard Sussex Program on CBW Armament and Arms Limitation, 1 November 2001. Available at http://www.fas.harvard.edu/~hsp/crim01.pdf.

Previous Steps Toward Criminalization

The BWC's 145 members have long recognized the need to further bolster compliance by integrating the treaty's legal prohibitions into national legal systems.[3] Although the BWC requires states to "take any necessary measures to prohibit and prevent" BWC violations under their jurisdiction, [4] this imprecise phrasing leaves ample room for interpretation as to exactly what is required. Moreover, the BWC's language stands in sharp contrast to the clear requirement in the Chemical Weapons Convention that member states adopt penal legislation for those who violate the treaty's prohibitions.[5]

A decade after the BWC entered into force, successively stronger and more explicit proposals began surfacing to reinforce the BWC's domestic legal status. In 1986, the Second Review Conference noted the importance of "legislative measures…designed effectively to guarantee compliance with the provisions of the Convention."[6] The Third Review Conference called upon each BWC member to make an annual voluntary data submission to the United Nations about activities that were pertinent to treaty compliance. Among the information to be provided was an annual questionnaire describing their national legislation, as well as any new amendments that had been made in the past year.[7] In 1996, the Fourth

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[3] There are 145 states parties to the BWC, not including Taiwan, which ratified the convention before the United States recognized the People's Republic of China as the sole government of China. Authorities in Taiwan have indicated that they will continue to abide by the terms of the treaty. US State Department, Bureau of Arms Control, fact sheet, "Parties and Signatories of the Biological Weapons Convention," 14 February 2002. Available at http://usinfo.state.gov/topical/pol/terror/01101809.htm

[4] Fully, Article IV of the BWC reads:

> Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons. Available at http://www.stimson.org/cbw.

[5] Article VII.1(a) of the CWC states: Each state shall "prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited to a State Party under this Convention, including enacting penal legislation with respect to such activity." Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction. Available at http://www.stimson.org/cbw.

[6] United Nations, *Final Document of The Second Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons Convention and on their Destruction*, Document BWC/CONF.II/13/11, 26 September 1986.

[7] Data related to the "Declaration of legislation, regulations, and other measures" was to be submitted to the United Nations Department of Disarmament Affairs. United Nations, *Final Document of The Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons Convention and on their Destruction*, Document BWC/CONF.III/22/Add. 2, 27 September 1991. Other confidence-building measures asked for states to declare their past activities in offensive or defensive biological weapons research, report unusual disease outbreaks, and identify all high containment facilities within their territory. For more on BWC confidence-building measures, see Marie Chevrier, "Doubts About Confidence: The Potential and Limits of Confidence-Building

Review Conference specifically called for states to pass penal legislation, stipulating that any nation that did not yet have such laws in place enact them "immediately."[8]

A handful of states have reacted to these increasingly forceful calls by passing or attempting to enact such legislation. A 1987 New Zealand law provides for "imprisonment for a term not exceeding 10 years for manufacturing, stationing, acquiring, possessing or having control over any biological weapon."[9] The United States criminalized possession of biowarfare agents without proper authorization for specific prophylactic, protective, or other peaceful research purposes in 1989.[10] France has adopted prison terms of five to seven years for "the offenses of developing, producing, possessing, stockpiling, buying and selling of biological and toxin-based weapons."[11] Canada's *Biological and Toxin Weapons Convention Implementation Act*, introduced in Parliament in the fall of 2001, is patterned after the BWC's broad prohibitions and establishes a domestic inspectorate to monitor compliance.[12]

Otherwise, the international drumbeat for domestic criminalization laws has apparently been to little avail. According to data that BWC members voluntarily submitted from 1997 through 2001, a majority of the BWC members providing such data—twenty-seven out of forty-five—had "nothing to declare" or "nothing new to declare" regarding penal legislation. A whopping ninety-eight BWC members failed to even submit any data whatsoever during this time period.[13]

Measures for the Biological Weapons Convention," in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, October 1995), 53-75.

[8] United Nations, *Final Document of The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons Convention and on their Destruction*, Document BWC/CONF.IV/9, 6 December 1996.

[9] New Zealand Ministry of Foreign Affairs and Trade, *New Zealand Nuclear Free Zone, Disarmament and Arms Control Act 1987*, 8 June 1997. Available at http://rangi.knowledge-basket.co.nz/gpacts/public/text/1987/an/086.html.

[10] See the Biological Weapons Antiterrorism Act of 1989, Public Law 101-298, 22 May 1990. In 2001, the provisions of this statute were expanded and strengthened in title VIII, section 817 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001, Public Law 107-56, 26 October 2001.

[11] United Nations Security Council, *Report Submitted by France to the Counter-Terrorism Committee Pursuant to Paragraph 6 of Security Council Resolution 1373 (2001) of 28 September 2001*, Document S/2001/1274, 27 December 2001, 11.

[12] Canada, House of Commons, Bill C-55 (first reading), 37th Parliament, 1st sess. Available at http://www.parl.gc.ca/37/1/parlbus/chambus/house/bills/government/C-55/C-55_1/90173b-10E.html.

[13] Graham Pearson and Nicholas Sims, "Article IV: National Implementation," in *Strengthening the Biological Weapons Convention: Key Points for the Fifth Review Conference*, Graham S. Pearson and Malcolm Dando, eds., 2002. Available at http://www.bradford.ac.uk/acad/sbtwc/key5rev/5thArtIV.pdf.

Views of the Industry Experts

The Bush administration advanced its criminalization proposals with the argument that individual states could pass dissimilar pieces of legislation and still effectively enforce international compliance with the BWC. Undersecretary of State John Bolton claimed that "it is not necessarily the case that one size fits all," and posited that if individual states took action, it would ostensibly avoid "slugg[ing] through seven more years of negotiation."[14] In some respects, the industry experts viewed this proposal as a step forward, but in others, they did not. The criminalization of offensive biological weapons activities makes such fundamental sense that most people, upon hearing that such laws are not in place globally, are hard-pressed to believe that such a gaping hole in the international legal system exists in this day and age. Put another way, domestic laws criminalizing activities that could threaten countless lives, not to mention the economic well being and stability of governments, are long overdue. However, the industry group saw the effectiveness of a criminalization initiative as dependent in large part on how it is executed, and therein lies the major deficiency of the US approach. Fortunately, this shortcoming can be corrected.

Given the years that have passed since proposals first began circulating for BWC members to enact such penal legislation, the prospects of moving toward the Bush administration's goal of establishing a comprehensive regulatory regime via a lattice work of national laws and extradition agreements would appear rather grim. A web of dissimilar national legislation—some more stringent while others more lenient—could well complicate international efforts to pursue and punish those who violate the BWC.[15] Bioterrorists could conduct their nefarious deeds in countries with statutes that do not empower law enforcement authorities to investigate and prosecute biocriminals vigorously.

The industry experts believed that a determined move to negotiate and enact uniform penal legislation, applicable to all individuals under international law, is far preferable to an approach that could yield glacial progress and a potpourri of laws. The Harvard-Sussex Program has developed a Draft Convention on the Prevention and Punishment of the Crime of Developing, Producing, Acquiring, Stockpiling, Retaining, Transferring, or Using Biological and Chemical Weapons. Accordingly, any person who commits any of the prohibited acts anywhere would risk prosecution or extradition if the person were found in the territory of a state that joins the criminalization convention. [16]

The US government has joined numerous treaties criminalizing other types of heinous crimes, such as airline hijacking and sabotage (1970 and 1971), hostage taking (1979), and theft of nuclear

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[14] US Department of State, International Information Programs, "Bolton Briefing on the Biological Weapons Pact," transcript of press conference, 20 November 2001. Available at http://usinfo.state.gov/topical/pol/terror/01112003.htm.

[15] "International Criminal Law and Sanctions to Reinforce the BWC," *The CBW Conventions Bulletin* no. 54 (December 2001): 1-2.

[16] Meselson and Robinson, *A Draft Convention*, 2001.

materials (1980). Such crimes are deemed "particularly dangerous or abhorrent to all regardless of the nationality of the accused or the place where the alleged crime was committed."[17] Crimes involving biological weapons fall under the same category. The industry group concluded that the US government and the international community should embrace a much stronger uniform criminalization regime to prevent and punish offensive biological weapons activities.

IMPROVING GLOBAL DISEASE SURVEILLANCE

Among several other proposals, the US government called upon the BWC's membership to support the strengthening of capabilities of the World Health Organization (WHO), the Office of International Epizootics, and the Food and Agriculture Organization (FAO) to detect human, animal, and plant disease outbreaks in a timely manner. The Bush administration asked that states also support the investigation and disease outbreak mitigation capabilities of WHO by quickly providing aid (e.g., medical assistance) in the event of an emergency.[18]

Disease surveillance is a phrase that describes the capability to detect disease outbreaks, whether natural or intentional, as well as the emergence of entirely new pathogens, the appearance of known pathogens in new geographic areas, or the reemergence of new antibiotic-resistant strains of old disease foes.[19] Infectious disease can spread across manmade borders effortlessly, so surveillance requires a multi-tiered approach. This section first outlines the efforts that the WHO's Department of Communicable Disease Surveillance and Response spearheads to coordinate disease surveillance at the institutional, national, and international levels.[20] Then, some of the challenges of disease surveillance are discussed, using the US program as an example. Finally, the industry group offers its thoughts on the US proposals.

The World Health Organization's Roadmap for Better Disease Surveillance

At the heart of successful disease surveillance is the ability to collect samples correctly and use the appropriate laboratory analysis techniques to identify the pathogen causing the disease outbreak.

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[17] Matthew Meselson, "International Criminalization of Chemical and Biological Weapons," [American Academy of Arts and Sciences] *Bulletin*, (Winter 2001). Available at http://www.amacad.org/blvlivn2/blvlivn2_28c.htm.

[18] States are asked to identify in advance what type of aid they would provide. US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," 9.

[19] According to WHO, over thirty new communicable diseases have been identified in the last two decades alone. World Health Organization, "WHO Opens an Office in Lyon (France) to Help Developing Countries Detect and Control Epidemics and Emerging Diseases," press release, 8 February 2001. Available at http://www.who.int/inf-pr-2001/en/pr2001-06.html.

[20] The US Centers for Disease Control and Prevention are a primary partner with WHO, providing support and resources for these efforts. Dr. David L. Heymann, Executive Director for Communicable Diseases, World Health Organization, statement to the Senate Committee on Foreign Relations, 107th cong., 1st sess., 5 September 2001.

Sometimes, the microscopic culprit is unexpectedly different from what might be indicated by patients' symptoms and other evidence observable to the naked human eye—possibly a new disease entirely. However, a lack of basic infrastructure and trained personnel hampers sampling and analysis efforts, particularly in developing countries. WHO is tackling the global disease surveillance challenge with a three-pronged effort, building institutional, national, and international capacities.

Institutionally, WHO partnered in 1997 with the US Centers for Disease Control and Prevention (CDC) to create the Training in Epidemiology for Public Health Intervention Network, a non-profit organization that creates, supports, and networks programs that educate individuals in epidemiology and public health practice.[21] WHO also helps countries link their laboratories to speed the analysis and interpretation of sample data. Disease surveillance requires not only the detection of an outbreak, but also the generation of a swift response. To that end, WHO opened an office in Lyon, France in 2001 that will both train laboratory technicians from developing countries and work to enhance the interconnectivity of national laboratories.[22]

On a national level, WHO is helping states put the appropriate laboratory and communications infrastructure into place to aid disease surveillance. Once laboratories identify a disease, that information needs to be reported to a coordinating authority, most often a Department or Ministry of Health. WHO provides states with standardized information as a baseline so that they can build from proven practices and standards. WHO supplies a "Communicable Disease Surveillance Kit" that includes three basic documents to steer countries in a common, constructive direction: 1) the WHO Protocol for the Evaluation of Epidemiological Surveillance Systems; 2) WHO Recommended Surveillance Standards; and, 3) the WHO Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens.[23]

From this common foundation, WHO then stresses that states should tailor their national surveillance plans to their individual circumstances. For example, WHO encourages countries to identify their own list of diseases that merit particular concern and prioritize monitoring for those diseases. Coordination of existing health assets in line with those priorities reduces costs and improves the

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[21] Currently more than twenty such programs operate worldwide. Regional meetings bringing participants in the programs together for conferences have been held in Africa, Asia, the Americas, and the Middle East. World Health Organization, "Integrated Disease Surveillance," fact sheet. Available at http://www.who.int/emc/surveill/index.html. See also, http://tephinet.org.

[22] The first class of technicians began their two-year training in April 2001. The group will be trained in the diagnosis and treatment of epidemic diseases frequently found in developing countries (e.g., cholera, yellow fever), as well as emerging diseases such as Marburg and Ebola. The course also discusses the monitoring and treatment of the increasing number of antimicrobial resistant infectious agents appearing in both developed and developing nations. Students will also be instructed in the use of various technologies to speed information sharing and communication. World Health Organization, "WHO Opens an Office in Lyon ," press release.

[23] World Health Organization, "Public Health Surveillance," slide show. Available at http://www.who.int/emc/slideshows/National_system/sld001.htm.

sustainability of the system, while at the same time allowing health authorities to identify any gaps that need to be addressed.[24]

Using this approach, some nations, including developing countries, have already seen the benefits of improved disease surveillance.[25] Moreover, some regional networks have also been formed to connect designated health authorities, permitting rapid communication so that countries near to an outbreak can take necessary precautions.[26]

Recognizing the importance of a global approach, WHO is bracing its institutional and national efforts with an international system dubbed the Global Outbreak Alert and Response Network. Begun in 2000, this network links seventy-two existing infectious disease laboratory networks and institutions worldwide, pooling their skills, information, and resources to deal with the threat of an outbreak.[27] Drawing from the network's assets, WHO has launched effective international responses to outbreaks in Afghanistan, Bangladesh, Côte d'Ivoire, Egypt, Ethiopia, Gabon, Guinea, Kosovo, Saudi Arabia, Sierra Leone, Sudan, Uganda, and Yemen.[28]

Challenges Facing Disease Surveillance

While WHO has done a yeoman's job strengthening disease surveillance capabilities worldwide, many stumbling blocks remain. Even the United States, which supposedly has ample resources, advanced technology, and skilled personnel, has had its own share of difficulty maintaining an effective disease surveillance system. From border to border, national surveillance programs have to be capable of reliably

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[24] Ibid.

[25] With the partnership of international organizations and nongovernmental organizations, Sudan launched its early warning and response network in 1999. Equipped with one hundred field radios and two e-mail connections, the network has ninety-one health workers trained in epidemiology and laboratory detection. Previously, response to an outbreak of a relapsing fever took 6 months during which time 400,000 cases developed and over 2,000 people died. In 2000, with the network's help, a similar relapsing fever outbreak was reported and contained within two weeks, resulting in 154 cases and eight deaths. "Early Warning and Response Network (EWARN), southern Sudan," *Weekly Epidemiological Record* 4, no. 77 (25 January 2002): 26.

[26] For example, the European Union has an Early Warning and Response System that connects the national health authorities of its member states. World Health Organization, Department of Communicable Disease Surveillance and Response, *Report of a Global Meeting on Communicable Disease Surveillance, Including Epidemic-Prone and/or Vaccine-Preventable Diseases*, Document WHO/CDS/CSR/NCS/2002.4, 25 January 2001.

[27] For example, one of the tools the global network accesses is the Global Public Health Intelligence Network (GPHIN) developed by HealthCanada for WHO in 1996. An automated system, GPHIN searches open source information from around the world looking for reports that might indicate a sudden surge in certain symptoms or other indications of possible disease events. See http://www.who.int/emc/global_outbreak_network.htm. The Global Outbreak Alert and Response Network also moves beyond surveillance and includes provisions for rapid response, another point in the US proposals. World Health Organization, Department of Communicable Disease Surveillance and Response, *A Framework for Global Outbreak Alert and Response*, Document WHO/CDS/CSR/2000.2. Available at http://www.who.int/emc-documents/surveillance/docs/whocdscsr2002.pdf.

[28] Further discussion can be found at http://www.who.int/emc/global_outbreak_network.htm.

and rapidly identifying hundreds of diseases, contending with a daily influx of tourists, business travelers, and immigrants, any of whom enter the country infected with a nonindigenous disease.

As in many other countries, US public health authorities and policy makers welcomed the advent of antibiotics, which rendered many formerly virulent illnesses conquerable. Yet, this positive development had unforeseen consequences. Experts have argued that the success of controlling diseases in recent decades has led to shrunken public health budgets, as policymakers witnessed modern medicine conquer disease after disease.[29]

After decades of neglect, in September 1999, concerns over bioterrorism sparked an injection of much-needed funds and attention into US disease surveillance system.[30] The CDC awarded $41 million to state health departments and a handful of larger US cities to enhance local capabilities to recognize a covert bioterrorist attack. Decades of neglect cannot be undone in a year or two, however. The CDC continues to highlight on its priority list the need to upgrade laboratories and other means of disease surveillance.[31]

The CDC's National Center for Infectious Diseases is the focal point of infectious disease surveillance activities. On a weekly basis, state laboratories send the CDC bacterial and viral isolates. Depending upon the jurisdiction, hospitals and laboratories may also be obligated to notify health authorities of the occurrence of certain diseases. Normally, a private local laboratory or hospital channels a disease notification report to the local health department, which may take action before or as the report is forwarded to the state health department and perhaps on to the CDC.[32]

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[29] See National Research Council, Institute of Medicine, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Respons*e (Washington, DC: National Academy Press, 1999). A January 1999 survey found that nearly 50 percent of local health agencies lacked high-speed connections to the Internet and 46 percent did not have the technical ability to send broadcast faxes. The same survey also found that 35 percent of the health departments covering areas with fewer than 25,000 inhabitants had no e-mail capabilities, and 30 percent had no Internet access whatsoever. Without safe and rapid communications links to the laboratories with requisite knowledge, the chances of recognizing and managing a bioterrorist incident effectively all but vanish. Michael Fraser, "Information Technology and Local Health Departments," presentation to the National Association of City and County Health Officials, Dearborn, Michigan, July 1999.

[30] The states and cities selected for the initial grants can be found in a CDC press release. See Centers for Disease Control and Prevention, "States Receive $40 Million for Stronger Public Health Preparedness for Bioterrorism," press release, 15 September 1999; Center for Civilian Biodefense Studies, "CDC Releases Close to $41 Million for Biodefense," *Biodefense Quarterly* 1, no. 2 (September 1999): 1–2.

[31] US Department of Health and Human Services, "HHS Initiative Prepares for Possible Bioterrorism Threat," fact sheet, 16 August 2001. Available at http://www.hhs.gov/news/press/2001pres/01fsbioterrorism.html.

[32] Scott F. Wetterhall, "Surveillance Systems," in *Proceedings of the Seminar of Responding to the Consequences of Chemical and Biological Terrorism*, Office of Emergency Preparedness (Washington, DC: US Public Health Service, Department of Health and Human Services, 11–14 July 1995), 1-104-5. The list of nationally notifiable diseases can be found at http://www.cdc.gov/epo/dphsi/infdis.htm.

For quite some time, relatively few US laboratories outside of the CDC and the US Army Medical Research Institute of Infectious Diseases even had the biosafety capacity to work with highly contagious and lethal diseases. Therefore, they would refer difficult, unknown cultures up the chain, with the hospital or private laboratory sending the unidentified samples to the local public health laboratory, which would pass the cultures on to its state counterpart. Since many state public health laboratories lacked the capacity to test for some of the more exotic, infrequently seen diseases, they in turn had to bump such cultures to the CDC or the Army's experts. With delays for the re-tests, several days, sometimes weeks, may pass before laboratory technicians unravel the mystery of what is causing a disease outbreak.[33] During a prolonged identification process, many lives could be lost.

Finally, the anthrax-letter attacks of 2001 exposed a problem with personnel training in the United States, as physicians prescribed highly potent antibiotics for individuals who were unlikely to have been exposed to anthrax.[34] Until the fall of 2001, many health professionals did not readily think that certain symptoms could be indicative of exposure to a biowarfare agent. For example, a physician in Pennsylvania's Allegheny County tested how alert his on-duty colleagues were to the stigmata of the smallpox, which had not been seen in the United States for decades. Of seventeen physicians quizzed, only one of the two infectious disease specialists who participated correctly connected the symptoms—including the virus' distinct blistering pattern—to smallpox.[35] Again, awareness has certainly been heightened since the fall of 2001, but still the training to recognize unusual infectious diseases is vital to effective disease surveillance.

Views of the Industry Experts

If man is to outmaneuver intentionally caused or natural disease outbreaks, effective disease surveillance has to become a global priority. Similar to the approach they took in chapters 2 and 4 of this report, the US industry experts commended WHO's multi-tiered—institutional, national, international—strategy to improve disease surveillance. Problems as complex as disease surveillance, BWC inspections, biosafety, biosecurity, and research oversight demand sophisticated approaches that leave no stone unturned.

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[33] Interviews with Amy E. Smithson, physician (29 May 2000); registered nurse/chief, EMS division, state department of public health (3 February 2000); physician, hospital department of emergency medicine (24 March 1999).

[34] Charles Ornstein, "Cure May Be Health Hazard; Many Doctors Bend to Pressure from Patients Who Want Antibiotics After Anthrax Scares," *Los Angeles Times*, 17 October 2001; Daniel Haney, "Doctors likely to prescribe antibiotics for questionable flu-like ills, just to be safe," *Associated Press*, 30 October 2001.

[35] Raymond DeMichiei, as quoted in Jonathan D. Silver, "Local Doctors Fail Their Test on Diagnosing Germ Terrorism," *Pittsburgh Post-Gazette,* 13 February 2000. Seven emergency department physicians and eight inpatient practitioners also participated in Dr. Michael Allswede's mini-survey. They were told that the patients initially had cold-like symptoms, but several days later experienced nausea, diarrhea, and a facial rash that moved to the torso. Shown photographs of people with blistering smallpox, the physicians were still stumped, considering lupus, toxic shock syndrome, and dozens of other diseases, but rarely the variola virus. The last natural case of smallpox occurred in Somalia in 1977.

Asking other nations to improve disease surveillance by supporting WHO and its sister animal and plant health agencies is certainly a good idea, as is the concept of identifying in advance what assistance a nation will provide to a country stricken with a pandemic. Proposals of this nature were first introduced decades ago. The principle of lending aid to a nation suffering the ramifications of a biowarfare attack is enshrined in the BWC.[36]

Such proposals sound like empty rhetoric unless concrete action is taken. Like they did with several of the other US initiatives, the industry experts felt the US proposal to improve global disease surveillance was lacking in substance. Therefore, they looked to WHO, the Office of International Epizootics, and the FAO for more constructive actions. Of the US government's uninspired proposal, the industry group concluded that Washington was advocating baby steps, when giant steps are needed.

INSTITUTING ETHICS CODES FOR SCIENTISTS

One of the proposals that the US government put forward at the BWC Review Conference asked the members of the treaty to institutionalize a code of conduct for their scientists who work with dangerous pathogens. The objective would be to have such scientists pledge not to conduct any activities for hostile purposes or in armed conflict. Governments could work through professional societies or organizations to integrate this oath into existing ethics codes or to build codes from scratch.[37]

Few people would have difficulty concluding that scientific activities purposefully directed at turning human, plant, or animal diseases into weapons of war cross the line of morally acceptable behavior. Biological warfare has long been condemned as morally reprehensible.[38] Yet, in decades past, many scientists have worked "gladly on military projects, . . . convinced their cause was right and their foe was evil."[39] In recognition of this fact, sporadic efforts have been made to have the scientists

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[36] Article VII states: "Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention." Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.

[37] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," 5.

[38] Modern efforts to ban the use of this type of weapon in war date back to the 1925 Geneva Protocol, which preceded the BWC by half a century and prohibits the use of germ and poison gas weapons. Note that scientists who are conducting research aimed at improving defenses against biological weapons—Article I of the BWC allowing the retention of biowarfare agents for "prophylactic, protective or other peaceful purposes"—are in a particular quandary since the boundaries between defensive and offensive research can be paper thin. For an illuminating discussion, see Marc Lappe, "Ethics in Biological Warfare Research," in *Preventing a Biological Arms Race*, Susan Wright, ed. (Cambridge, Mass.: MIT Press, 1990),78-99. Also, Jane M. Orient, "Chemical and Biological Warfare: Should Defenses Be Researched and Deployed?" *Journal of the American Medical Association* 262, no. 5 (4 August 1989): 644-8.

[39] Robert Sinsheimer explains that scientists are pulled by allegiances to their nations, to the international fellowship of scientists, and to the human race. Robert L. Sinsheimer, "Scientists and Research," in *Preventing a Biological Arms Race*, 71, 73. Examples include US scientists who worked on the Manhattan Project in World War II to develop the atomic bomb, not to

themselves, without whom horrific weapons could not be created, take a more active role in halting the development of arms. The tool most often discussed for such purposes is a scientific code of ethics. The logic behind this proposition is as follows:

> Some modalities of warfare—nuclear and biological weapons—would seem to have the potential for unprecedented catastrophe and for the destruction of the very cathedral of knowledge, which scientists have striven to create. They represent a perversion of the greatest accomplishments of cumulative generations of scientific endeavor and insight. Their use—and their development certainly makes possible their use—would make meaningless the lives of every scientist of every time. . . .Biologists need to take steps now to avoid the militarization of their achievements. If history is any guide to the future, waiting to protest the use of novel weapons in a future conflict will be of no avail.[40]

The pages that follow review the status of efforts to establish scientific codes of conduct, distinguishing between various approaches to this type of activity. Intermingled with this status review is a discussion of the advantages and drawbacks of ethics codes.

An Overview of Scientific Codes of Conduct

According to a survey on scientific ethics codes published in 2002 by the Stockholm International Peace Research Institute, not that many professional scientific societies appear to have established codes of conduct. Of the seventy-one international scientific organizations found in an Internet search, eleven had a code of ethics available online. Just 12 percent of the 267 national or regional scientific organizations had posted an ethics code on their website. Moreover, only two of the ethics codes stipulated any specific ethical boundaries regarding chemical or biological weapons work.[41] Another survey, conducted for the International Council for Science, found 115 ethical standards governing scientific research. This study differentiated between fourteen types of standards (e.g., oaths, manifestos,

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mention the top American scientific talent employed in the now-defunct US biological and chemical weapons programs. Similarly, tens of thousands of Soviet scientists worked in the USSR's nuclear, biological, and chemical weapons programs. Discussions of why British and South African scientists worked on biological and chemical weapons can be found, respectively, in Brian Balmer, "Killing 'Without the Distressing Preliminaries': Scientists' Defense of the British Biological Warfare Program," and Chandre Gould and Peter Folb, "The Role of Professionals in the South African Chemical and Biological Warfare Programme," *Minerva*, 40, no. 1 (2002): 57-75 and 77-91. On the point of scientists being coerced to perform weapons work, see Rita R. Colwell and Raymond A. Zilinskas, "Bioethics and the Prevention of Biological Warfare," in Raymond A. Zilinskas, ed., *Biological Warfare—Modern Offense and Defense* (Boulder, Colo.: Lynne Rienner, 2000), 231.

[40] Sinsheimer, "Scientists and Research," 74, 76.

[41] Note that the survey covered only Internet sites employing the English language. Also, some of the codes may have more general-purpose statements asking their adherents not to use science for hostile purposes. Additional scientific organizations also may have established codes of ethics. Jacqueline Simon and Melissa Hersh, "An Educational Imperative: The Role of Ethical Codes and Normative Prohibitions in CBW-Applicable Research," *Minerva* 40, no. 1 (2002): 52, 54.

codes, guidelines, pledges) that thirty-nine international and seventy-six national scientific organizations had issued in twenty-three areas of science.[42]

In some scientific disciplines, the concept of a code of conduct is well established. Perhaps the best-known code of ethics is in the Hippocratic oath of the medical profession, whose members also belong to national and international medical associations espousing first-do-no-harm ethical principles.[43] Ethics codes have been around for a long time in other branches of science, but seem to have lost whatever luster they may have had when they were originally created. These codes do not appear to be an essential reference point for scientists.[44]

One of the reasons that ethics codes may not be influential is that they are not particularly well publicized. The industry experts provided an on-the-spot demonstration of this, since the majority of the group conceded they were unaware of the specifics of the ethics code espoused by the main US professional society in their discipline, the American Society for Microbiology.[45] Instead of being popularized among a professional society's membership, nowadays such codes may sit on the shelf after initial committee drafting or occasional review.[46]

Another reason that ethics codes may not play a more prominent role in the conduct of science traces back to how scientists are educated. At college, the time students spend with scientific mentors and peers appears to be especially fertile for imparting ethical principles.[47] Unless colleges and universities emphasize instilling proper behavioral codes in students, giving them a framework for the ethical dilemmas they will face, an important opportunity is missed to put them on a sound ethical and

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[42] The scientific organizations involved in these efforts were from twenty-three countries on six continents. See Kathinka Evers, *Standards for Ethics and Responsibility in Science: An Analysis and Evaluation of the Content, Background, and Function*, a study performed for the Standing Committee on Responsibility and Ethics in Science and the Standing Committee on Freedom in the Conduct of Science, as referenced in *Annual Report 2001: Standing Committee on Responsibility and Ethics in Science* (Paris: International Council for Science, 2001), 2.

[43] The Hippocratic Oath states: "I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect." Lappe, 84-5.

[44] Heinz C. Luegenbiehl, "Codes of Ethics and the Moral Education of Engineers," *Business & Professional Ethics Journal* 2, no. 4 (Summer 1983): 41-61.

[45] Most participants had vague knowledge that the American Society for Microbiology had an ethics code, but beyond that, they could make no comment.

[46] Simon and Hersh, "An Educational Imperative: The Role of Ethical Codes and Normative Prohibitions in CBW-Applicable Research," 44.

[47] "Most ethical precepts are acquired by informal exchanges with mentors and fellow students." Lester G. Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," paper presented at the Sixth ISODARCO Beijing Seminar on Arms Control, October/November 1998, 5.

professional footing.[48] For boundaries in the life sciences, this is especially true, since scientists have to know of the existence of behavioral norms against biological weapons if they are to honor them.[49]

Proponents of scientific ethics codes argue that they "would have a strong impact on a community that prides itself on peer review and ethical behavior."[50] Moreover, advocates say that a widely accepted ethics code would influence scientists to resist pressure from their governments to do weapons work. Ideally, protections for those who might blow the whistle on illicit weapons work would go hand-in-hand with the establishment of ethics codes.[51] The industry experts discussed this latter point, some noting that the existence of a code might encourage whistle blowers to reveal covert weapons programs. Finally, instituting codes of conduct helps to burnish the public image of science and generate support for research.[52]

Professional codes of ethics also vary in form from laudable albeit general conduct statements to very specific prohibitions. The code espoused by the American Society for Microbiology, which in its proposal the US government mentioned as a model platform from which to build, is general in nature. This code does not include any particular guidance regarding research with possible application to biological weapons or other types of arms. Rather, members of the American Society for Microbiology are to "aspire to use their knowledge and skills for the advancement of human welfare" and "shall not commit scientific misconduct, defined as fabrication, falsification, or plagiarism."[53] Many scientific

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[48] "Researchers must be given the tools to make decisions in this ambiguous environment. These tools can include ethical guidelines or the integration into science curricula of discussions and material which provides students with (a) an awareness of the ethical issues involves, and (b) with the intellectual tools to make ethical decisions." Jacqueline Simon, "Ethics and the Application of Genetic Technology to Warfare," paper presented at The Mind Challenges Genes Conference, 1 July 2001, 1-3. Available at http://projects.sipri.se/cbw/berlin.pdf.

[49] On this point, see Jean Pascal Zanders, "Introduction," *Minerva* 40, no. 1 (2002): 6.

[50] Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 7.

[51] In his discussion of whistle blowers, Paldy gives examples of defectors, such as Vladimir Pasechnik and Ken Alibek, who gave first-hand accounts of the former Soviet germ warfare program, and Vil Mirzayanov, who unveiled the USSR's advanced chemical weapons work. Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 5. Alibek's tale is told with Stephen Handelman in *Biohazard* (New York: Random House, 1999). For Mirzayanov's personal account of the Soviet chemical weapons program and the consequences he suffered for blowing the whistle on it, see Vil S. Mirzayanov, "Dismantling the Soviet/Russian Chemical Weapons Complex: An Insider's View," in *Chemical Weapons Disarmament in Russia: Problems and Prospects*, (Washington, DC: Henry L. Stimson Center, October 1995), 21-33.

[52] Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 7.

[53] The code of ethics for the American Society for Microbiology, approved by the society's governing council in 2000, is composed of five guiding principles and six rules of conduct. These excerpts are the ones most relevant to the topic at hand, an ethical ban on bioweapons work. The American Society for Microbiology has established a review process for possible breaches of its code of ethics. The code of ethics is available on the society's website, but accessible only to members. The society's website can be found at http://www.asm.org.

organizations instruct their members to go about their affairs with honesty and integrity and to serve their fellow citizens through the positive use of their knowledge and skills.[54]

Another approach to a code of conduct plays into the general worry that ethics-minded scientists have about the possible harmful application of their work. Although scientists are not omniscient—they cannot know in advance the outcome of some experiments or all future applications of their work—scientists can undertake to deliberately and specifically consider the implications of their work.[55] The Life Sciences Network of New Zealand has embraced this approach in a statement about principles of conduct.[56]

Finally, an ethics code can be worded to forego work on weapons in general or biological weapons in particular. The 1984 Uppsala Code of Ethics incorporates a pledge not to use science for purposes of war.[57] Right to the point at hand, the Australian Society for Microbiology's code of ethics obligates its members "not to engage knowingly in research for the production, or promotion of biological

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[54] For instance, the code of the Institute of Electrical and Electronic Engineers (IEEE) says: "Members shall, in fulfilling their responsibilities to the community: Protect the safety, health, and welfare of the public and speak out against abuses in these areas affecting the public interest." Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 3. See also, Luegenbiehl, "Codes of Ethics and the Moral Education of Engineers," 47.

[55] "When Einstein deduced the equivalence of matter and energy he could not plausibly have anticipated that his equations would find expression in the atomic bomb. Nor could Scheele, the discoverer of chlorine gas, have conceived of its military application." Sinsheimer, "Scientists and Research," 72

[56] The principles of conduct of the New Zealand Life Sciences Network, Inc. state:

> Biotechnologists should use the principle of precaution. This principle implies that in scientific research and the application of its results (as far as can be foreseen at that moment) the start point should be that one should not progress unless one can make plausible that no harmful or irreversible consequences will occur, that the risks can be sufficiently estimated, and that the possible side effects are justified for the community by the purpose and the expected advantages of the application.

New Zealand Life Sciences Network, *Code of Conduct.* Available at http://www.lifesciencesnetwork.org/pb/about/code_ethics.asp.

[57] The Uppsala Code of Ethics for Scientists states: "Scientific efforts shall therefore not aim at applications or skills for use in war or oppression.... Scientists who form the judgement that the research which they are conducting or participating in is in conflict with this code, shall discontinue such research, and publicly state the reason for their judgement." Bengt Gustaffson et al., "Focus On: The Uppsala Code of Ethics for Scientists," *Journal of Peace Research* vol. 21, no. 4 (1984), 312. The 1988 Buenos Aires Oath, written by Anonymous, similarly asks that scientists examine the consequences of their work to assure that it is "truly in the bests interests of society and peace." Lappe, "Ethics in Biological Warfare Research," fn. 11. In this vein, one scholar proposes having the International Council of Scientific Unions disperse to all scientific bodies a generic no-weapons-work code. The suggested language for such a code is: "Scientists, engineers, and scientific and technical professionals should not participate in any research and development or scientific or technical support activity in violation of international arms control agreements to which their nations are signatories." Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 4.

warfare agents."[58] The Biologists Pledge also includes specific prohibitions not to work on biological weapons.[59] Other scientific organizations have simply forsworn work on all mass destruction weapons.[60] Even governments have begun to issue specific, thou-shalt-not-engage-in-bioweapons-work policies. In what is apparently a first-of-its-kind measure for a government, the Government of Queensland, Australia adopted a "best practice" code that applies to all government agencies and government-funded entities and should be observed by private research centers, laboratories, hospitals, companies, and universities.[61]

Views of the Industry Experts

Taking all of this into account, the industry experts candidly discussed the nonproliferation utility of scientific codes of ethics. On the positive side, several of the industry experts agreed that a code of ethics might encourage whistleblowers to call attention to prohibited or questionable work. They also saw ethics codes as helping to build public trust in scientific endeavors, which, although a benefit, is not germane to BWC compliance.

Although one individual in the group strongly backed the concept of moving forward with establishing codes of conduct, the rest of the experts were much less enthusiastic. Their comments were mostly of the "it wouldn't hurt" variety, but they doubted that a conduct code would stop them were they intent on proliferating biological weapons. The experts concluded that a conduct code did not constitute

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[58] This particular prohibition is final item on the Australian Society for Microbiology's twelve-item code of ethics. Australian Society for Microbiology, "Code of Ethics." Available at http://www.theasm.com.au/docs/ethics/default.asp.

[59] When the Council for Responsible Genetics and the Coalition of Universities in the Public Interest circulated this pledge in 1987, 1,000 signed up that year. The pledge states: "We, the undersigned biologists and chemists, oppose the use of our research for military purposes. . ..We believe that biomedical research should support rather than threaten life. Therefore, we pledge not to engage knowingly in research and teaching that will further the development of chemical and biological warfare agents." Appendix K in *Preventing a Biological Arms Race*, 412; see also, Paldy, "A Code of Ethics on Arms R&D for Scientists and Engineers," 3.

[60] On 16 July 1995, the fiftieth anniversary of the Trinity nuclear test, the International Network of Engineers and Scientists for Global Responsibility opened for signature its Appeal to Engineers and Scientists. The third item of this appeal states: "I pledge not to take part in the development and production of weapons of mass destruction and of weapons that are banned by international conventions." International Network of Engineers and Scientists for Global Responsibility, Standing Committee on Ethical Questions, 1995. Available at http://www.inesglobal.org/ines3.html. The Western States Legal Foundation, Natural Resources Defense Council, Los Alamos Study Group, and Tri-Valley CARES co-sponsor an oath that states: "I pledge never to participate in the design, development, testing, production, maintenance, targeting, or use of nuclear, biological, or chemical weapons or their means of delivery; or in research or engineering that I have reason to believe will be used by others to do so." An online "signing" form can be found at http://www.lasg.org.

[61] Noting that Australia is a signatory to the *Biological and Toxin Weapons Convention* (1972), and has played a major role in securing international compliance with the Convention, we will not use biotechnology (or any other technologies) to develop biological weapons for use in human warfare or terrorism, and will not assist any other organisations, persons or countries to develop, produce, duplicate, stockpile or utilise such weapons.

Code of Ethical Practice for Biotechnology in Queensland, 1st ed., (Brisbane: Department of Innovation and Information Economy, 2001), iii, 12. Available at http://www.diiesrq.qld.gov.au/publications/biotechnology/coe.pdf.

much of a barrier, especially in the absence of any specified, enforced consequences for rule breakers. Rather than look to codes of ethics to inhibit biological weapons proliferation, the industry experts came down strongly on the side of establishing mandatory biosafety, biosecurity, and research oversight standards accompanied by noncompliance penalties and a robust BWC inspection process, as other segments of this report relate.

Chapter 4
Considering US Proposals for Enhanced Biosafety, Biosecurity, and Research Oversight

Of the proposals that the US government tabled to stand in for a monitoring protocol for the Biological and Toxin Weapons Convention (BWC), the industry experts reacted most positively to those calling for BWC members to improve standards for biosafety, biosecurity, and oversight of genetic engineering research. They tempered their praise with criticism of the state-by-state structure of the proposals, which they saw as undercutting their potential efficacy. The industry group recommended instead that the United States advocate international adoption of common minimum standards in each of the areas, based on current US regulations and guidelines, or their equivalent.

Taking the US government's biosafety, biosecurity, and research oversight initiatives in turn, this chapter reviews the industry group's discussion of pertinent domestic efforts. The industry experts then explain why some changes are needed domestically and how to achieve them. Improvements at home will pave the way for the successful promotion of similar initiatives internationally. As one participant noted, "If we don't walk before we run, if we don't set up things at home first to serve as an international model, I'm not going to count on anyone else to do it."[1] In each topical area, the industry group makes specific recommendations to strengthen the US proposals. Prior to the discussion of the individual proposals, the discussion briefly focuses on three factors that will underpin the viability of any international moves to enhance biosecurity, biosafety, and oversight of genetic engineering research.

The first factor key to the success of any new standards will be the articulation of agreed lists of select human, animal, and plant pathogens. With such reference lists, scientists and institutions will no longer have to wonder whether their operations should trigger the use of certain biosafety, biosecurity, and research oversight practices. Select agent lists should: 1) stratify agents according to risk; and, 2) be no longer than necessary. Lists that do not meet these criteria defeat their own purpose because, as one industry expert observed, "Not everything can be high risk."[2] Facility operators find it too confusing and burdensome to work with exceedingly long lists.

The industry group cited as constructive models the Centers for Disease Control and Prevention's (CDC's) select agent list for human pathogens and toxins and the Australia Group's core and warning

[1] Dr. Jennie Hunter-Cevera, 10 August 2002. Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, holds a PhD in microbiology and has well over twenty years of research and managerial experience in US industry and research institutions.

[2] Dr. Robert Goldberg, 9 August 2002. Dr. Robert Goldberg, PhD in medical microbiology, has over thirty years of research and administrative experience in US industry and at the National Cancer Institute.

lists for human, animal, and plant microorganisms.[3] For examples of poorly conceived lists, they pointed to some of those maintained by US Department of Agriculture.[4]

The second factor central to the implementation of any new standards is education. The industry experts were disturbed that the academic institutions charged with instilling good scientific practices were not upholding their responsibilities, particularly regarding principles of biosafety. Two of the industry participants expressed alarm at the lax biosafety practices they had witnessed at some universities, which sometimes devote insufficient resources to this vital area.[5] Without appropriate instruction and supervision from biosafety officers, young scientists graduate with bad biosafety habits, virtually ignorant of the biosafety rules they go on to break routinely, sometimes at their peril.[6] The industry experts also recognized the need for colleges and universities to promote study of the "less glamorous scientific disciplines" (e.g., microbial forensics, maintenance of culture collections and databases, documentation,

[3] The CDC periodically reviews and updates its select agent list, which stands at thirty-six human toxins and pathogens. The relevant section of the federal code, 42 CFR 72, can be accessed at http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm. The Australia Group is an export control cooperative of over thirty governments that harmonize export control policies for the purpose of hindering chemical and biological weapons proliferation. The Australia Group's control lists can be found at http://www.australiagroup.net/control_list/bio_agents.htm. For more on the Australia Group's operations, see Amy E. Smithson, *Separating Fact From Fiction: The Australia Group and the Chemical Weapons Convention* (Washington, DC: Henry L. Stimson Center, March 1997).

[4] Industry experts complained that some APHIS agent lists are too lengthy and do not sufficiently differentiate between different levels of risk, which creates inordinate delays to permit work with certain agents. The Regulated Plant List, available on APHIS' Plant Protection and Quarantine website at http://www.aphis.usda.gov/ppq/regpestlist, is eleven pages long and catalogs more than 400 different plant pathogens. In contrast, the new section of federal code created to fulfill the requirements of the *Public Health Security and Bioterrorism Preparedness and Response Act* lists only nine plant pathogens that US facilities must declare to APHIS. "The listed agents and toxins are viruses, bacteria, or fungi that can pose a severe threat to a number of important crops, including potatoes, rice, soybeans, corn, citrus, and stone fruit." "Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession," *Federal Register* 67, no. 155 (12 August 2002): 52383-52389. Discussed in more detail later in this chapter, the Public Health Security and Bioterrorism Preparedness and Response Act became Public Law 107-188 on 12 June 2002.

[5] Research grants do not contain line items for biosafety officers, and one expert recalled the example of a researcher who worked on *Staphylococcus aureus* for four months, thinking it was *Bacillus anthracis*. She continued: "When visiting some universities, I have been shocked at the lack of biosafety officers, procedures, guidelines, orientation, training for graduate students, undergraduates. It's just an accident waiting to happen." Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, 10 August 2002. Another expert brought up another example: "Remember that Yale researcher a couple years ago who inadvertently contaminated himself with a South American hemorrhagic fever virus and then got on the train to Boston? It was later found out that the institution did not realize that he did not have the proper controls in place, nor did he have the training to work with a Level III virus." Dr. Eric Utt, 9 August 2002. Dr. Eric Utt, health and safety manager at a large US pharmaceutical company, is a PhD microbiologist, widely published author, and patent holder.

[6] "In some academic settings, had I not known what was required, no one would have corrected the people who were bringing in soil samples containing pathogens from other states and all over the world. For example, in one location, they had no idea they needed the Plant Protection and Quarantine forms and the permits to work with those pathogens." Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, 10 August 2002. The group agreed that young scientists who join the industry ranks often get their first exposure to proper biosafety practices in that setting. The industry experts also decried the tendency of universities to use overhead from research grants to support English, history, and sociology departments instead of to hire biosafety officers. As one industry expert declared: "Chaucer never killed anybody, but hepatitis has." Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

physiology) that are so important to the conduct of good science, not to mention the appropriate training of the support staff that assists scientists working with dangerous pathogens.[7]

Outside of academia, US commercial facilities tend to run their operations by the regulatory book, providing ongoing training for personnel. However, the industry experts doubted that all sites working at higher biosafety levels were continuing to educate their employees in proper, updated practices. The industry experts argued that from the time scientists first enter the laboratory until they retire, continual education in all scientific standards must be promoted as a fundamental tenet of safe, sound science.

Finally, but by no means least importantly, the industry experts stressed the need to articulate and enforce penalties for noncompliance with regulations. Absent stiff consequences and the occasional check-up from regulatory authorities to keep facility operators on their toes, many a rule would be ignored. According to the seriousness of the violation, the industry group suggested that individuals could be punished with loss of pay, fines, suspension, or loss of job. Penalties for institutions, which also must be held accountable, included fines, suspension or loss of licenses, and loss of government grants.[8]

Therefore, as part and parcel of any international standards for biosafety, biosecurity, and oversight of genetic engineering research, the industry specialists recommended the establishment of internationally agreed risk-stratified select agent lists for human, plant, and animal pathogens and toxins. They urged that universities and all organizations practicing the life sciences waste no time whatsoever in rectifying shortcomings in educating students in the basics of appropriate scientific practices and providing professionals with ongoing, updated training.[9] Next, they insisted the drafters of international standards stipulate penalties for noncompliance and create mechanisms to monitor compliance and administer punishment, when necessary.

PUTTING BACKBONE INTO THE US BIOSAFETY INITIATIVE

[7] For example, proper air handling is a key part of a barrier facility, yet there is a dearth of heating, ventilation, air conditioning specialists who are truly experts in the regulations and materials needed for a facility working with dangerous pathogens. Another example would be individuals who are fully versed in what types of biosafety cabinets are needed for what types of materials and activities. Without knowing what type of cabinet is needed, facilities might end up with equipment inappropriate to their needs.

[8] Expressing the group's consensus view: "Without effective sanction authorities and abilities to impose appropriate penalties, this is not going to work." Dr. George Pierce, 10 August 2002. Dr. George Pierce, a PhD microbiologist who is currently a professor of applied and environmental microbiology at Georgia State University, has over twenty years of experience in the US pharmaceutical industry.

[9] Although there is some movement at institutions of higher learning to develop more training programs, "In my mind, they can't move fast enough." Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, 10 August 2002.

The US government proposed that the members of the BWC individually commit to adopt and implement tough biosafety procedures for work with dangerous microorganisms based on the World Health Organization's guidelines for human pathogens or their equivalent, the Office of International Epizootics' guidelines for animal pathogens or their equivalent, and national guidelines for plant pathogens. In advancing this proposal, the US government observed, "biosafety procedures and practices vary enormously from country to country."[10]

In the United States, the disturbingly high occurrence of laboratory-acquired infections, which came to light in 1951, 1965, and 1976 surveys of 5,000 US laboratories, drove the development of US biosafety practices. This trio of surveys revealed that less than 20 percent of the 3,921 cases of research-related illnesses reported among laboratory workers were associated with a known accident, though in over 80 percent of the cases the infected individuals worked with the causative agent.[11] Evidence that even more robust biosafety practices are sorely needed can be found in the unacceptably high frequency with which laboratory researchers continue to be infected with such diseases as brucellosis, hepatitis, and tuberculosis.[12] Even the US military's premiere research laboratory is not immune to such incidents.[13]

Concerns about laboratory-associated illnesses moved the CDC and the National Institutes of Health (NIH) to compile the primary US resource manual for biosafety practices and standards, titled *Biosafety in Microbiological and Biomedical Laboratories*.[14] Referred to hereafter as the CDC/NIH *Biosafety Manual*, this core reference book describes recommended biosafety equipment, defines the four biosafety levels, and explains the recommended precautions to be taken with various dangerous pathogens. Though an excellent resource, the different editions of the CDC/NIH *Biosafety Manual* give

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[10] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001, 8. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

[11] S.E. Sulkin and R.M. Pike's research is summarized in the introduction of US Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. (Washington, DC: General Printing Office, 1999), 1-2.

[12] Reasons for certain diseases appearing more commonly may include the lack of an effective vaccine, high infectivity virulence, or frequency of use in research. For example, less than ten *brucella* organisms can cause a brucellosis infection, and an effective vaccine is still lacking for this disease. Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002. For discussions of laboratory infections from brucella, see Pier Luigi Fiori et al., "*Brucella abortus* Infection Acquired in Microbiology Laboratories," *Journal of Clinical Microbiology* 38, no. 5 (May 2000): 2005-6; E. Martin-Mazuelos et al., "Outbreak of *Brucella melitensis* among Microbiology Laboratory Workers," *Journal of Clinical Microbiology* 32, no. 8 (August 1994): 2035-36.

[13] In May 2000, a microbiologist at the US Army Institute for Infectious Diseases (USAMRIID) contracted glanders after handling laboratory equipment without wearing gloves. Previously, the last case of glanders seen in the United States was in 1945. Centers for Disease Control and Prevention, "Laboratory-Acquired Human Glanders – Maryland, May 2000," *Morbidity and Mortality Weekly Report* 49, no. 24 (23 June 2000): 532. Earlier this year, also at USAMRIID, a civilian scientist tested positive for anthrax exposure, but having been vaccinated, did not contract the illness. David Dishneau, "Fort Detrick worker tests positive for anthrax exposure," Associated Press, 19 April 2002.

[14] CDC and NIH, *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. (1999).

uneven coverage to different pathogens. In the most recent version, anthrax, tularemia, and brucella received two pages of coverage apiece, while the discussion of prions spanned thirteen pages.[15] Accordingly, those just learning biosafety practices could get skewed impressions of the infectivity and relative biosafety risks of various diseases based on their length of coverage in the CDC/NIH *Biosafety Manual*.[16] Industry experts advised that future editions not just update information on pathogens, but also retain previously published data.

The CDC/NIH *Biosafety Manual* has a great deal in common with the Laboratory Biosafety Manual issued by the World Health Organization's Communicable Disease Unit. Industry experts said that other models for the implementation of stronger biosafety practices can be found in the cooperation of the US nuclear and chemical industries with their respective government administrators, the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, in regulating the possession, transfer, and use of nuclear materials and hazardous chemicals. The industry experts noted that other countries (e.g., Canada, the United Kingdom) have also issued biosafety guidance that is essentially equivalent to US standards. Indeed, they noted that incorporating some foreign standards could elevate US practices.[17] The industry group was widely critical of the fact that the CDC/NIH *Biosafety Manual*, unlike the Canadian and British biosafety measures, is only advisory.

Only two categories of US facilities reliably observe biosafety guidelines. Facilities receiving US government monies follow the guidelines because they can lose their grants if they do not. Commercial manufacturers also comply because the overall US regulatory environment propels scrupulous attention to good laboratory and manufacturing practices, quality assurance, and quality control. For other institutions, the CDC/NIH *Biosafety Manual* guidelines are optional. Bemoaned one of the experts, the US biosafety system is therefore "based on voluntary compliance and the good intentions of the individuals attempting to comply."[18] The recent explosion of bioterrorism research monies could well

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[15] CDC and NIH, *Biosafety in Microbiological and Biomedical Laboratories*, 89-92, 99-100, 134-47.

[16] "This manual does not maintain an historical database of agents of concern. Although there is a lot of information, it's just not what you'd call one-stop shopping." Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002. Another group member countered, "It isn't supposed to be a textbook." Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

[17] Europeans and Canadians have elevated disposal to a chapter in their regulations because of the danger of not properly disposing of organisms and waste. If not properly trained, researchers might think that simply autoclaving used laboratory tools and equipment is sufficient, not realizing that it is necessary to have validated autoclaves and load patterns. Many students come out of universities thinking that "121 degrees Centigrade for fifteen minutes will kill everything; but the problem is it has to hit every place and you have to demonstrate it." Expert 1, 10 August 2002. Expert 1, a senior vice president overseeing operations, product development and manufacturing at a US biopharmaceutical company, has over twenty years of experience in the pharmaceutical industry and holds a PhD in biology.

[18] Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002. To which another group member rejoined, "The path to hell is paved with those good intentions." Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

compound these unfortunate circumstances as a dramatic influx of scientists unlikely to have proper biosafety training (e.g., chemists, physicists, microbiologists, engineers) embark on projects that entail work with dangerous pathogens.[19]

In contrast, the group observed, facilities that employ animals in research and tests are governed by a detailed regulatory system that requires licenses for such operations and annual compliance inspections.[20] Under this system, a principal investigator works with other facility personnel to develop specific practices or protocols for animal handling, experimentation, and emergencies. The biosafety officer at an animal facility is considered a critical node in the research team, whereas when facilities conducting other types of research appoint a biosafety officer, this individual can be a less actively involved administrative functionary. Animal research facilities are required to have an Institutional Animal Care and Use Committee to review and approve all pertinent research activities. Because certification takes place at the institutional level and the lack thereof could bring operations to a halt, the facility director bears personal responsibility for overseeing compliance.[21] Since the animal use regulations are in the federal code, a breach equates to breaking the law. The US biosafety "guidelines" simply do not garner the same respect and adherence. For this reason, the group overwhelmingly recommended a domestic change to full regulatory status, with a continuing relaxed approach for clinical laboratories.[22]

Until the 1996 US law regulating the transfer of certain dangerous human pathogens,[23] there was virtually no oversight to determine whether facilities requesting dangerous strains from culture collections had the proper biosafety set-up to handle those organisms. One industry expert marveled: "I found it amazing that you had to get a license to put a deck on your house, but anybody with a Bachelor's degree

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[19] Grant-making agencies and institutions would be well advised to confirm the biosafety background of potential grantees before awarding monies.

[20] For more detail on how the U.S. Department of Agriculture's Animal and Plant Health Inspection Service administers the Animal Welfare Act, including licensure and unannounced inspections of every registered facility in the country, go to http://www.aphis.usda.gov/oa/pubs/inspect.html. Organizations that receive funding from a public health service agency (e.g., CDC, NIH) are bound by a separate set of regulations enforced by the Office of Laboratory Animal Welfare at NIH. More information can be found at http://grants2.nih.gov/grants/olaw/references/phspol.htm.

[21] "At most institutions the chairman of the IACUC is a senior facility member, and in industry senior personnel also serve on the IACUC to make sure things happen correctly." Dr. Eric Utt, health and safety manager at a large US pharmaceutical company, 10 August 2002.

[22] Under current US guidelines, clinical laboratories are allowed to conduct activities that would otherwise be considered biosafety level 3 under biosafety level 2 precautions. This approach is advisable due to the sheer volume of unknown samples that clinical laboratories receive daily.

[23] This law was prompted by Larry Wayne Harris' use of a false facility letterhead to acquire three vials of *Y. pestis*, the causative agent of bubonic plague, from the American Type Culture Collection. The transfer regulations are contained in 18 USC, Sections 175-178 and 2332, 42 CFR 72. For more on the biological misadventures of Larry Wayne Harris see, briefly, Box. 2.5 in Amy E. Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the US Response*, (Washington, DC: Henry L. Stimson Center, October 2000), 41-2.

could work with any organism."[24] Quipped another: "They told you how to open the vial or container, but they never bothered to ask or check if your facility had the appropriate facilities or training to handle that organism. The biological safety officer was supposed to do that, but some institutions have biosafety officers in name only."[25] If biosafety licensure was until recently an erratic affair in the United States, which is considered to be a biosafety pacesetter, the industry group shuddered at what might be found elsewhere.

Instead of relying on national preferences that may materialize unevenly and slowly, the industry experts recommended strengthening the US biosafety proposal by requiring an international biosafety standard. A proposal that leaves states the leeway to follow or disregard guidelines and the flexibility to craft the basic principals of their own domestic practices fails to deal with the very problems that the US government seeks to address, namely the complete absence of biosafety practices in some countries and the wide variance of such practices in others. Moreover, the industry experts suggested that while the World Health Organization guidelines would be an improvement, a higher minimum standard would be comprised of the best practices from current domestic guidelines, with the generally high-caliber CDC/NIH *Biosafety Manual* serving as the basis for new international standards.

All countries, in other words, should be obligated to adhere to mandatory universal biosafety standards, complete with noncompliance penalties.[26] The group rejected the idea that facilities would find compliance with such biosafety practices onerous or burdensome.[27] One participant summed up the group's thoughts as follows: "In many cases, biosafety defines a certain level of more rigorous science. It improves science."[28]

STRENGTHENING THE US BIOSECURITY INITIATIVE

[24] Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

[25] Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, 10 August 2002. Note that many biosafety officers may not even be aware that such strains were requested, unless the researcher informs them. Similar to the standard practice in the chemical industry, the Canadian health ministry has created material safety data sheets for individual biological agents that provide information such as infectivity levels, methods of transmissions, and recommended precautions. These sheets are accessible online from the Office of Laboratory Security, Population and Public Health Branch, HealthCanada at http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/index.html.

[26] Note that a relaxed approach would continue to be appropriate for clinical laboratories.

[27] This activity was likened to the creation of Occupational Safety and Health Administration regulations and the institution of quality assurance laws in the 1960s and 1970s. Once these laws were on the books, facilities that did not abide by them went out of business. Douglas Jaeger, 10 August 2002. Douglas Jaeger, current president of the Society for Industrial Microbiologists and holder of two master's degrees, recently retired after a thirty-five year career with a major US pharmaceutical company where he rose to the manager of custom fermentation and bioprocessing.

[28] Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002.

Similar to its biosafety proposal, the US government's biosecurity initiative asked individual states to commit to adopt national regulations governing access to and transfer of dangerous pathogens, including possible restrictions on where work with dangerous pathogens may be conducted and who may obtain and possess specific microorganisms for such purposes. The US government also proposed that nations report to international authorities any "adverse events" (e.g., accidental release of a dangerous pathogen) that could affect other countries.[29]

Although specific laws regarding the transfer of etiologic agents have been on the books for over twenty years, the industry experts said there is still an abundance of confusion, ignorance, and disturbing casualness exhibited in the transfer of dangerous organisms. Any US scientist trying to determine the right procedures to ship hazardous biological materials has to wade through the regulations and guidelines posted by at least a dozen different government agencies and international organizations, as Table 4.1 denotes. When faced with this regulatory hydra, no wonder many scientists find it easier to tuck a tube into their suit jacket pocket and board a plane.[30]

Spurred by two bioterrorist incidents that highlighted the weaknesses in the US regulatory system,[31] Congress passed laws to regulate the transfer and receipt of dangerous human pathogens and to monitor more closely the facilities dealing with dangerous human, animal, and plant pathogens.[32] Under a 1996 law, the CDC began to certify the facilities applying to receive dangerous human pathogens on the

[29] US Department of State, "New Ways to Strengthen the International Regime," 4.

[30] Other types of rules are also broken despite the extensive training on the various shipping requirements that new scientists in industry receive. For instance, strains still arrive in laboratories daily, improperly marked or not designated as dangerous at all. Dr. Jennie Hunter-Cevera, president of the University of Maryland Biotechnology Institute, 10 August 2002.

[31] The first of these incidents involved Larry Wayne Harris, as footnote 23 describes, the second were the anthrax letter attacks of the fall of 2001, which indicated a possible theft of this pathogen from a facility. Steve Fainaru and Joby Warrick, "Deadly Anthrax Strain Leaves a Muddy Trail," *Washington Post*, 25 November 2001; Rick Weiss and Susan Schmidt, "Capitol Hill Anthrax Matches Army's Stocks; 5 Labs Can Trace Spores to Ft. Detrick," *Washington Post*, 16 December 2001; William J. Broad and Judith Miller, "Inquiry Includes Possibility of Killer from a U.S. Lab," *New York Times*, 2 December 2001.

[32] On 12 June 2002, the Public Health Security and Bioterrorism Preparedness and Response Act became Public Law 107-188.

Table 4.1: Current Regulations for the Shipment of Dangerous Pathogens.**

Organization	Type of Regulation or Guidelines
US Centers for Disease Control and Prevention	Importation, Transfer, and Receiving of Select Human Pathogens
US Animal and Plant Health Inspection Service	Importation of Etiologic Agents of Animals and Plants
US Public Health Service	Interstate Shipment of Etiologic Agents
US Postal Service	Mailability of Etiologic Agents
US Department of Transportation	Shipment of Hazardous Materials
US Occupational Safety and Health Administration	Occupational Exposure to Dangerous Pathogens
US Department of Commerce	Exportation of Select Human, Animal, and Plant Pathogens
International Air Transport Association	Dangerous Goods Regulations
International Civil Aviation Organization	Sending of Dangerous Pathogens via the International Mail System
World Health Organization	Transfer of Dangerous Biological Materials
Universal Postal Union	Mailing of Dangerous Pathogens
World Federation of Culture Collections	Shipment of Dangerous Pathogens
United Nations Committee of Experts on the Transport of Dangerous Goods	Shipment of Dangerous Pathogens

** The CDC certifies facilities to receive and handle dangerous pathogens and administers regulations governing the Importation of Etiologic Agents of Human Disease, as regulated in the federal code in 42 CFR 72 and 42 CFR 71 and 71.54. APHIS oversees the regulations regarding the importation of etiological agents of livestock, poultry, and other animal diseases and the federal plant pest regulations, respectively, see 9 CFR 92, 94, 95, 96, 122 and 130 and 7 CFR 330. The Commerce Department's export rules are specified in 15 CFR 730 to 799, and the US Postal Service's regulations on mailing etiologic agents are in 39 CFR 111. The regulations of the US Transportation Department are located in 19 CFR 171-178, and the Occupational Safety and Health Administration's rules related to exposure to bloodborne pathogens are in 29 CFR 1910.1030.

International Air Transport Association's Dangerous Goods Regulations require that packaging for dangerous biological materials meet the standards set out in IATA packing instruction 602 (class 6.2). See International Air Transport Association, Dangerous Goods Regulations, 39th ed. (Montreal: IATA, 1998). The International Air Transport Association developed its packaging rules in conjunction with the International Civil Aviation Organization. Pertinent guidance from World Health Organization is contained in Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (Geneva: World Health Organization, 1997); Intergovernmental Committee for the Cartagena Protocol on Biosafety, "Handling, Transport, Packaging and Identification (Article 18)," Document UNEP/CBD/ICCP/1/6, 25 September 2000.

The World Federation for Culture Collections maintains a list of guidelines that encourage member organizations to adhere to applicable international or national standards., including one for the shipment of cultures: See World Federation for Culture Collections, Guidelines for the Establishment and Operation of Collections of Microorganisms, 2nd ed., 1999. Similarly, the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods presents model regulations, including suggested lists of principal dangerous goods, general packing requirements, etc. United Nations Economic and Social Council, Committee of Experts on the Transport of Dangerous Goods, UN Model Regulations on the Transport of Dangerous Goods, 12th ed., foreword. Available at http://www.unece.org/trans/danger/publi/unrec/mr_nature_e.html.

select agent list.[33] While the CDC has only a few years of experience administering these transfer regulations, the industry experts also pointed to the tight system that the Nuclear Regulatory Commission has long overseen as a model for certifying the fitness of facilities to receive hazardous materials.[34]

A second law, passed in 2001, stipulated a deadline for some 190,000 US facilities that might have involvement with past or ongoing dangerous pathogens work to inventory the holdings in their culture collections and report to federal authorities the possession of any agents found that are on designated lists of human, animal, and plant pathogens.[35] The rationale behind this requirement is that transfer and receipt regulations address the activities of facilities from the point in time in which they are implemented, leaving the culture collection holdings of a multitude of facilities in place. If unaddressed, individuals with access to the freezers in these facilities could rummage through their contents in search of dangerous pathogens for foul play. Hence, this law requires that facilities inventory culture collections and "clean the house" of dangerous pathogens that they have no legitimate need to keep on hand.

The industry experts explained that many facilities do not have a firm idea of just what is in their freezers, partly because of the aforementioned tendency of scientists to slip sample vials into their jacket pockets. Moreover, it is not uncommon for scientists to change jobs or retire, leaving behind their personal cache of special samples.[36] Tucked unobtrusively amidst a sea of other vials, these personal collections often remain undisturbed for years in corporate or university freezers.[37]

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[33] These transfer regulations, which grew out of the Antiterrorism and Effective Death Penalty Act, are in 18 USC, Sections 175-178 and 2332, 42 CFR 72.

[34] Under the Nuclear Regulatory Commission's well-policed regulations, "when an institution receives a radio-labeled or radioactive package, that package is quarantined until it is swipe-tested to make sure there is no contamination on the outside. Then that package is released only to a trained individual who signs for the package and whose laboratory is enrolled in the Radio/Chemical Safety Program. That laboratory is inspected regularly." Dr. Eric Utt, health and safety manager at a large US pharmaceutical company, 10 August 2002. Other industry experts held the Nuclear Regulatory Commission's transfer, access, and safety regulations in similarly high regard, partly because both researchers and administrators are required to be aware of the regulations and noncompliance penalties.

[35] These regulations were born out of the aforementioned Public Health Security and Bioterrorism Preparedness and Response Act passed on the heels of the anthrax letter attacks in the fall of 2001. The select agent lists, published in the Federal Register, comprised thirty-six human pathogens (eighteen of which are also contained in the animal pathogen list, because they threaten both humans and animals), twenty-four livestock diseases, and nine plant pathogens. Reporting forms were mailed directly to facilities and also made available online. By 10 September 2002, facilities were to return their human pathogens inventory results to the CDC and their plant and animal pathogens inventory results to USDA's Animal and Plant Health Inspection Service. A copy of the law can be found at http://www.cdc.gov/od/ohs/lrsat/bioterro.htm. See also, Stephen Mitchell, "Feds Scramble to List Bioterror Holdings," United Press International, 13 August 2002; Diane Jean Schemo, "Sept. 11 Strikes at Labs' Doors," *New York Times*, 12 August 2002.

[36] When asked what percentage of strains in facility freezers were properly certified and documented, answers varied according to type of facility. The group estimated 100 percent for manufacturing plants, 65 to 80 percent for development facilities, but only 10 to 25 percent of the freezer contents would be properly registered in research laboratories.

[37] For example, in a March 2002 audit of US Agriculture Department laboratories, investigators discovered that a retired scientist had left behind a sample of *Salmonella*, a biosafety level 2 agent, in the freezer of a government laboratory. The

With these very circumstances in mind, the industry experts recommended bolstering the US biosecurity proposal by requiring nations to bring their biosecurity practices up to an agreed minimal international standard, patterned after the US transfer and access regulations.[38] To account for the dangerous pathogens present in laboratory freezers around the world, the industry experts proposed adding a clean house requirement for facilities globally. They estimated that within three months facilities could inventory their holdings and notify appropriate national authorities if they discover any human, animal, or plant pathogens on select agent lists not included in their current registration. While consulting with national authorities about the proper disposal of any such select-list pathogens, the vial(s) in questions would be stored securely.[39]

In addition, the industry experts suggested that governments consider another aspect of biosecurity—physical security requirements. Due to break-ins and vandalism from animal activists, [40] many industrial, university, and government laboratories have found it advisable to upgrade the physical security on their premises, installing security cameras, alarm systems, and card key entry procedures. As accounting and reporting procedures are put in place for facilities working with select-list agents, these facilities will become more readily identifiable because of reported information and/or the required posting of certain warning signs.

Consequently, the industry specialists warned that terrorists seeking biological agents for harmful purposes might consider institutions working with dangerous pathogens worthy targets for theft or terrorism. No US regulations require enhanced physical security for industrial or academic facilities working with dangerous pathogens.[41] To reduce the possibility of theft of a virulent strain or sabotage at such facilities, the industry group advised institutional, national, and international policy makers to make heightened physical security precautions (e.g., guards, fences) at pertinent facilities an item on the priority list.

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sample remained in the inventory, unbeknownst to laboratory officials, even after the laboratory ceased to operate at that biosafety level. US Department of Agriculture, *Audit Report: Oversight and Security of Biological Agents* (Washington, DC: Office of the Inspector General, March 2002), 8-9.

[38] The industry experts argued for a flexible construction that could be adapted to technical changes.

[39] Note that the industry experts argued that facilities operators should not be required to identify the contents of any vials that are unlabeled or that have labels that cannot be read. Instead, they should be allowed to destroy the contents of such vials using appropriate safety precautions.

[40] In the Department of Agriculture's audit, investigators documented five break-ins at the department's biosafety level 2 laboratories. "Although officials…did not express any concerns that biological material could have been removed, only two of the laboratories had current inventories that could be used to make such a determination." US Department of Agriculture, *Audit Report: Oversight and Security of Biological Agents*, 13.

[41] A *de facto* approach to physical security (e.g., building entry codes) exists at some facilities.

CREATING MORE RIGOROUS OVERSIGHT OF GENETIC ENGINEERING RESEARCH

To contend with proliferation dangers presented by modern genetic engineering research, the Bush administration proposed that nations that belong to the BWC "sensitize" scientists to the "possible biological weapons implications" of genetic engineering research. The United States also suggested that individual countries "explore" national oversight concepts with nongovernmental organizations (e.g., professional societies, national academies of science), possibly formulating recommendations for the review of proposed genetic engineering experiments.[42]

The industry experts had high praise for the NIH's prescient approach to guiding safe recombinant DNA research, which dates to the mid-1970s.[43] Since the publication of the original NIH *Guidelines for Research Involving Recombinant DNA Molecules*, regulatory progress has kept pace with what many have described as a revolution in the life sciences.[44] Not all of the outcomes that this revolution enabled have been benign. For example, Soviet scientists engineered various biowarfare agents to make them resistant to antibiotic treatment.[45] Experiments with good intentions also went bad. In January 2001, scientists and non-scientists alike were shaken when Australian researchers announced that during experiments with the mousepox virus, they had unintentionally created a more lethal virus that destroyed the immune systems of the mice.[46] Such developments have disturbing implications for countries or terrorists seeking an advanced biowarfare capability. Yet, amidst this scientific revolution, the industry group lauded the NIH's guidelines as a "reasonable, rational, living document that provides a beautiful framework for any institution to conduct DNA recombinant research safely and sanely."[47]

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[42] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," 5.

[43] In 1975, the government convened experts pertinent to recombinant DNA research for discussions in Asilomar, California. The outcome of this meeting was the framework for the first edition of the NIH guidelines. Recalled one of the industry experts, "Some of the first experiments in DNA recombinant research were done at the NIH when I was there. Even then, oversight was in place. You had to go into the BL4 facility at Frederick, make the application, list the protocols, and go through a lot of hoops to get access to that facility." Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

[44] For a discussion of what scientific advances may portend for bioweapons, see chapters 5 and 6, Malcolm Dando, *Biological Warfare in the 21st Century: Biotechnology and the Proliferation of Biological Weapons*, (New York: Brassey's, 1994), 86-129.

[45] See Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999).

[46] Researchers at Australian National University urged strengthening of the Biological Weapons Convention after their experiment on mouse contraception went off track. Ronald J. Jackson, et al., "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox," *Journal of Virology* 75, no. 3 (February 2001): 1205-10. Available at http://jvi.asm.org. See also, Clive Cookson, "Scientists Convert Virus into Killer," *Financial Times*, 12 January 2001.

[47] Dr. Robert Goldberg, PhD in medical microbiology and thirty-plus year industry and research veteran, 10 August 2002.

While the industry experts supported the US government's inclination to address the potential biological weapons proliferation threat resident in genetic engineering research, they declared that the US proposal significantly misgauged the urgency of the matter by stopping at requests that states sensitize scientists to proliferation risks and look into possible national oversight measures. Given the rapid advancements in the field, the industry group recommended a more distinct and targeted approach, based on the NIH's guidelines as the best foundation for the standards that should ultimately oversee such research worldwide.[48] Rather than having a stifling effect on genetic research, the industry group characterized the NIH guidelines as a "good road map for people working in the area."[49]

Just as Rome was not built in a day, research institutions and countries must gradually work toward the NIH guidelines. Accordingly, the industry experts suggested beginning with just the reporting requirements, working progressively toward adopting minimum research oversight standards as a next step, and eventually adopting the NIH guidelines in total.[50] Implemented in incremental fashion, an international standard would foster increasing transparency, coordination, and oversight of genetic engineering research.

CONCLUDING THOUGHTS ABOUT IMPLEMENTATION

To achieve the US government's desired aim of strengthening the international regime against biological weapons, the industry experts believed that the international community should push forward with the agreement and enactment of common minimum standards that include penalties for infractions of biosafety, biosecurity, and genetic research oversight regulations. This trio of regulations should work separately but also in concert, reinforcing one another so that closer tabs can be kept on possibly dangerous biological activities. Appreciative of the complexities of regulating biosafety, biosecurity, and genetic engineering research, the industry group counseled a step-by-step approach to ease institutions and governments into the implementation of universal standards. Once international standards are agreed, nations would pass laws requiring pertinent institutions to operate accordingly. On the heels of these steps, countries would establish national regulatory infrastructures, progress that would eventually be capped by the creation of international coordination and oversight capacities.

In each functional area, individual institutions that have not previously practiced biosafety, biosecurity, and/or oversight of genetic engineering research would have much to do. For example,

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[48] The group also gave high marks to the extensive British guidelines for overseeing genetic research.

[49] Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002.

[50] Of the initial step that countries must take, one industry expert said: "Just as there are basic levels for biological safety; there should be basic levels for recombinant DNA work, which implies basic types of reporting." Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, 10 August 2002.

facilities working with dangerous pathogens need to have a well-trained biosafety officer as well as an institutional biosafety committee composed of fully trained, competent individuals. This infrastructure would assure fulfillment of the institution's responsibility to provide ongoing biosafety training of its employees. The biosafety officer would also check the adherence of project personnel to biosafety protocols throughout the lifetime of a project. Should problems occur, the biosafety officer would play a key role in the investigation and subsequent adjustment of biosafety practices to reduce the possibility that problems would recur. For proposed projects, the biosafety officer would assist in the principal investigator's assessment of safety risks, the suitability of the facility's containment, materials handling, and waste treatment procedures, and other factors pertinent to safe conduct of the envisioned research.

In the area of biosecurity, the biosafety officer would inaugurate, if necessary, the requisite protocols to receive dangerous pathogens and ensure that only essential personnel have access to them. The biosafety officer would ensure that personnel working with or nearby dangerous pathogens received refresher training about workplace rules, doing the same for those engaged in genetic engineering research. While an institutional biosafety committee could grant permission for less hazardous types of advanced research, scientists planning to initiate certain types of experiments (e.g., cloning toxins with certain levels of lethality, introducing antibiotic resistance into an organism) would first have to obtain the permission of the recombinant DNA advisory committee.

Similarly, nations that lack government offices to administer biosafety, biosecurity, and genetic research oversight regulations would need to establish such a capacity. After a reasonable agreed upon grace period to allow institutions to come up to speed, national authorities would be responsible for monitoring adherence with various regulations through reporting requirements and inspections, as necessary. Specifically with regard to genetic engineering research, a national oversight authority would review and approve experiments, certify personnel and facilities, and assume, vis-à-vis the laboratories, responsibility for assessing risk and setting levels of containment. The national authorities would then track individual projects, including the disposition of all genetically modified organisms. National authorities would also hand out fines and other penalties to institutions and individuals found in violation of the biosafety, biosecurity, and research oversight rules.

Ultimately, years from now, the industry group could foresee the creation of an international organization that would perform some of the tasks described above for the national authorities, but at an international level. First, this body would be charged with coordination of national efforts and updating of standards, monitoring tools, select agent lists, and penalties to keep pace with technical developments. International authorities would also oversee the progress of biosafety and biosecurity monitoring efforts. With regard to oversight of genetic engineering research, this body would ramp up gradually, beginning just with the registration of DNA recombinant experiments with Class III and IV organisms to compile an index of such activities worldwide. Eventually, the industry experts envisioned that international authorities would play an important role in the review and approval of proposed genetic engineering research.

While the industry experts believed that implementing this suite of biosafety, biosecurity, and research oversight recommendations would strengthen international efforts to retard biological weapons proliferation, the industry experts also noted that these actions would have additional positive repercussions. Facilities that employ proper safety and containment protocols will reduce the potential for accidental release of dangerous diseases. The biosafety and biosecurity standards that the industry experts endorsed constitute good laboratory and manufacturing practices. As the pharmaceutical and biotechnology facilities in other countries adopt such standards, they will encounter easier access to US and other advanced markets. Finally, in the event that additional research and field trials prove the feasibility of a monitoring system for the BWC, as Chapter 2 discusses, inspectors would find the documentation, standard operating procedures, and oversight activities that the biosafety, biosecurity, and genetic engineering research standards require useful benchmarks in helping to determine whether a particular facility's operations are consistent with its stated purpose(s).

Chapter 5
Concluding Observations and Recommendations

The 1972 Biological and Toxin Weapons Convention (BWC) typifies that decade's arms control treaties in that it lacks mechanisms to gauge states' compliance with the treaty's sweeping ban of offensive bioweapons activities. In the early 1990s, the international community began to confront the convention's weakness when it became unmistakably clear that the former USSR, a founding member of the treaty, had hidden an extensive and advanced covert germ weapons program for decades.[1] This and other noncompliance revelations led to the inauguration of Ad Hoc Group negotiations charged with strengthening the BWC through development of a structured monitoring protocol.[2]

As Chapter 1 reviews, the Ad Hoc Group labored for over six years to overcome the technical and political challenges involved in such a negotiation. In July 2001, in the face of international pressure to accept the Ad Hoc Group's efforts, the Bush administration issued an unqualified rejection of the draft monitoring protocol.[3] The US government finalized its opposition to a formal BWC monitoring system at the treaty's Fifth Review Conference, calling in December 2001 for the dissolution of the Ad Hoc Group and an end to negotiations.[4] Instead, the US government offered alternative proposals in place of a legally binding multilateral agreement. The US alternatives can be placed into two categories: 1) a pair of traditional monitoring techniques that involve inspections; and 2) assorted domestic steps to enhance

[1] The Soviet germ weapons program comprised over fifty facilities, most of them under the cover of legitimate commercial activities. Roughly 65,000 scientists and technicians researched, developed, tested, and produced tons of agents such as plague, anthrax, and smallpox. A first-hand account of the USSR program can be found in Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999).

[2] According to the US government, roughly a dozen countries, including Iran, North Korea, and Iraq, are thought to have offensive biowarfare efforts underway. US Department of State, International Information Programs, "Statement of Under Secretary of State for Arms Control and International Security John Bolton to the Fifth Review Conference of the Biological Weapons Convention," Geneva, Switzerland, 19 November 2001. Available at http://www.state.gov/t/us/rm/janjuly/6231.htm. For example, when United Nations (UN) inspectors entered Iraq after the Gulf War to monitor the elimination of missiles and weapons of mass destruction capabilities, they uncovered the extent of Iraq's efforts to weaponize human, animal, and plant diseases. R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: UN Pursuing 25 Germ Warheads it Believes are Still Loaded with Deadly Toxin," *Washington Post*, 21 November 1997. A digest of UN inspectors' biological-weapons-related findings in Iraq can be found in United Nations Special Commission on Iraq, *Final Compendium*, Document S/1999/94, 25 January 1999, Disarmament Report Annex C.

[3] "The draft protocol that was under negotiation for the past seven years is dead in our view. Dead, and it is not going to be resurrected. It has proven to be a blind alley." US Department of State, International Information Programs, "Bolton Briefing on the Biological Weapons Pact," transcript of press conference, 20 November 2001. Available at http://usinfo.state.gov/topical/pol/terror/01112003.htm.

[4] This proposal was offered with literally only minutes left in the proceedings and left many conference attendees shocked and angry. Seth Brugger, "BWC Conference Suspended After Controversial End," *Arms Control Today* 32, no. 1 (January/February 2002).

regulatory, statutory, and other mechanisms related to the handling of dangerous pathogens, the conduct of science, the detection of disease outbreaks, and the criminalization of offensive bioweapons activities.[5]

While unpopular, the US government's dismissal of the draft BWC monitoring protocol was necessary, according to two groups of US industry technical experts who scrutinized the Ad Hoc Group's handiwork and found it wanting. The Henry L. Stimson Center's Chemical and Biological Weapons Nonproliferation Project assembled both groups. The first was composed of individuals with roughly 200 years of collective experience in the pharmaceutical and biotechnology industries as well as in research institutes and universities. These industry experts basically concurred with the Ad Hoc Group on the inspection techniques that could be used to monitor compliance, but they roundly disputed how the draft protocol was structured, arguing key issues like timeframes and inspection team composition. In a May 2001 Stimson Center report entitled *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol*, this industry group concluded that given sufficient time on site and various inspection methods at their disposal, the right number of well-trained inspectors could verify whether a commercial facility's activities were consistent with its stated purpose.[6] The second group of industry experts echoed the conclusions reached by the first.

The Stimson Center convened a second group of industry experts because most of the Bush administration's alternative proposals hold potential implications for US industry. This second group had even more cumulative hands-on knowledge than its predecessor, benefiting from over 280 years of experience in industry as well as in academic and research institute settings. This chapter summarizes their unvarnished analysis of the US proposals, beginning with those related to actions on the part of individual nations and then moving on to the traditional inspection-based alternatives. The industry experts make several recommendations grounded in their technical experience for the best ways to move forward with these proposals. On the whole, the second group found the US government's traditional monitoring proposals lacking in validity and the proposals for action by individual states attractive at first glance, but certainly not extensive enough to strengthen the regime against biological weapons in a meaningful manner.

ALTERNATIVE PROPOSALS: INDIVIDUAL STATE ACTIVITIES

All save two of the alternatives that the US government offered constitute domestic steps that nations would undertake individually to oversee activities involving dangerous pathogens and genetic engineering research more closely, to prosecute bioterrorists, and to identify disease outbreaks rapidly.

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[5] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

[6] The Henry L. Stimson Center in Washington, DC, published this report, which also drew upon expertise of defense contractors, researchers from universities and research institutes, and veterans of inspections in the former USSR and Iraq. See Chapters 4 and 5 for the viewpoints of industry experts. The industry experts met twice to discuss the issues, on 29-30 June 2000 and 23-24 August 2000.

Explaining the structure of these proposals, a senior Bush administration official said "it is not necessarily the case that one size fits all."[7] Asking individual states to take action might appear to be an easier and swifter route to progress, but the industry experts recognized that without any minimum standards to guide these efforts, the results might be anything from insignificant to counterproductive.

Given the deaf ear that most BWC members have previously turned to requests for even the simplest of voluntary actions on their part, the US proposals might not generate much in the way of results. For example, at the 1986 BWC Review Conference member states agreed to provide data annually on matters related to biological research, high biosecurity laboratories, and suspicious disease outbreaks. In 1991, the BWC's members agreed to provide additional types of data to the United Nations to promote transparency about compliance with the BWC. During the first ten years where such data exchanges were to occur, not once did a majority of BWC member states participate—not even to check the "nothing to declare" box on the reporting form.[8] As discussed in Chapter 3, the 1996 Review Conference also strongly urged states to pass criminal legislation barring offensive biological weapons research. Yet, as of 2001, only twenty-seven of forty-five states that provided any information to the United Nations said they had done anything in this regard, while ninety-eight states failed to submit any data whatsoever.

Therefore, with the current US proposals, the industry experts reasoned that some nations would take no action at all, others could design their laws and regulations in ways that purposefully abetted covert activities, and still others simply do not possess the requisite experience to develop adequate controls for various biological activities. The resulting hodgepodge of regulatory and legal mechanisms would only further fragment efforts to coordinate international nonproliferation activities in the future. Far preferable to having every state go its own way, the industry group recommended mandatory universal standards.

Disease Surveillance, Criminalization, and Scientific Ethics Codes

The industry specialists backed the US government's call for countries to support the disease outbreak and response capabilities of the World Health Organization, the Office of International Epizootics, and the Food and Agriculture Organization. Disappointed that the Bush administration did not offer a more substantive initiative, the group deferred to the World Health Organization and its sister

[7] Under Secretary of State for Arms Control and International Security John Bolton made this comment specifically with regard to the proposal on criminalizing offensive biological weapons activities. US Department of State, "Bolton Briefing on the Biological Weapons Pact," transcript of press conference.

[8] See Marie Chevrier, "Doubts About Confidence: The Potential and Limits of Confidence-Building Measures for the Biological Weapons Convention," in *Biological Weapons Proliferation Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, January 1998), 53-75.

organizations as the international entities most qualified to advance human disease surveillance globally.[9] The industry group strongly agreed with the idea that criminal penalties should be imposed upon anyone, anywhere, who is found engaging in offensive biological weapons activities. Yet, the group worried that under the proposed US approach, nations that intentionally or unintentionally construct more lenient punishments might become havens for bioterrorists. To address concerns about other activities that could cause grave loss of life (e.g., airline hijacking, theft of nuclear materials), the US government has backed international criminalization treaties. Therefore, in Chapter 3 the industry participants endorsed the idea of a tough international penal standard, embodied in an accord to criminalize biological weapon activities.[10]

Group members gave mixed reviews to the nonproliferation utility of professional codes of conduct for scientists who work with dangerous pathogens. Under the US proposal, countries would work with the professional scientific societies and nongovernmental organizations to augment existing codes or put in place ethics codes that commit scientists not to use their knowledge or abilities in the life sciences for hostile purposes.[11] The industry experts thought this was a "nice" suggestion, but questioned whether this initiative would really restrain any individual intent on wreaking biological havoc. In short, the group felt that ethics codes were more of a feel-good measure than a substantive curb against biological weapons activity. However, some of the industry experts did point out that some scientists might find guidance in ethics codes that helps them to blow the whistle on illegal or questionable activities.

Biosecurity, Biosafety, and Genetic Engineering Research

The industry experts responded enthusiastically to the concept of promoting biosafety, biosecurity, and oversight of genetic engineering research, but in Chapter 4 they explained why this set of US proposals fell short of the mark. The group highlighted the significant progress that the United States and other nations with advanced pharmaceutical and biotechnology industries have made in these areas, pointing to relevant guidelines that the Centers for Disease Control and Prevention (CDC) and the National Institutes for Health (NIH) have issued.[12] Rather than asking other states to reinvent the wheel,

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[9] The World Health Organization's Department of Communicable Disease Surveillance and Response has been working with individual countries for over a decade to build the capacity to monitor and respond to infectious disease outbreaks, whether natural or manmade. The organization's web address is http://www.who.int/emc/surveill/index.html.

[10] Matthew Meselson and Julian Robinson, *A Draft Convention to Prohibit Biological and Chemical Weapons Under International Criminal Law*, The Harvard Sussex Program on CBW Armament and Arms Limitation, 1 November 2001. Available at http://www.fas.harvard.edu/~hsp/crim01.pdf.

[11] The American Society for Microbiology has a general ethics code. However, several members of the industry group that belong to this organizations admitted that they were not acquainted with the code, nor aware of what might befall individuals who failed to live up to it.

[12] US Department of Health and Human Services, Centers for Disease Control and Prevention and the National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed., (Washington, DC: General Printing Office, 1999).

the United States should revise its proposals to promote the adoption of global mandatory standards modeled after those set by CDC and/or NIH, or their equivalent. For example, the industry experts suggested that the minimum international biosecurity standards be modeled after US regulations governing access to, transfer of, and chain-of-custody of select pathogens and toxins.[13] A single international biosafety standard would also cut back on the confusion that current circumstances generate, wherein multiple national and international entities oversee different aspects of biosecurity, leading to a tangle of rules that vary in scope, application, and enforcement.

The industry experts identified two significant holes in the US government's approach to biosecurity. The first stems from the fact that access and transfer restrictions would institute accountability only from the point at which they were enacted, but do nothing about the culture collections already present in facilities. Accurate and complete inventories are often the exception rather than the rule, even in government laboratories.[14] The industry group strongly endorsed the adoption of a global "clean house" measure that would require numerous facilities to take scrupulous stock of the dangerous human, animal, and/or plant pathogens and toxins in their possession. The group allotted three months for facilities to complete the inventory, after which the institutions would be responsible for notifying national authorities of the presence of any select-list pathogens that their facility's current registration does not cover.[15] Any such unwanted strains, which could well have been on freezer back shelves for decades, would then be responsibly documented, verified, and destroyed. The second biosecurity gap that industry experts believed policymakers must consider tackling relates to improvements to the physical security of sites conducting dangerous pathogens work, since such locations could become targets for theft, sabotage, or other biocrimes.

Particularly in the area of biosafety, the United States has its own work to do. Although the current CDC/NIH manual, *Biosafety in Microbiological and Biomedical Laboratories,* is packed with useful information, the guidelines therein are only mandatory for those laboratories that receive US government grants. Non-federally funded institutions may choose the terms and degree, if any, of their compliance. The United States should begin with making these CDC/NIH biosafety standards mandatory in all US facilities, allowing relaxed procedures only in clinical laboratories due to the volume and nature

[13] For example, the CDC certifies facilities to receive and handle dangerous pathogens and administers regulations governing the Importation of Etiologic Agents of Human Disease. The relevant section of the federal code are 42 CFR 72 and 42 CFR 71.

[14] Illustrative problems are documented in US Department of Agriculture, *Audit Report: Oversight and Security of Biological Agents* (Washington, DC: Office of the Inspector General, March 2002), 8-9.

[15] Should facility operators come across unlabelled vials or labels that cannot be read, industry experts said that they should not be required to determine the contents of the vial. Rather, the clean house regulation would direct that such vials be destroyed using proper procedures.

of the samples these facilities receive.[16] Improving US domestic practices would buttress a US call for worldwide standards.

The industry group concurred with the US government that issues specific to genetically modified organisms were important enough to discuss separately. Recombinant DNA research advancements pose particular challenges for attempts to guard against the abuse of the life sciences. The industry experts again offered as the best model the NIH's *Guidelines for Research Involving Recombinant DNA Molecules*, which they characterized as the most comprehensive and reasonable layered oversight system available to keep close tabs on the conduct of potentially risky experiments.

The success of biosafety, biosecurity, and research oversight standards depends on the proper education of personnel, the articulation and enforcement of penalties for regulatory infractions, and the creation of select lists of pathogens and toxins deemed particularly dangerous to humans, animals, and plants. The backbone of the full and thorough implementation of standards is the proper training of personnel, but industry experts said not all facilities provide ongoing training for their staffs. Likewise, classroom instruction on biosafety essentials has been noticeably on the decline in US colleges and universities in recent years. These dismal educational circumstances, they argued, must be rectified with no delay.

Next, the industry experts emphasized that some facilities would not bring their practices up to standards unless noncompliance penalties were enforced. Depending upon the seriousness of the violation, suggested penalties for individuals were loss of pay, fines, suspension, or loss of job. Recommended penalties for noncompliant institutes included fines, suspension or loss of licenses, and loss of government grants. Third, the industry experts lauded the conciseness of the select agent lists that the CDC and the Australia Group have issued, but they were critical of the unwieldy lists that the US Department of Agriculture relied on to regulate pathogens until 2002, when the department began to issue some revisions.[17] To facilitate the implementation of standards, the international community should jointly develop concise lists of select pathogens, stratified according to the different risks of certain agents. While these lists should be thorough, ones that are too lengthy would undermine the ability of facilities to comply with the regulations.

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[16] As discussed in Chapter 4, US guidelines allow clinical laboratories to conduct selected activities typically considered biosafety level 3 at biosafety level 2 conditions because of the large number of unknown samples they receive.

[17] The Australia Group, a consortium of over thirty nations focused on blocking chemical and biological weapons proliferation, posts its biological control lists on its website at http://www.australiagroup.net/control_list/bio_agents.htm. Public Law 107-188, the *Public Health Safety and Bioterrorism Preparedness and Response Act of 2002,* which requires US facilities to report possession of biological agents that pose a danger to humans, animals, and plants required that pertinent lists from the CDC and the Agriculture Department's Animal and Plant Health Inspection Service (APHIS) be reviewed. Any changes to the human agent select list are reflected in the relevant section of the federal code, 42 CFR 72, available at http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm. New sections of the code dealing with animal and plant list are, respectively, 9 CFR 121 and 7 CFR 331. These new lists are considerably shorter than the lists that the Agriculture Department previously used to regulate animal and plant pathogen research. For an example of a pre-2002 list, see APHIS' *Regulated Plant Pest List* found online at http://www.aphis.usda.gov/ppq/regpestlist/.

The industry experts understood that their recommendations for universal biosecurity, biosafety, and research oversight standards would require changes in regulations and practices around the world. The magnitude of change would be so significant in some locales that the industry group advised a phased implementation of international standards, which would unfold as follows:

- Agreement on international standards for biosafety, biosecurity, and oversight of genetic engineering research, including specification of penalties and of risk-stratified lists of select agents for human, animal, and plant pathogens and toxins;
- Passage of domestic regulations, including noncompliance penalties for individuals and their respective organizations;
- Institution of requirements to strengthen training of biosafety, biosecurity, and research conduct practices in universities, research institutes, and industry and to install ongoing training for the professionals staffing institutions working with genetically modified organisms and dangerous pathogens and toxins;
- Enhancing or creating the appropriate institutional infrastructures to perform such functions as the proper training of personnel, the review of pertinent research proposals, and the evaluation of risk assessments and containment for proposed projects;
- Establishment of a domestic office or agency to coordinate and oversee national efforts, to certify that all pertinent institutions meet regulatory standards, and to enforce penalties, if necessary;
- Creation of an international capacity to coordinate efforts at the national level, identify and eliminate gaps, update standards to keep pace with technical developments, and administer the improved standards.

As the domestic and subsequent international oversight capabilities mature, they would progress from the administration of biosafety and biosecurity regulations to additional responsibilities for the review, approval, and tracking of research projects involving genetic engineering.

ALTERNATIVE PROPOSALS: TRADITIONAL INSPECTION ACTIVITIES

While emphasizing the actions that individual states should take, the Bush administration did not completely rule out a role for inspections to help police the BWC. In the event of a suspicious disease outbreak or an allegation of biological weapons use, the United States endorsed investigation by the United Nations Secretary General. In a second US proposal, bilateral consultations to resolve compliance ambiguities could also incorporate data exchanges and one BWC member voluntarily offering another access to the site(s) of compliance concern.[18]

[18] US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," 6-7.

The industry group questioned the merits of both of these proposals, as Chapter 2 relates in more detail. The United Nations Secretary General has held authority to launch investigations of suspicious disease outbreaks and/or biological weapons use since the late 1980s; over a quarter of a century ago, the BWC vested the United Nations Security Council with the power to investigate any compliance problem.[19] Yet, not a single compliance investigation has occurred, despite the very questionable circumstances surrounding the 1979 outbreak of anthrax in Sverdlovsk and persistent allegations of other covert biological weapons programs. Another drawback of this proposal, as the industry group noted, is that it does not provide for investigation of suspicious research or production facilities.

As for the dubious value of a voluntary inspection, industry experts observed that any country hiding prohibited activities would certainly scrub a site clean before offering access, therefore making it very unlikely that violators might be found. The industry group was perturbed by the very idea that their facilities might end up part of a monitoring charade wherein inspections were not structured to confirm whether facilities were legitimate or serving as a cover for weapons activities. They also worried that governments might opt for political reasons to "volunteer" industry facilities for inspection, which would force companies to bear the burdens of an ineffective inspection with inconclusive results.

The industry experts emphasized that any BWC monitoring effort needs to produce a determination of whether a facility's endeavors are consistent with its legitimate stated purpose or with illicit biological weapons activities. Just as their predecessors did in *House of Cards*, the second group of industry experts argued that effective monitoring could be achieved if the right set of multidisciplinary inspectors used the inspection tools and tactics described in Chapter 3. Moreover, the second group of industry experts stated that the inspectors would be better positioned to accomplish their tasks if stiffer biosafety, biosecurity, and research oversight practices were implemented worldwide. Among other things, these standards would foster additional documentation that inspectors can check. Company employees would be expected to know certain standard operational biosafety and biosecurity procedures for their facility, and inspectors would know there was something amiss if they did not. Thus, the industry group noted the possible synergy between a formal BWC monitoring system and their recommended biosecurity, biosafety, and genetic research oversight standards.

Again, like their predecessors, this second group of industry experts strongly recommended that the Bush administration proceed with research and field trials to test a full range of BWC monitoring tools and methods in a variety of settings. After all, basic research and field testing are crucial to making informed decisions about the future of any sort of inspection-based monitoring protocol. A 1999 law stipulates that the US government conduct such BWC inspection trials at government installations,

[19] For more discussion on the Secretary General's current, limited authority and the United Nations' investigations of chemical and toxin weapons use, see Jonathan B. Tucker and Raymond A. Zilinskas, "Assessing US Proposals to Strengthen the Biological Weapons Convention," *Arms Control Today*, 32, no. 3 (April 2002): 10-4. The United Nations' original authority is stated in Articles V and VI, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*.

industry sites, and academic institutions, followed by an analysis of the monitoring benefits and risks that could be expected from such inspections.[20] To lay the groundwork for such trials to proceed, the second group of industry experts decided to construct plans for potential trial inspections to test the practicability of their preferred monitoring strategies, tactics, and tools. Trial plans will be prepared for two distinct types of industry sites, manufacturing plants and research and development facilities.

CONCLUDING OBSERVATIONS

According to experts from the US pharmaceutical and biotechnology industries, the US government and the international community have their work cut out for them if meaningful mechanisms are to be put in place to detect, deter, and punish offensive biological weapons activities. Taken as a whole, the industry experts assessed the Bush administration's alternative proposals as lacking in substance and force. The industry group was genuinely puzzled that their government would advance such tepid proposals after the bioterrorist attacks of 2001 and in view of the continuing efforts of national and subnational actors to acquire biowarfare capabilities. Now, the industry experts argued, is the very time to get serious about fortifying the BWC's behavioral norm against biological weapons with strong detection, deterrence, and enforcement capabilities.

Finally, the group acknowledged that more rules and penalties are not typically something that representatives of industry advocate. However, at crucial times when action is needed, one can be part of the problem or part of the solution.[21] When it comes to issues associated with the biological weapons threat, the US industry experts expect their government and their industry to be aggressive problem-solvers. Biological weapons proliferation is such a complex problem that uncoordinated, uneven action on the part of individual states and weak on-site inspection procedures—the probable results of the proposed US alternatives—will hardly make a dent. Much stronger US initiatives to improve the international regime against biological weapons, revised according to the compliance-through-science approach recommended in this report, are in order.

[20] The 1999 National Security and Corporate Fairness Under the Biological Weapons Convention Act, Public Law 106-113, 29 November 1999.

[21] One of the industry experts noted, "Some people are just going to be nuisances, others sticklers for doing absolutely everything by the letter of the law, and still others are not going to do anything. At the end of the day, the middle of that bell curve is still the right thing to do. The international community needs to back these regulations and have the ability to monitor these activities responsibly." Expert 1, 10 August 2002. Expert 1, a senior vice president overseeing operations, product development and manufacturing at a US biopharmaceutical company, has over twenty years of experience in the pharmaceutical industry and holds a PhD in biology.

Appendix: Participant Biographies

Robert Goldberg recently retired after fifteen years at a US pharmaceutical company that ranks in the top 25 on the Fortune 500 list with over $45 billion in 2001 sales. His last job with this firm was executive director for strategic and scientific planning. He began his industry career by working for three years as a technician at a major US pharmaceutical company after receiving a BS in biology from Villanova. He went on to earn an MA and PhD in medical microbiology from the Hahnemann School of Medicine at Drexel University, doing post-doctoral research with Dr. Fred Rapp at the Hershey Medical Center at Pennsylvania State University. Afterwards, Dr. Goldberg spent eleven years at the National Cancer Institute of the National Institutes of Health, working in administration and research related to virology, cell biology, and molecular biology. During that time, he was also a participant in US/USSR cancer research exchanges, including some on-site research in the former USSR. Following retirement, Dr. Goldberg has been an independent consultant for a major US pharmaceutical company and has been on the board of directors of the Hepatitis B Foundation.

Robert Hamilton is a senior scientist and group leader at a large biotechnology company that has sales approaching $2 billion annually. A PhD microbiologist, he has more than eighteen years of experience in industrial biotechnology including yeast, E. coli, and mammalian cell culture process development and manufacturing process improvement. Among his proficiencies are troubleshooting at large scale, project management, directing research and development laboratories, Good Manufacturing Process regulations, regulatory filings for chemistry, manufacturing, and control sections at the IND and NDA (BLA) stages as well as validation and regulatory aspects involved in process change implementation. Prior to joining industry, Hamilton spent five years as a postdoctoral research fellow at the Department of Biological Chemistry at the Pennsylvania State University College of Medicine. He holds a US patent and has had a dozen articles published in key peer-reviewed journals.

Jennie Hunter-Cevera is president of the University of Maryland Biotechnology Institute, which encompasses the Center for Advanced Research in Biotechnology, the Center for Marine Biotechnology, the Center for Agricultural Biotechnology, the Institute of Human Virology, and the Medical Biotechnology Center. Hunter-Cevera received her doctoral degree in microbiology from Rutgers University, beginning her industry career at E.R. Squibb in Princeton, New Jersey, as a researcher and later moved to Cetus Corporation. In 1990, she started a consulting company specializing in biotechnology, agricultural and industrial microbiology, bioremediation, and pharmaceuticals. Hunter-Cevera then went on to direct the Department of Environmental Biology and Biochemistry for the Lawrence Berkeley National Laboratory. There, she started the Center for Environmental Biotechnology, where she remained until becoming president of the University of Maryland Biotechnology Institute in 1999. Hunter-Cevera is also a principal investigator of two cooperative programs sponsored by the Department of Energy with Ukrainian institutes to screen rare botanical and microbial extracts throughout

the former Soviet Union. She has also worked on *Bacillus anthracis* biomarkers, specifically saspB, which is now a classified assay.

Douglas Jaeger retired in 2002 from a US pharmaceutical firm with 2001 revenues in excess of $15 billion after a thirty-five year career there as an engineer, superintendent, group leader, section manager, and, from 1985 to 2002, as the manager of custom fermentation and bioprocessing. In that capacity, Jaeger oversaw project teams and fermentation projects involving a wide variety of microorganisms and processes, with efforts varying from $50,000 to multi-million dollar, multi-year manufacturing contracts. Over the years, he worked with numerous microorganisms, including recombinanat and conventional cells and non-traditional fermentation microorganisms. He directed the expansion of fermentation and strain improvement operations, including the design and construction of a state-of-the-art fermentation pilot plant with computer-controlled and monitored fermenters. Jaeger holds a BS in chemical engineering and an MS in fermentation biochemistry from the University of Wisconsin. He also holds an MBA from Loyola University, focusing on operations research. Jaeger is the president-elect of the Society for Industrial Microbiologists.

Robert Maigetter joined Immunomedics, Inc., in 2002 as vice president of operations, after eight years in the same capacity at Immune Response Corporation. Between 1975 and 1995, Maigetter held a number of research positions at Merck, becoming the senior manager of biotechnology manufacturing in 1990. Among his many achievements at Merck, he received the Merck Management Council Award for development of PNEUMOVAX®, a vaccine against multiple strains of *Streptococcus pneumoniae*. Before his tenure at Merck, he spent two years as a research microbiologist at the Illinois Institute of Technology Research Institute. Dr. Maigetter received his MS and PhD degrees in microbiology at Ohio State University and recently earned a degree in science, engineering, and business from the University of Pennsylvania. He has served on the American Society for Microbiology Biotechnology Task Force and the editorial board of the Journal of Industrial Microbiology. Dr. Maigetter is the author of some thirty-five publications and holds two patents.

George Pierce became a professor of applied and environmental microbiology at Georgia State University in 2000. Prior to his transition to academia, Pierce worked for nearly ten years at Cytec Industries, formerly American Cynamid, where his last position was manager of technology development and engineering. He has also held senior research posts with Battelle Memorial Institute and at Celgene Corp., where he was the director of research and development. His research interests include development and scale-up of microbial processes for pollution prevention, site remediation and restoration at Superfund and Resource Conservation and Recovery Act sites, scale-up and development of commercial biotechnology products, development of enzyme based and fermentation based products, and regulatory affairs and compliance in the area of environmental and industrial microbiology. A PhD in microbiology from Rensselaer Polytechnic Institute, Pierce has also been an adjunct professor at Rensselaer and at Ohio State University. He has numerous publications and patents in biotechnology and

has served in several professional organizations, including as the director of the Society for Industrial Microbiology.

James Poupard is the director of strategic microbiology in the Research and Development division of GlaxoSmithKline, where he has been employed since 1990. During his first eleven years with the company, he was the group director for clinical microbiology and antimicrobial profiling. Since 2001, he has been the head of GCS strategic microbiology. At the Medical College of Pennsylvania from 1986 to 1990, Poupard was the director of clinical microbiology and laboratory medicine/pathology. From 1974 to 1986 at Bryn Mawr Hospital, he was the director of microbiology and director of laboratory processing. For the Hospital of the University of Pennsylvania, he served as the clinical microbiology supervisor from 1968 to1974. Among his numerous faculty positions, Poupard has held professorships in microbiology, pathology, and laboratory medicine at the Medical College of Pennsylvania and Thomas Jefferson University. His research has covered a range of issues, including antimicrobial susceptibility testing. Dr. Poupard holds an MS in clinical microbiology from Thomas Jefferson University and a PhD from the University of Pennsylvania. He began his forty-plus year career in 1961 as a technologist in analytical chemistry and in virology at Wyeth Laboratories.

Eric Utt is a health and safety manager focusing on environmental health and safety at the central research laboratories of a large pharmaceutical firm with over $30 billion in 2001 revenues. In this capacity, he ensures compliance with federal, state, local, and corporate regulations pertaining to safety, health, and medical surveillance programs and systems. Previously as a biosafety officer, he developed and maintained biological safety programs for all corporate research and affiliated sites. He joined the company in 1993 as a research scientist, moving thereafter to positions as a senior research investigator and scientist. His research has explored the use of molecular and cellular biological techniques and animal infection models to study pathogenesis to identify novel vaccine candidates and has employed molecular genetic methods to identify new antibacterial drug targets. As a postdoctoral fellow in the early 1990s at the National Center for Infectious Diseases, Centers for Disease Control and Prevention, he research involved the causative agents of influenza, tuberculosis, and hantavirus. With a PhD in microbiology and molecular biology from the University of Florida and an MS in microbiology from the University of Central Florida, Dr. Utt is a patent holder who has presented and published widely on a variety of topics.

Industry Expert 1 is a senior vice president at a US biopharmaceutical company overseeing operations, product development, and manufacturing. Prior to joining this firm, this expert served as vice president of manufacturing operations and process development at a US vaccine manufacturer, where he was responsible for all phases of vaccine manufacturing, including bulk manufacturing, filling, and packaging. Previously, this individual, who holds a PhD in biology, was the senior director for biological manufacturing at a US pharmaceutical company with roughly $40 billion in annual sales. In this capacity, he was responsible for manufacturing licensed bulk biologicals, including several vaccines. Earlier, this individual served as the director of the department of gene expression sciences and as the associate

director of the biological process sciences department in one of the largest pharmaceutical companies in the world. A former president of the Society for Industrial Microbiology, this expert is also a member of other professional organizations.

Industry Expert 2 is a vice president of clinical affairs at a leading US pharmaceutical company. Before joining this firm in 2000, he established US operations for a European-based biotech startup. From 1996 to 1999, this individual was vice president of clinical affairs at a mid-size biopharmaceutical firm. From 1992 to 1996, as director of clinical research, this participant was responsible for clinical trials of vaccines, focusing on children's diseases. Previously, he was a clinical investigator at the US Army Medical Research Institute of Infectious Diseases, where he also participated in inspections of former Soviet and Iraqi biological weapons facilities. With an MD from Albany Medical Center and a PhD in microbiology from Rutgers University, he has also been a private practice physician. He has published widely on vaccine issues and exotic diseases.

Industry Expert 3 is the director of antibacterial research at a major US pharmaceutical company generating over $13 billion in 2001 revenues. He has a PhD in molecular genetics from Columbia University and over twenty years of experience in research and industry, having begun his career as a postdoctoral fellow at a major US research institute, where he studied plasmid replication and virulence in *Staphylococcus aureus*. After becoming an associate at this research institute, he continued his work on plasmid replication, antibiotic resistance and staphylococcal virulence through 1994. In 1987, he became a senior scientist and then a group leader at what was then an in-house biotechnology company at the research institute—working on antimicrobial peptides and bacteriocins. In 1993, he was a group leader in anti-infectives research at a pharmaceutical laboratory that his current company absorbed. In 1997, this expert became an associate director in bacterial genetics and subsequently moved to his current position. The author of over fifty papers and book chapters, this individual serves on four editorial boards, has chaired a major conference on staphylococcal diseases, and is a member of the Bacteriology and Mycology I National Institutes of Health Study Section.

About the Project

The Chemical and Biological Weapons Nonproliferation Project examines the panoply of issues associated with the reduction of the threat from chemical and biological weapons. Launched in January 1993, the project spans topics ranging from the international treaty mechanisms, namely the Chemical Weapons Convention (CWC) and the Biological and Toxin Weapons Convention (BWC), to weapons destruction technologies, unconventional terrorism, the utility of export controls, and the status of chemical and biological weapons programs in various countries. The project serves as a problem-solver and an information clearinghouse in these general subject areas. Project publications include:

- *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol* (May 2001) emphasizes the need for more technical research and field trials of inspection techniques before conclusion of a BWC verification protocol. House of Cards' findings are based on a series of brainstorming sessions with 35 experts recruited from top US universities, pharmaceutical and biotechnology companies, research institutes, and defense firms, as well as veterans of inspections similar to those that might be used to monitor this treaty.

- *Ataxia: Chemical and Biological Terrorism and the US Response* (October 2000) provides a comprehensive analysis of the threat of unconventional terrorism in the United States, federal programs to prepare "first responders" for terrorist attacks using chemical and biological weapons, and local perspectives on responding to large-scale chemical incidents or disease outbreaks.

- *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes* (December 1999) investigates the progress of US and western efforts to stem "brain drain" and the smuggling of weapons-usable materials from over 100 facilities scattered across several countries.

- *Rudderless: The Chemical Weapons Convention at 1 1/2* (September 1998) examines the progress that has been made thus far in reducing the chemical weapons threat, as well as the problems plaguing the full and effective implementation of the CWC.

- Other reports include: *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (January 1998); *Chemical Weapons Disarmament in Russia: Problems and Prospects* (October 1995); *The Battle to Obtain US Ratification of the Chemical Weapons Convention* (July 1997); *Separating Fact from Fiction: The Australia Group and the Chemical Weapons Convention* (March 1997); *The US Chemical Weapons Destruction Program: Views, Analysis, and Recommendations* (October 1994); *Implementing the Chemical Weapons Convention: Counsel from Industry* (January 1994). The project also issues a periodic newsletter, *The CBW Chronicle*.

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