# 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.