Chapter 5
Concluding Observations and Recommendations

After major violations of the Biological and Toxin Weapons Convention (BWC) came to light in the early 1990s,[1] the international community inaugurated Ad Hoc Group negotiations to strengthen this 1972 treaty with a compliance monitoring protocol. Given the difficulties inherent in monitoring this treaty's sweeping prohibitions on offensive germ weapons activities, the negotiators have had to fight their way forward. They have produced a labyrinthine draft BWC protocol text overflowing with technical detail. Quantity, however, does not always equate to quality.

Few outside of a relatively small community of diplomats, policy makers, and government arms control and national security analysts have waded through this tome, much less penetrated the rather closed process of Ad Hoc Group negotiations with policy or technical input. Operating on the more-heads-are-better principle, the Henry L. Stimson Center's Chemical and Biological Weapons Nonproliferation Project decided to dip into reservoirs of nongovernmental technical expertise in search of fresh thoughts and recommendations about the prospects and problems of BWC monitoring. The Stimson Center recruited technical experts from three types of facilities likely to fall under the monitoring umbrella of a BWC protocol, namely research institutes and universities, pharmaceutical and biotechnology companies, and defense contracting firms. The Stimson Center asked these groups to brainstorm the technical aspects of BWC monitoring, showering them with questions to facilitate their discussions. A fourth group was composed of inspection veterans, who imparted the lessons they learned from US BWC trial and mock inspections, visits under the 1992 trilateral agreement to confirm the closure of the former Soviet biowarfare program, and United Nations Special Commission on Iraq inspections.

This chapter presents the observations and recommendations of these four expert panels. The following section briefly captures their thoughts about such matters as BWC monitoring tools, strategies, costs, and effectiveness. On these issues, the brainstormers came out mostly in alignment with the technical substance and monitoring concepts in the draft BWC protocol. Next, the chapter reviews key points where the brainstormers disagree with some of the technical parameters that the Ad Hoc Group has proposed to govern inspections. The discussion then moves to matters where related inspection experience can offer insights about such intricate BWC monitoring issues as the protection of confidential business information and the management of inspectors' access on site. Functioning solely as an "honest broker" facilitator for these brainstorming meetings, the Stimson Center takes no credit for and does not necessarily endorse the views and conclusions that these technical experts espoused. The bottom line,

[1] At this time, long-held suspicions that the Soviet Union had a huge covert biowarfare program were publicly confirmed by high-level defectors from this effort. Also, the United Nations sent inspectors into Iraq after the Gulf War to verify the elimination of Iraqi missile and weapons of mass destruction capacities. Those inspections revealed Iraq's germ warfare program. A first-hand account of the USSR program can be found in Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999). Briefly, on the Iraqi program, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: U.N. Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997.

according to the brainstormers, is that the Ad Hoc Group negotiators have much more work ahead of them if they are to achieve a meaningful, feasible BWC monitoring protocol.

POINTS OF ALIGNMENT BETWEEN THE BRAINSTORMERS AND THE BWC PROTOCOL NEGOTIATORS

Both the industry and academic experts turned to the same monitoring tools—such as advance research on facilities to be inspected, visual observation, documentation review, interviews, and sampling and analysis—that those involved in efforts to strengthen the BWC have been contemplating since the early 1990s.[2] With regard to the use of sampling and analysis, they observed that a great deal remains up in the air regarding the procedures for this important inspection tool. Without validated sampling and analysis protocols, many pharmaceutical and biotechnology industry companies would have reason to shy away from, if not outright resist, the imposition of a BWC monitoring regime. Both industry and academic experts called for technical research in the area of sampling and analysis.

The academic and industry groups unfolded their own strategies for applying the aforementioned monitoring tools on site. Their strategies share common threads with what is known in arms control circles as "managed access" inspections, wherein inspectors and host officials work out compromises on the spot to satisfy inspection and host site needs. Both groups specified ways for the inspectors to ratchet up the intensity of monitoring activities so that the inspectors could determine a site's status. The academic group would have inspectors square ambiguities with a three-tiered inspection approach. Inspectors would curtail their activities after the first level of inspection if they did not find evidence of noncompliance, but if compliance concerns arose inspectors would proceed to the more intrusive tactics of a second tier inspection. The academic group designed a third level of inspection that could be used if necessary to pinpoint a suspected violation. In their monitoring formula, the industry experts direct inspectors to focus on any inconsistencies that did not fit with a facility's stated activities. This group recommended that the inspectors make use of monitoring tools in various combinations. For example, inspectors could cross-check stacks of documentation exhaustively against interviews and visual observations. Chapters 3 and 4 of the report relate fully the inspection strategies of these two groups.

Having created their own BWC monitoring strategies, the academic and industry experts then estimated how effectively their techniques would work in their respective settings. Academic and research institute experts assigned moderate or high effectiveness ratings to the monitoring activities in the first two levels of inspection at laboratory facilities, while predicting that a level three inspection

[2] Note that the industry group discussed the use of photography and videotapes, but the academic and research institute group did not. Chapter 2 contains an overview of international efforts to craft a monitoring regime for the BWC, including a discussion of the Ad Hoc Group of Verification Experts, which met in 1992 and 1993 to evaluate monitoring technologies and strategies.

would be highly effective.[3] A bit more circumspect, industry experts graded the effectiveness of monitoring to discern legitimacy or weapons-related work at a manufacturing facility according to the area in which the tools were applied. They handed out one low effectiveness rating, four medium ratings, five high ratings, and one very high effectiveness rating.[4]

In contrast, the members of the defense contractors group were quite dubious about the possible utility of BWC inspections at their facilities. In their discussions, the defense contractors had difficulty escaping the obvious Achilles heel of attempting to monitor this treaty: A lethal seed culture could be placed in any vat, anywhere, to kick off an offensive program. The inspectors, they said, would probably never come across that hidden collection of "nasties" at defense facilities, but those sites would nonetheless incur the burden of inspections.[5] Accordingly, the defense contractors had very meager expectations for the effectiveness of BWC inspections at defense sites awash in capacities and biological agents. "They might find a few rare smoking guns, but all of the other defense sites are going to fall in a "maybe" category."[6] In the view of another contractor, however, just being able to "determine that a facility was in the middle ground" would constitute an effective BWC inspection and therefore be something of a positive step, as long as the inspectors could rule out that a facility had crossed the line into offensive activities.[7]

Although opinion was somewhat divided among defense contractors about the desirability of instituting a BWC monitoring regime, they unanimously recognized that the activation of a BWC protocol would bring them to a crucial decision point, namely whether their companies should forsake defense contract work entirely.[8] The burdens that they predicted would result from regular BWC inspections could well jeopardize their relationships with commercial firms, making the costs of

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[3] For more detail, see tables 3.1, 3.2, and 3.3 and the discussion on pages 34, 40, and 43, respectively.

[4] Note that the industry group pegged a few ratings variably, giving low to medium effectiveness grades or other variations according to whether a sample was taken and the area in which the monitoring tools were applied. See table 4.2 and discussion on page 76.

[5] Defense Contractor 6 made the strongest statement in this regard: "They're not preventing people from doing it, they're not effectively being able to detect whether they're doing it, but they're putting legitimate companies out of business with their monitoring." Defense Contractor 6, the senior vice president and co-founder of a biotechnology research contracting company, has over fifteen years of experience in molecular genetics. In concurrence: Defense Contractor 5, director of microbiology and special government projects; and Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. Defense Contractor 5, working at a small defense contracting research company, has a PhD in microbiology. Defense Contractor 7 has a PhD in microbiology.

[6] Defense Contractor 2, principal research scientist, 28 August 2000. Defense Contractor 2, a scientist at a medical research facility, is a veterinarian and a PhD microbiologist. Defense Contractor 6 used the same phrase, "the maybe category," to describe where just most defense companies' capabilities, much less the presence of agents, would place them.

[7] Defense Contractor 1, staff scientist in biotechnology, 28 August 2000. Defense Contractor 1, a scientist at a large research contractor, has an MA in cellular and molecular biology.

[8] This group fully appreciated that countries (e.g., Iraq, the Soviet Union) had violated the BWC and that it was important to detect and halt cheating, they were just extremely skeptical that desirable monitoring and compliance outcomes were within the realm of possibility.

continuing as a defense contractor outweigh the benefits.[9] The inspection veterans group, which was similarly skeptical about the effectiveness of BWC inspections, agreed that BWC monitoring could create an atmosphere that was not conducive to legitimate defense work (e.g., development of new vaccines, testing of protective gear).[10] The costs of BWC monitoring (e.g., lost productivity) were also an issue for the academic and industry groups, which, like the defense contractors, argued that inspected sites should be reimbursed for such costs.[11]

Despite the burdens accompanying inspections, the academic, industry, and defense contractor groups saw reason for some sort of non-challenge inspection activity, not just a monitoring protocol dependent on challenge inspections alone. The tendency for those evaluating arms control verification activities is to dwell on an inspection regime's ability to nab cheaters, but from the perspective of the academic and industry experts, a major purpose of BWC monitoring should be to demonstrate that legitimate facilities are just that: lawful. Non-challenge monitoring, in their view, would establish the legitimacy of inspections and provide a baseline from which to identify cheating. Also important, non-challenge inspections would allow the inspectors to become as adept as possible with their tools and strategies, decreasing the potential for critical fumbles on challenge inspections. Of a BWC protocol built solely on challenge inspections, one defense contractor said, "That's worse, a worse connotation even if you're found innocent."[12] In other words, the brainstormers' support of non-challenge monitoring rested on the ability of such inspections to avoid erroneously tarring all university laboratories, research

[9] Some said they fully expected the losses to be greater than what they make in their defense work. Defense Contractor 3, senior technical adviser; Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 3, employed at a large, nonprofit research organization, holds a PhD in physics. Also worrying that inspections would delay contract work, possibly bringing penalties from clients: Defense Contractor 1, staff scientist in biotechnology, 28 August 2000.

[10] Inspection Veteran 8 stated that inspections could foster a backlash against biodefense work as being controversial or politically unpopular, a possibility that other veterans also thought could occur. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[11] According to one contractor, the US government should indemnify companies "for all costs of the inspection because basically companies would be sticking their necks out for their country by receiving these inspections, putting their investors' money, their time, even their careers on the line." Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, 28 August 2000. While seconding the idea of reimbursement, other members of the defense contracting group that it would not occur because the tab would be too high. Defense Contractor 1, staff scientist in biotechnology; Defense Contractor 2, principal research scientist; Defense Contractor 3, senior technical adviser; and Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. One contractor, for instance, ran up a bill of approximately $100,000 to prepare for and host a Chemical Weapons Convention inspection. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering.

[12] Defense Contractor 2, with others concurring. People are much more likely to recall the accusation than the outcome of the trial, so this group worried that even an "innocent" verdict from a challenge inspection would damage their reputation. Several defense contractors were anxious about non-challenge inspections as well, underscoring the importance of probable cause for a non-challenge inspection at one of their sites. Defense Contractor 3, senior technical adviser; Defense Contractor 5, director of microbiology and special government projects; Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company; Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000.

institutes, pharmaceutical, biotechnology, and defense contractor facilities with suspicion that they are somehow operating outside of the law when inspectors are not present.

POINTS OF DISAGREEMENT BETWEEN THE BRAINSTORMERS AND THE BWC PROTOCOL NEGOTIATORS

Of note, the academic and industry groups caveated their effectiveness assessments to their stipulations about the timeframes governing inspections and the number and caliber of the inspectors deployed. On several important inspection parameters, these experts therefore differed with what the BWC's negotiators have envisioned.[13] One area of divergence concerns the draft protocol provision that two weeks advance notice be given for one type of non-challenge visits that would last no longer than two days. Another timeframe in the draft text that drew objections was the twelve hours notice prior to the arrival of a challenge inspection team in the host country. A second major difference of opinion concerns the number of inspectors to be deployed. The draft text states that non-challenge teams will consist of no more than four members. As for the qualifications of the inspectors, the brainstormers found the draft text short on specificity.[14]

The academic experts thought that two weeks advance notice should be required for a non-challenge inspection, but the industry group took issue with such a long period of notice. While such a long advance notice appealed to them as corporate hosts of an inspection, they recommended that inspectors give a week's advance notice, thereby decreasing the time that a dirty facility would have to put its house in order. As for notice of a challenge inspection, the industry experts stated that two days advance notice was about right from the inspectors' viewpoint. The pharmaceutical and biotechnology industries would be uncomfortable with such a short lead-time but might come to accept it, they thought, if challenge inspection terms were well framed. The Food and Drug Administration conducts no-notice

[13] In the last topic broached with the academic and industry experts, Stimson facilitators solicited their views on the monitoring provisions in the draft BWC protocol by showing them tables summarizing the key features of the April 2000 rolling text. See 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*, BWC/Ad Hoc Group/51, 6 April 2000. The facets of the text that drew their attention remained substantially the same in the March 2001 draft protocol, segments of which are cited in this paragraph.

[14] One category of non-challenge visits, randomly-selected transparency visits, would proceed from two weeks advance notice, while voluntary clarification visits, another group of non-challenge visits, require only seven days notification. Both types of non-challenge visits shall not exceed two days. For provisions about advance notice and inspection team size for randomly-selected transparency visits, see United Nations, *Draft Composite Text*, Article 6(B), paragraphs 22 and 26. The guidelines for voluntary clarification visits can be found at United Nations, *Draft Composite Text*, Article 6(C), paragraphs 82 and 85. Generally speaking, the draft text stipulates that a BWC inspectorate would be staffed by "such scientific [and] technical. . . as may be required." See 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 (Future), 30 March 2001, Article 16, paragraph 41. Specifically regarding investigations, the draft notes that investigation personnel shall be recruited "on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns." United Nations, *Draft Composite Text*, Annex on Investigations (Annex B), paragraphs 1 and 2. The draft text contains no further requirements for inspector qualifications.

inspections, so the concept is not unheard of in industry. The industry experts also worried that the challenge inspection framework might be worded in such a way as to make it less effective than a routine inspection.[15] Should the guidelines for challenge inspections allow host officials to decline inspectors' requests for access and information, they believed that the endeavor would be stripped of any teeth that it otherwise might have had.

While no one envied the inspectors of the Chemical Weapons Convention (CWC) their jobs, everyone agreed that the tasks before the BWC inspectors would be more demanding. Chemical warfare agents and the ingredients that go into them are known, as are their degradation by-products. Analytical chemists and chemical engineers can go to a plant site and reliably identify these substances. Moreover, the brainstormers described the pace of technical developments in the chemical manufacturing arena as relatively static in comparison to the speed with which technical advances are transforming pharmaceutical and biotechnology research, testing, and manufacturing facilities. Not only would BWC inspectors have trouble keeping abreast of such technical advances, the range of specialties necessary to clarify what is truly going on at research and development laboratories, pilot plants, and manufacturing facilities is much wider. These sites encompass many types of technologies and products. For these reasons, the academic and industry brainstormers had very strong views about the quality and number of inspectors needed to unravel the complexities they would undoubtedly encounter in the field.

The academic and research institute experts argued that the skills and experience of the inspectors would be paramount to their ability to detect when the fine line from legitimate research to offensive bioweapons work was being crossed in a laboratory setting. As one participant stated, one in a thousand such sites inspected might be the tip of an offensive bioweapons program, "and these are the people who are going to have to be able to tell that."[16] Due to the need to avoid false accusations and also to catch BWC violators, the individuals selected for these jobs, they felt, should be true experts in their fields. The basic credentials for inspectors should be a professional degree in a pertinent field or noteworthy, extensive experience in research or as an independent investigator at a research institute. The academic brainstormers believed that a team of five to seven inspectors would be needed to inspect university and research institute facilities. The core of this team should be individuals with skills in biosafety engineering, aerobiology, molecular biology, and computers. Someone in this core group should be a

[15] In the April 2000 rolling text, the phrase that concerned the industry group was that inspection activities would proceed "with appropriate consent by the receiving State Party." Similar wording, intended to create a balance between inspection and host state rights is found in the March 2001 text in several places, for example with a requirement in paragraph 152 that inspectors show host state officials their inspection plan before beginning any investigatory activities and consider host comments on that plan. Interviews are to be conducted with the "explicit consent of" interviewees "in the presence of [host] representatives" and records are to be examined "only when required to fulfill" the inspection mandate. Similarly, the terms that frame the launch of challenge investigations at facilities would also sap such inspections of their potency because they can proceed only if approved by a simple majority of the Executive Council. See United Nations, *Draft Composite Text*, BWC/Ad Hoc Group/CRP.8 (Future), Annex B, Section C, paragraphs 152, 155, and 162; Article 9 (F)(e).

[16] Academic Expert 1, PhD in microbiology, 16 August 2000. Academic Expert 1 is a virology professor in the Department of Microbiology and Immunology of a major US university.

highly experienced inspector. Depending on the site being inspected, additional skill sets should be added. For example, someone with expertise in tuberculosis, alpha virus, or fungal research should be on any inspection team going to sites concentrating in these research areas. The need for specialized expertise on an inspection was driven home during the trial inspection that the Stimson Center conducted at a biosafety 3 level research laboratory to test the academic group's proposed monitoring tools and strategies. During this trial, which is fully described in box 3.1 at the end of chapter 3, two experienced inspectors resolved a few issues of monitoring concern but, lacking expertise in this laboratory's area of research concentration, did not pick up on the significance of clues that the laboratory's operators had planted to indicate possible foul play.[17]

Similarly, industry brainstormers believed that highly skilled, well-trained inspectors would be key if inspectors were to figure out whether an unusual strain was a "smoking gun" at a manufacturing plant collocated with interesting research and development capacities. This job, they said, was not for bean counters. When considering candidate inspectors, the BWC inspectorate should emphasize experience over education. Inspectors should have at least a bachelor's degree in a pertinent scientific area. More importantly, inspectors should have a minimum of eight to ten years experience in scale-up activities, operations management, activities along the chain from research and development to commercialization, or multi-purpose industry consulting. As a rule, the industry group agreed that all team members should receive auditing training.

According to the industry group, the teams headed for manufacturing sites should be large enough to span multiple disciplines well, not just superficially. The composition of an inspection team should be tailored to what is known in advance about a site's activities, but the team should at a minimum encompass the following areas of expertise: biochemical engineering; industrial microbiology; 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. Also, even though the industry group recommended that legal and administrative support staff remain on-call at inspectorate headquarters, someone on the team should have a working knowledge of service contracts and other routine legal matters.

Even without legal or administrative field staff, both the academic and industry experts clearly thought that non-challenge inspections required more than four inspectors. A non-challenge inspection team would expand even more if one heeded the counsel of the inspection veterans group. These experts

[17] Briefly, Lt.Col. Karen Jansen (USA, ret.) and Dr. David Franz, former commander of the US Army Medical Research Institute of Infectious Diseases, mounted a one-day inspection of the Tuberculosis Center at the Public Health Research Institute in New York City. The planted clues included media not used for tuberculosis, a suspiciously mislabeled strain in the freezer holding the culture collection and a corresponding entry in the logbook, and a blood plate in an incubator streaked with *Bacillus subtilis*, a bacteria in the same genus as *Bacillus anthracis*.

pointed out that the effectiveness of an inspection team can be punctured by the failure to include enough interpreters and translators, leaving the inspectors at the mercy of local interpreters or handicapped in front of a mound of records that they cannot read.[18] Accordingly, non-challenge inspection teams should also include a sufficient number of translators and interpreters to facilitate the inspectors' work.

The error of deploying undermanned inspection teams would be compounded, both academic and industry experts agreed, if the non-challenge inspection terms did not allow the inspectors enough time on site to determine much of anything. Again, from their vantage points, a non-routine inspection was as much about establishing compliance as it was about trying to determine noncompliance. Compliant facilities should get a clean bill of health, not have the inspectors leave a question mark hanging over their heads. The academic group believed that three days would probably be needed for large research laboratories, while for commercial sites, the industry group judged the time required for non-challenge inspections to be five days.[19] The industry group also objected to the times allotted in the draft protocol for certain non-challenge inspection activities. For example, the draft BWC protocol terms state that an introductory briefing could stretch to three hours and the site tour that followed must not exceed two hours.[20] In contrast, the industry group's monitoring strategies centered on getting the inspectors off the mark quickly and more aggressively. In their approach to non-challenge inspections, as chapter 4 describes, an interactive facility tour should begin right after perfunctory introductions and last at least a day, if not longer. In the words of one industry expert, "two hours is a high school tour," not worth anything in terms of monitoring assurance.[21] Likewise, the industry experts advocated getting down to brass tacks during a challenge inspection faster than the draft BWC protocol.[22] In a challenge inspection,

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[18] In Iraq, United Nations inspectors found translating the financial, technical, and personnel records to be an overwhelming task, requiring them to copy all documents and carry them back to headquarters for translation. Note that interpreters who are well-versed in local customs can also cue inspectors to more subtle meanings, not to mention save them from making unintentional cultural missteps. "An interpreter that can give inspectors the feeling of what people are saying, not just the words, makes a huge difference." Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant. Inspection Veteran 7, a PhD scientist, served on several United Nations Special Commission on Iraq missions, was on the host team during the mock inspection at Dugway Proving Ground, Utah, and took part in a follow-on round robin exercise.

[19] Several members of the industry group indicated that if inspectors at their site needed even more time in a regular type of inspection, their plants would probably grant permission for them to stay longer to get questions answered.

[20] *Procedural Report of the Ad Hoc Group of the States Parties* BWC/Ad Hoc Group/51, 6 April 2000, Article III(D)(II)(A), paragraphs 34 and 36. The provision for on-site briefings was bracketed, while the tour time limit was not. In the March 2001 chairman's text, the briefing and tour durations for randomly-selected transparency visits can be found at Article 6(B), paragraphs 33 and 35. United Nations, *Draft Composite Text*, BWC/Ad Hoc Group/CRP.8 (Future), 30 March 2001.

[21] Dr. George Pierce, manager of technology development and engineering, Cytec Industries, 23 August 2000. Dr. Pierce has since become professor of applied and environmental microbiology at Georgia State University where he draws not only on his academic credentials, a PhD in microbiology, but also over twenty years of experience in research and industry. See chapter 4, which describes the interactive nature of industry group's tour strategy, with inspectors working from key site diagrams and asking questions along the way. This chapter also lays out the group's strategy for sampling and analysis.

[22] As set forth in the April 2000 rolling text, facility investigations could last no longer than eighty-four consecutive hours. In a facility investigation, the rolling text envisioned sampling as a tool of last resort, introduced only when the inspection team concluded that sampling was necessary to fulfill the investigation mandate. However, the draft did allow the host to volunteer a sample at any time during the investigation in order to clear up any lingering non-compliance concerns. The

the industry group called for samples to be taken at various locations around a facility early on, stored thereafter in a lock box for possible analysis later, if needed. So, while the academic and industry brainstormers agreed with the BWC negotiators on the basic monitoring tools to be used, they differed markedly on important quantitative and qualitative aspects of the inspections.

Consequently, after reviewing summaries of the draft inspection terms in the BWC rolling text, the following exchange occurred as the industry group gave their overall assessment:

> Dr. Amy E. Smithson:[23] "So, how did the negotiators do? Would you like to give them a grade, professors?"
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> Dr. Allen Laskin:[24] "That's about a 'D.'"
>
> Smithson: "Why a 'D'?"
>
> Dr. Robert Hamilton:[25] "Well, they did have an outline. I guess that's something."
>
> Smithson: "Would anybody go higher or lower than a 'D'?"
>
> Dr. George Pierce:[26] "I think a 'D' is a good grade because that's really about the worst grade you can get. Sometimes an 'F' shows a little innovation."

The industry group observed that the private sector would not want to participate in an empty exercise, so putting together inspection terms that would actually provide ways to differentiate between the good guys and the bad guys would be a pre-requisite for industry's willing cooperation with BWC monitoring. In their view, such inspection terms were possible, but significant revisions of some of the draft protocol's technical nuts and bolts were in order: Even the best inspection tools in the world will be of marginal utility if the inspectors are not true experts in their fields and are not given sufficient time to do their jobs.

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investigation sampling provisions went on to state that whenever possible, samples were to be analyzed on-site. If on-site analysis were impossible, the rolling text permitted samples to be analyzed at certified off-site laboratories, with duplicate samples staying in the host's possession. *Procedural Report of the Ad Hoc Group of the States*, BWC/Ad Hoc Group/51, 6 April 2000, Article III(G), paragraphs 50–61. The April 2000 provisions are largely unchanged in the March 2001 draft composite text.

[23] Smithson, a senior associate at the Henry L. Stimson Center with a PhD in political science, facilitated this exchange, which took place during the 23 August 2000 meeting.

[24] Dr. Allen I. Laskin, president of Laskin/Lawrence Associates, has a PhD in microbiology and over thirty years of experience in industry.

[25] Dr. Robert Hamilton, senior scientist and group leader at a US biotechnology firm, holds a PhD in microbiology and cell biology and has over twenty-five years of experience in research and industry.

[26] Dr. George Pierce, former manager of technology development and engineering, Cytec Industries.

FACTORING PERTINENT INSPECTION EXPERIENCE INTO THE BWC PROTOCOL

One of the hot-button issues for the industry, academic, and defense contractor groups was the possibility that confidential business information would be lost during the course of an inspection or via the inspection report. Experience, however, does not indicate that such losses have occurred in other arms control treaty inspections. Asked point blank whether his firm had lost proprietary business data as a result of a CWC inspection, one of the defense contractors who participated in that brainstorming group stated simply, "No."[27] A similar question was posed to a staff member at the US chemical industry's main trade association, the American Chemical Council. By mid-April 2001, over twenty US chemical plants had been inspected under the CWC with US firms registering nary a complaint about loss of confidential business data.[28] Another US chemical industry representative reiterated this point by saying, "Trade secrets are staying that way, the way they should."[29] Nor were problems with loss of confidential business information arising as a result of CWC inspections elsewhere in the world. As of mid-April 2001, the Technical Secretariat, the CWC's international inspection agency, had conducted over 275 inspections at chemical industry plants worldwide. According to a senior Technical Secretariat official, none of these inspections resulted in either industry officials or host state governments lodging a complaint that inspections had compromised confidential business data.[30]

These circumstances should not be taken to mean that implementation of the CWC has been a cakewalk for the chemical industry. Problems were bound to crop up during the global inauguration of a declaration and inspection regime of the CWC's intricacy and intrusiveness.[31] For the most part, however, both industry and Technical Secretariat insiders say that CWC inspections have gone smoothly

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[27] Defense Contractor 4, 28 August 2000. Defense Contractor 4 is president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients. This individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry. More of this individual's observations about hosting a CWC inspection in 2000 can be found in chapters 3 and 4.

[28] American Chemical Council representative, interview with author, Washington, DC, 9 April 2001. Also, US government official, telephone interview with author, Washington, DC, 1 May 2001.

[29] Richard H. Burgess, who was with E.I. DuPont de Nemours & Company during the CWC's formative years, at a 26 April 2001 report release meeting in Washington, DC. Burgess addresses trade secret protection issues on page 42 in his essay, "Chemical Industry and the CWC," in *The Chemical Weapons Convention: Implementation Challenges and Solutions*, Jonathan B. Tucker, ed. (Washington, DC: Monterey Institute of International Studies, April 2001). See also, Frederick L. Webber, "A US Industry Perspective on Implementation of the Chemical Weapons Convention," *OPCW Synthesis* (November 2000): 16–19. *Synthesis* is the quarterly publication of the Organization for the Prohibition of Chemical Weapons.

[30] Senior official at the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons, telephone interview with author, 19 April 2001. Not long after the CWC's activation on 29 April 1997, the Technical Secretariat began inspecting industrial facilities that manufacture, process, or consume certain proliferation-risk chemicals in above-threshold quantities. The tally of inspections at Schedule 2, 3, and discrete organic chemical/phosphorous-sulfur-fluorine plants stood at 278 in mid-April 2001. For the CWC's provisions governing industry inspections, see the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction. More about the treaty's status can be found at: www.opcw.org.

[31] For several industry perspectives on the CWC's early years, see the November 2000 issue of *OPCW Synthesis*.

at industry sites. Roughly 20 percent of the time, according to one insider's estimate, the inspectors and host officials have used negotiations and managed access techniques to address industry concerns to demarcate inspectors' access to sensitive areas or records, resulting in all instances in resolutions acceptable to both industry hosts and inspectors.[32] The chemical industry's experience with the CWC is indicative that with the designation of appropriate precautions and concerted efforts on the part of inspectors and host officials, loss of proprietary data in a BWC monitoring context is not the unavoidable catastrophe that some have made it out to be. Certainly, that was the conclusion reached by the academic and industry brainstormers, who saw ways to use planning, training, redaction of documents, shrouding, negotiation, and other techniques to steer clear of revealing proprietary data while still allowing the inspectors to go about their tasks.

Other field inspection experience appears to bode less well for a BWC monitoring regime. According to the inspection veterans group, the degree of access granted during an inspection can be an unreliable barometer of dirtiness or legitimacy. Policy makers and negotiators, the inspection veterans argued, have all too little appreciation for how managed access works in practice. To illustrate the convoluted situations that can arise, veterans of trilateral inspections in the former Soviet Union observed that as their Russian hosts became accustomed to the inspection process, they allowed fairly comprehensive access to facilities that had been deeply involved in biological warfare research, development, testing, and production. "I saw plenty in Russia and had the pictures to prove it. You don't need to be denied access to be uncomfortable."[33] Likewise, a former United Nations Special Commission on Iraq inspector said, "I had the same reaction at Al Hakem. The Iraqis kept insisting it was a single-cell protein plant, but it obviously wasn't."[34] While the Iraqis at first gave United Nations inspectors access to the facilities at the heart of their biowarfare program, they became increasingly obstructionist as the inspectors began tightening the noose on this program.[35] Had the trilateral inspection process not been

[32] Senior official at the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons, telephone interview with author, 19 April 2001.

[33] Continued this individual, "They would take us where we wanted to go and we could figure it out, but they never admitted to anything." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico. Also having the same experience at another Russian facility, Inspection Veteran 5, participant in two US trial inspections and a mock inspection. Inspection Veteran 5, a PhD scientist, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. As chapter 2 explains, a 1992 agreement between the United States, Russia, and the United Kingdom touched off a series of inspections, later curtailed, to ascertain whether the former Soviet biowarfare program had indeed ended.

[34] Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant, 27 April 2000.

[35] "Occasionally, we had to break down a few doors, cut off locks when they lost keys. What really got sticky was when we did no-notice inspections at undeclared facilities. It got ugly at Ministry of Defense facilities. We weren't allowed into presidential palaces or military facilities." Ibid.

aborted, the inspection veterans believed that the Russians may well have embraced the on-again, off-again approach that the Iraqis took, drawing the line at access to their core military facilities.[36]

Adding complications to how inspections might unfurl at possibly noncompliant sites, veterans of mock inspections in the United States said that things can go wrong (e.g., lost keys, equipment being moved) even at sites that have a cooperative outlook and have practiced receiving inspections. Such gaffes made the operators of these facilities look like they were attempting to hinder the inspectors.[37] Moreover, denial of access to areas of concern during one of the two major US trials played into the inconsistencies that the inspectors had uncovered during review of the site's records. Unable to understand the materials flow and the purpose of the facility's large capacity, "the team could not determine with *high* confidence what was going on in the site."[38] Inspection veterans had seen both BWC violators and legitimate facilities go all over the map on access, with dirty sites opening doors and legitimate facilities closing them because of logistic clumsiness or their inability to figure out how to allow access yet protect sensitive data.

With a cynicism borne perhaps from experience, the veteran inspectors did not necessarily view managed access techniques as the answer. Policy makers, said one of the participants in the inspection veterans group, tended to portray managed access as "wonderful; it will be your salvation." However, said this individual, "I don't believe it. Because of the dual-use nature of biologicals, equipment, and facilities, any time access is denied, the suspicion alarm goes off. "[39] Another inspection veteran chimed in with: "Managed access is the fourth great lie, right after 'the check is in the mail.'"[40] By their own

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[36] "We were not in their core capabilities. We were in a Russian quark environment, in their mobilization centers, which they considered giveaways. These weren't the military facilities that they were really trying to protect." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Four facilities—Sergiyev Posad, Kirov, Yekaterinburg, and Strizhi—have been named as being the center of the former Soviet biowarfare program. To date, the Russian government has not permitted outsiders into these sites, although via the International Science and Technology Center, Initiatives for Proliferation Prevention, and the Civilian Research and Development Foundation collaborative grant programs, Western government officials and scientists have had fairly liberal access at the dozens of other facilities that were involved in the biowarfare program. For more on these collaborative grant efforts, 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). As chapter 2 explains, the trilateral inspections were abandoned in 1994.

[37] Inspection Veteran 2, trilateral and mock inspection participant; and Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[38] Emphasis added. The host facility cited proprietary data and the inspectors' lack of proper vaccinations as reasons for refusing access to requested areas. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Confirming this account: Inspection Veteran 5, participant in two US trial inspections and a mock inspection.

[39] Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000.

[40] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Similarly, Inspection Veteran 3 described managed access as automatically "setting up a confrontation. Something is not going to be shown, which defeats the purpose of being as

admission, the inspection veterans' scorching assessment of the potential of managed access to resolve inspectors' concerns was influenced in no small part by the trilateral experience, where giving the Russians unfettered access at US sites made no noticeable difference in the outcome.[41] Still, other recollections that the inspection veterans offered tended to undercut their strong criticism of managed access. "In many cases," said one veteran stated, "you can readily give the explanation and provide an alternative."[42]

While the inspection veterans as a whole remained to be convinced of the technical feasibility of monitoring the BWC, this group did coalesce around a couple of conclusions concerning managed access. First, no amount of access can convince inspectors who have already made up their minds, so what managed access boils down to is how open-minded and reasonable the inspectors and hosts are. Second, managed access, no matter how skillfully wielded, may still leave some questions unanswered.

In a perfect world, all situations would be clear-cut and managed access would provide explicit answers to all questions. Those who would endeavor to monitor the BWC must contend with the real and mercurial nature of modern laboratories and pharmaceutical facilities, where virulent characteristics can be spliced into genes and, in a matter of moments, manufacturing plants can be flushed of incriminating evidence.[43] Add to that reality the dishonesty and determination typical of treaty violators and the odds against successful monitoring of the BWC get even longer. In the face of such odds, those drafting the BWC protocol would be imprudent to dismiss the insights gained from field inspection experience.

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open as possible." Inspection Veteran 3, trial inspection observer and mock inspection participant. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[41] Russian visits to US pharmaceutical and biodefense sites resulted in accusations of cheating on the BWC. According to the veterans, the Russians, having had their own offensive biowarfare program unmasked, came in determined to make mountains of molehills at US sites. "In the trilats, it wasn't possible to satisfy the Russians. The chief Russian inspector always came in with a list of questions or a piece of data—sometimes laughably old—to try to nail the site. We gave them an explanation, and it didn't matter, they said we were guilty. They said smoke bombs were bio munitions!" Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Other trilateral inspection veterans gave similar accounts.

[42] Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000. This same individual was very critical of managed access, yet gave several examples, described in box 4.1, where alternative means were found. Another veteran described how Occupational Health and Safety Administration records were shown to back up the host officials' explanation that an area was closed to inspectors because it had been contaminated with beta emitters. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000.

[43] Whereas years ago, cleaning a manufacturing facility was a labor-intensive endeavor consuming roughly a workday, experts from the industry group stated that clean-in-place technology now enables the sterilization of an entire production system with the push of a button.

FINAL THOUGHTS ABOUT THE COURSE AHEAD

Some would argue that the draft BWC protocol text is built upon just such experience. Commendably, several nations participating in the negotiations have staged BWC trial inspections.[44] The brainstormers pointed out, however, that a test is only as good as the strength of the criteria governing it. To the extent that the individuals assuming the role of inspectors in these trials already knew their way around the inspected facilities or were well-acquainted with those hosting the trials, then the results of these exercises can be questioned. In such situations, the "inspectors" have difficulty conjuring suspicions that their colleagues or a familiar facility could be misbehaving, so factors are glossed over that might cause uncertainty and friction in more authentic circumstances. However, if trials are held at sites unfamiliar to the inspectors and all of the participants are strangers with varied technical backgrounds, then the trial begins to approach the dynamics of an actual inspection. The nuances of an international inspection could be further mimicked if the trial participants were native speakers of several different languages.[45] Trials set up in this fashion force the inspectors and the hosts to contend with multiple challenges as the facility's status is being examined. Valuable lessons can be gleaned as inspectors maneuver to clarify ambiguities and host officials endeavor to protect data unrelated to treaty compliance.

To a person, all of the technical experts that participated in the brainstorming series believed that additional technical research and field trials, if well designed, would greatly serve the purposes of an eventual BWC protocol. These experts were not assured that the terms on the table as of April 2000 would work well for either inspectors or host facilities. The draft protocol appears to have bent over backward to minimize the inconvenience and intrusiveness of inspections to host facilities. While it is important to hold down the burden of inspections, skimping on inspection manpower and time on site could yield poor results that inspected facilities might find more offensive than full-blown inspections. Additional research and tests would take time to mount, and time would also be needed to refine the protocol text according to the lessons learned. Unless negotiating coups of the like rarely seen in Geneva occur, these further activities would mean that a monitoring protocol would not be completed in time for the November 2001 BWC Review Conference. Some have forecast that failure to conclude a protocol by then would jeopardize the negotiations.[46]

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[44] The United Kingdom, Canada, Spain, Germany, Switzerland, Denmark, Finland, Iceland, Norway, Sweden, Austria, and Iran held trials at a variety of sites, including pharmaceutical research and production, biodefense, and vaccine production facilities.

[45] Inspection Veteran 9 offered this critique of some of the BWC trials that have been held, as well as recommendations for more rigorous exercises. Several other veterans strongly seconded these remarks. For the difficulties that can crop up because of language barriers and varying technical backgrounds, see box 4.1.

[46] As one analyst noted, "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). Also, "Political Decisions Needed Soon on Germ-Warfare Treaty: Chairman,"

Such breathless predictions are overly pessimistic. Longtime observers of the Geneva negotiation process are accustomed to deadlines that slip. While no one aspires to duplicate the two-decades plus marathon that generated the CWC, a fully developed, technically sound product that has widespread political support is far preferable to an immature one viewed tepidly in various capitals.

Moreover, delays are not always detrimental. A delay that stimulates technical improvements in the draft protocol and augmented political support from governments and the private sector would be a delay well worthwhile. BWC monitoring procedures need to work effectively and dependably in the field. International security and the viability of an industry essential to global health will rest partly on this protocol's performance. Surely, those stakes are important enough to warrant an all-out effort to secure technically sound BWC monitoring procedures that enable inspectors to differentiate reliably between legitimate and illicit facilities and inspected sites to safeguard sensitive data unrelated to treaty compliance during that process.

Over the years, the US government has spoken perhaps loudest about the seriousness of the biological warfare threat. For instance, Secretary of State Colin Powell said while serving as the Chairman of the Joint Chiefs of Staff that "Of all the various weapons of mass destruction, biological weapons are of the greatest concern to me."[47] Therefore, the United States bears a special responsibility to see that all possible efforts are made to secure a technically sound BWC monitoring protocol. For the past several years, the US role in the BWC protocol negotiations has been anything but distinguished, not approaching the technical prowess and political determination that the United States displayed in the latter stages of the CWC's negotiations. During those talks, the US government forged a constructive partnership with the US chemical industry and held demanding field trials at a variety of locations. Along with research from other countries, the US trials provided the necessary technical input for meaningful, workable verification procedures. Through the inevitably bumpy opening years of the CWC's implementation, the technical sturdiness of the CWC's verification procedures has been demonstrated repeatedly. Common sense requires that key technical details of a BWC protocol be worked out before party plans are made for the treaty signing ceremony.

The time has come for the US government to put resources behind its rhetoric. The administration of President George W. Bush needs to do more than just carry out an interagency review of the draft BWC protocol text. What is called for is a technical research and field testing program worthy of the momentous proliferation problem that is being addressed. Nor can the US pharmaceutical and biotechnology industries continue to hide behind rhetoric. The Pharmaceutical Research and

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Associated Press, 31 March 2000.

[47] General Powell made this statement at a 15 March 1993 hearing of the Base Realignment and Closure Commission. For more on the threat of biological warfare, see US Department of Defense, *Proliferation: Threat and Response* (Washington, DC: US Government Printing Office, January 2001); and US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington, DC: Government Printing Office, August 1993).

Manufacturers of America long ago declared its willingness to "offer expert assistance to the US Government to help ensure that any Compliance Protocol to the Biological Weapons Convention is scientifically and technically sound."[48] Years later, this statement rings empty since there have been no industry field trials of prospective monitoring procedures. In this report, technical experts from the pharmaceutical and biotechnology industries charted a course for BWC monitoring that they believe could earn industry-wide support. Therefore, it is incumbent upon both US industry and the US government to mount good faith efforts to test fully the assorted permutations of BWC monitoring technologies and strategies.

After more than five years at the negotiating table, the effort to reach a BWC compliance protocol appears to be at the proverbial crossroads. Some participating governments seem poised to drive for the approval of a technically weak agreement. Others seem content to make such a superficial show of participation in the talks that the process could wander fruitlessly for years on end. Either outcome risks consigning the BWC to a house of cards existence. An impotent monitoring protocol would implode sooner or later, and absent the political will to conduct the requisite research, field trials, and tough negotiation, the BWC would remain a nice international behavioral norm, violated at will and possibly with impunity. One need only scan international newspapers and official government reports worldwide to see germ weapons repeatedly depicted as one of the most colossal threats facing mankind now and in the future. If that is indeed so, then the governments negotiating a BWC monitoring protocol surely owe their citizens better outcomes than those that destine the international community's principal mechanism for biological weapons nonproliferation and arms control for insolvency.

[48] Note also that this organization stands in opposition to "any Compliance Protocol that does not fully protect the confidential business information of its member companies." Pharmaceutical Research and Manufacturers of America, "PhRMA Position on a Compliance Protocol to the Biological Weapons Convention," 9 January 1997. Available online at http://srpub.phrma.org/phrma/01.09.97.phrma.bwc.html.

Appendix: Participant Biographies

Corrie Brown has worked at the University of Georgia College of Veterinary Medicine as professor and head of the department of veterinary pathology since 1996. She received her DVM from Ontario Veterinary College at the University of Guelph. After practicing for a short period in western New York, she did a combined residency/PhD in comparative pathology at the University of California at Davis. Board certification (ACVP) and PhD were both attained in 1986. She was an assistant professor of pathology at Louisiana State University briefly before joining the US Department of Agriculture at Plum Island, where, as head of the pathology section, she specialized in the diagnosis and pathogenesis of foreign animal diseases. Her professional interests are in infectious diseases of food-producing animals, emerging diseases, agroterror and international veterinary medicine. She has over 250 scientific publications and presentations. She currently serves as coordinator of international veterinary medicine for the College of Veterinary Medicine.

Nancy Connell earned her PhD in bacterial genetics from Harvard Medical School, where she studied gene expression during the stationary phase of growth in *Eschrichia coli*. She then held a postdoctoral position at Albert Einstein College of Medicine where she developed live recombinant vaccines. In 1992 Dr. Connell joined the Department of Microbiology and Molecular Genetics in the medical school at the University of Medicine and Dentistry of New Jersey. Using genetic and cell biological approaches, her laboratory focuses on intracellular metabolism of *Mycobacterium tuberculosis*, a bacterium that infects and replicates in macrophages. She has a joint appointment in the department of medicine and is the director of molecular mycobacteriology at the New Jersey Medical School National Tuberculosis Center. In addition to mycobacterial metabolism, her laboratory has been examining the molecular basis of resistance in multidrug-resistant clinical strains of *M. tuberculosis*. Finally, Dr. Connell has been working for many years in the area of the control of proliferation of biological weapons.

David R. Franz has been the vice president of the Chemical and Biological Defense Division of Southern Research Institute since 1998. He retired from the US Army at the rank of colonel, having served as commander of the US Army Medical Research Institute of Infectious Diseases. During over twenty years on active duty, Franz was a group veterinarian for the 10th Special Forces Group before going on to assignments at four of the Medical Research and Development Command's laboratories. Armed with a DVM from Kansas State University and a PhD in physiology from Baylor College of Medicine, Franz conducted research and published in the areas of frostbite pathogenesis, organophosphate chemical warfare agent effects on pulmonary and upper airways function, the role of cell-mediated small vessel dysfunction in cerebral malaria, and most recently, medical countermeasures to the biological toxins. Franz was the chief inspector on two United Nations Special Commission on Iraq biological warfare inspection missions to Iraq and was technical advisor on long-term monitoring. He was also a member of the first two US/British teams to visit Russia in support of the Trilateral Joint Statement on Biological Weapons.

Jerry Goldstein is a professor of microbiology and chairman of the Botany/Microbiology Department at Ohio Wesleyan University. Dr. Goldstein earned a PhD in microbiology from the University of Wisconsin-Milwaukee where he began research on the effectiveness of antiviral drugs on polio, vaccinia, herpes and adenovirus-infected cells. Currently his laboratory is involved with cloning, sequencing, and expressing a variety of bacterial protease genes in various expression vectors.

Robert Hamilton is a senior scientist and group leader at a large biotechnology company that has sales approaching $2 billion annually. A PhD microbiologist with more than seventeen 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. Hunter-Cevera received her doctoral degree in microbiology from Rutgers University in New Jersey in 1978. Dr. Hunter-Cevera began her career at E.R. Squibb in Princeton, NJ 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, which is operated by the University of California as part of the Department of Energy's national laboratory system. 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.

Karen Jansen (Lt.Col., ret.) served as a US Army Chemical Corps officer from 1978 in a variety of command and staff positions that included assignments in Germany, Saudi Arabia, and South Korea. With a background in microbiology and immunology, she made contributions to US chemical and biological weapons defenses. From 1991 to 1992, Jansen was a chemical and biological weapons inspection operations officer for the United Nations Special Commission on Iraq (1991-1992), having participated in six and led four inspection missions. She was subsequently posted as a chemical inspection team chief to the US On-Site Inspection Agency. Jansen has an MS in microbiology from North Carolina State University.

Barry Kreiswirth has more than twenty years of microbiology research experience. For nearly ten years, Kreiswirth has directed the Tuberculosis Center at the Public Health Research Institute (PHRI) in New York City. With the burgeoning tuberculosis epidemic in Russia, the program's most recent work has focused on efforts to develop demonstration tuberculosis control projects that could form a model for replication throughout Russia. Prior to his current role, Kreiswirth headed the New York City Department of Health Phage Typing and Antibiotic Susceptibility Testing Laboratory. He had previously spent four years as a research scientist and postdoctoral fellow at PHRI. A PhD in microbiology, he has had dozens of articles published in such journals as *Emerging Infectious Diseases*, *Journal of the American Medical Association*, *Clinical Microbiology*, and *Journal of Infectious Diseases*, and is a member of the American Association for the Advancement of Science, American Society for Microbiology, and the New York Academy of Sciences.

Allen I. Laskin is president of Laskin/Lawrence Associates and serves as an independent consultant in microbiology and biotechnology. For fourteen years, Laskin was assistant director of microbiology at the Squibb Institute for Medical Research. He subsequently spent fifteen years as head of biosciences research at Exxon Research and Engineering Company. Later, he was instrumental in developing the New Jersey Center for Advanced Biotechnology and Medicine and became its first associate director. He then spent three years as president of Matrix Laboratories, a small start-up biotechnology company, before starting his current consulting activities. Laskin, who holds a PhD in microbiology, has received several awards and honors. He is a fellow of the American Academy of Microbiology, the American Association for the Advancement of Sciences, the Society for Industrial Microbiology, and the New York Academy of Sciences. He has authored numerous scientific papers and US patents, is the editor or co-editor of many books and book series, and is a senior editor of the *Journal of Industrial Microbiology and Biotechnology*.

Theodore Myatt is a doctoral candidate at the Harvard School of Public Health in the where he is studying the airborne transmission of common cold pathogens and their relation to building management. Mr. Myatt earned his master's degree in environmental management from Duke University and interned at the Centers for Disease Control and Prevention in Atlanta. Subsequently, he was a biological safety officer at UCLA's Office of Environment, Health, and Safety. In addition, Mr. Myatt now serves in the Division of Epidemiology and Immunization at the Massachusetts Department of Public Health.

George Pierce became a professor of applied and environmental microbiology at Georgia State University in late 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, Pierce has also been an adjunct profession at Ohio State University and at the Rensselaer Polytechnic Institute. He has numerous publications and patents in biotechnology and has served in several professional organizations, including a stint as the director of the Society for Industrial Microbiology.

Steven J. Projan is the director of antibacterial research at Wyeth-Ayerst Research, which is the research and development division of American Home Products Corporation. He has a PhD in molecular genetics and over twenty years of experience in research and industry, having begun his career as a postdoctoral fellow at the Public Health Research Institute in New York City, where he studied plasmid replication and virulence in *Staphylococcus aureus*. After becoming an associate at the Public Health Research Institute, Projan continued his work on plasmid replication, antibiotic resistance and staphylococcal virulence though 1994. In 1987 Projan became a senior scientist and then group leader at Applied Microbiology, Inc.—then an in-house biotechnology company at the Public Health Research Institute—working on antimicrobial peptides and bacteriocins. In 1993, Projan moved to Lederle Laboratories, which Wyeth-Ayerst Research absorbed, as a group leader in anti-infectives research. Four years later, Projan became an associate director in bacterial genetics and subsequently moved to his current position. The author of over fifty papers and book chapters, Dr. Projan is a past chair of the Gordon Research Conference on Staphylococcal Diseases, a member of the Bacteriology and Mycology I National Institutes of Health Study Section, and serves on four editorial boards.

Robert Shope is a professor of pathology in the Center for Tropical Diseases at the University of Texas Medical Branch at Galveston. He graduated with a BA in zoology and went on to earn an MD from Cornell University Medical College. Before joining the University of Texas he was a professor of epidemiology and head of the Division of Infectious Disease Epidemiology at Yale University's Department of Epidemiology and Public Health. Dr. Shope's research activities are mainly in the epidemiology of arboviruses and rodent-associated viruses, anti-viral compounds, vaccines and emerging infectious diseases. His career also includes a stint as a Captain in the US Army Medical Research Corps during which he was stationed at the US Army Medical Research Institute for Infectious Diseases. Dr. Shope is a member of numerous committees and programs including the International Committee on Taxonomy of Viruses, the Defense Department's Biomedical Technology Area Review and Assessment, and the Institute of Medicine's Committee on Research and Development Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents.

Amy E. Smithson has been a senior associate at the Henry L. Stimson Center since 1990. In January 1993, she initiated the Chemical and Biological Weapons Nonproliferation Project, which conducts analytical research across the spectrum of complex topics associated with the control and elimination of chemical and biological weapons. She has published widely in journals, testified before Congress, and is

frequently consulted by the media. Before her tenure at the Stimson Center, she worked at Pacific-Sierra Research Corporation and the Center for Naval Analyses. She holds a PhD in political science from George Washington University.

Anne Vidaver is head of the Department of Plant Pathology at the University of Nebraska-Lincoln. She received her PhD in bacteriology with a minor in plant physiology from Indiana University in Bloomington. Vidaver has more than thirty-five years of teaching experience, as well as research in phytopathogenic bacteria and bacteria associated with plants. Her work has included systematics, epidemiology and control, plasmid, bacteriophage and bacteriocin characterization and genetics. She has served as an advisor or consultant to several companies and federal agencies. She has authored or co-authored over 180 scientific articles and a book. In collaboration with colleagues, she also holds two patents.

Robert Zagursky is a distinguished research scientist for research and development at Wyeth-Lederle Vaccines, a business unit of Wyeth-Ayerst Research, which is a division of American Home Products Corporation. Zagursky has eighteen years of experience in industry: seven years in research and development of bacterial vaccines at Wyeth-Lederle Vaccines; three years in research and development of eukaryotic expression and HIV research at DuPont Merck Pharmaceutical Company; and nine years in corporate research and development studying fluorescent DNA detection and PseudoRabies viral recombination at E.I. DuPont de Nemours & Co. Zagursky, who holds a PhD in biological science, also has two years postdoctoral experience in bacterial research at the US Army Medical Research Institute for Infectious Diseases. He is a recent recipient of American Home Products' Exceptional Achievement Award and Team of the Year Award, a member of the American Society for Microbiology, and a member of the editorial board for *BioTechniques*.

Academic Expert 1 is a PhD microbiologist and a virology professor in a major US university's microbiology and immunology department. This expert's research has focused on the molecular genetics of alphavirus pathogenesis, the design of molecularly cloned vaccines, and the development of alphaviruses as in vivo and in vitro expression systems. This individual is also a founding scientist of a commercial enterprise for applications of an innovative vaccine delivery technology.

Academic Expert 2 is a pathology professor at a top-ten US medical school. The director of a tissue typing laboratory, this physician's research is in the area of autoimmune endocrine disease, having helped define the basis of the autoimmune response to thyroid autoantigens. In particular, this person's recent work has focused on epitope mapping of thyroid peroxidase, a major autoantigen in autoimmune thyroid disease. His laboratory has used molecular biologic techniques to identify the specific epitopes recognized in thyroid peroxidase and shown that the recognition of this autoantigen is heterogeneous in different individuals. This expert, who has published numerous articles, has also served on the editorial boards and as a review for several professional journals.

Defense Contractor 1 is a staff scientist in the biotechnology sector of a large contract research organization that handles both governmental and private clients. This individual holds an MA in cellular and molecular biology and concentrates on method development and validation in molecular biology.

Defense Contractor 2 is a principal research scientist at a medical research facility that works primarily under government contracts and is part of a large global technology development company. A PhD microbiologist and veterinarian, this individual is an anatomic pathologist with in-depth experience in veterinary medicine and research.

Defense Contractor 3 is a senior technical adviser at a large a nonprofit organization focusing on basic and applied research, product development and policy studies in a range of fields of science. A PhD in physics, this individual has over thirty-five years of instrumentation development experience, over twenty years of direct experience working on several government and industry committees concerning weapons of mass destruction.

Defense Contractor 4 is president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients. This individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry.

Defense Contractor 5 is the director of microbiology and special government projects for a small defense contracting research firm. The recipient of a PhD in microbiology and an MS in human genetics, this individual is a board-certified medical technologist who has co-authored numerous peer-reviewed journal articles. Previously, this person served in the US Air Force as chief of molecular biology in a clinical investigation facility.

Defense Contractor 6 is senior vice president, director, and co-founder of a biotechnology research contracting firm. Previously, this individual managed a research laboratory in a cancer center in the microbiology, biology, and immunology department of a university. With over fifteen years in molecular genetics, this individual is the co-inventor of US patents and co-author of over peer-reviewed journal articles and book chapters.

Industry Expert 1 is the associate director for fermentation development at a US vaccine company that specializes in the development and manufacture of bacterial and viral vaccines and is a division of a Fortune 100 pharmaceutical firm. He holds a PhD in microbiology and has thirteen years experience in process development and scale up for the production of new and licensed vaccines for infants and adults. He also has extensive background working with biosafety level 2 and 3 microorganisms and designing facilities for large scale biosafety level 2 and 3 operation.

Industry Expert 2 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 expert, 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 drug companies globally. This expert was previously the president of the Society for Industrial Microbiology and is a member of other professional organizations.

Industry Expert 3 is a senior research scientist at a small US biotechnology company that is a subsidiary of a larger firm that specializes in the discovery, analysis, and manufacture of proteins to be used in new applications. After receiving a PhD in biochemistry, this individual began a career in industry and research that has stretched over twenty-five years. This expert has worked in several research positions at a large US chemical corporation with well over a billion dollars in annual sales where his research concentrated in the field of polymers for biomedical applications. Prior to joining industry, he held research positions in two different research institutes of the National Institutes of Health. His bibliography contains more than eighty published pieces, he holds over ten patents, and he is a member of several professional associations.

Industry Expert 4 is president and chief executive officer of a small US biotechnology company focusing on novel therapeutics for the pharmaceutical and dietary supplement industry. The firm is a wholly-owned subsidiary of a privately held international company that sells cosmetics and supplements overseas. This individual holds a PhD in microbiology.