Living Weapons

Biological Warfare and International Security

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2

Verification

Preventing the spread of biological weapons is perhaps the most difficult proliferation challenge facing the international community. This does not mean that traditional arms control and nonproliferation tools should be abandoned, but policymakers must recognize that such measures are less effective at halting the spread of biological weapons than other types of weapons. Verification, the ability to confirm whether a nation is complying with its obligations, is the foundation of effective arms control and disarmament. Fortunately, during the cold war, the most threatening military forces—strategic nuclear weapons—required large industrial facilities to develop, produce, and test them. These facilities were either visible to overhead reconnaissance systems or had distinct signatures that could be detected at long range.[1] Even chemical weapons programs require

1. On the "reconnaissance revolution," see John Lewis Gaddis, "The Long Peace: Elements of Stability in the Postwar International System," *International Security* 10, no. 4 (1986): 123–25.

industrial-scale production facilities and large stockpiles of munitions in order to pose a significant military threat.[2]

The core problem in verifying compliance with biological arms control and disarmament agreements is that the capabilities for conducting the research, development, production, and testing of biological weapons are virtually identical to those employed by defensive programs and in legitimate civilian enterprises. Biotechnology-related capabilities and activities that cannot be justified as having a civilian purpose—such as working with dangerous pathogens or experimenting with aerosols of biological agents—can be legitimate activities for a biological defense program. There are few aspects of a BW program that are unique to offensive applications and that are readily detectable by outsiders. Advanced biotechnologies may make it unnecessary to maintain large dedicated production plants, stockpiles of bulk agents, or filled munitions that would provide intelligence agencies or inspectors with a smoking gun.

The first part of this chapter provides a primer on the 1972 Biological Weapons Convention and describes the evolution of the treaty to date. The BWC prohibits the development, production, stockpiling, acquisition, and retention of biological weapons. The BWC, however, does not include any mechanism for verifying that states are complying with the treaty. As a result, the international community has been engaged in an ongoing effort since 1975 to strengthen the treaty. International negotiations to create a compliance protocol for the treaty ended in 2001 after the United States rejected the draft protocol. Since 2003 state parties to the treaty have met annually to exchange ideas and proposals on national voluntary mechanisms for strengthening the treaty.

In the second part of this chapter I argue that the multiuse nature of biotechnology, the overlap between offensive and defensive activities, the need for secrecy, and the lack of signatures for offensive BW programs makes it difficult to distinguish between offensive and defensive or civilian activities. When offensive and defensive activities cannot be differentiated, cooperation and arms control become extremely difficult. This is especially true when the military capabilities in question favor the attacker, as was shown to be the case in regard to biological warfare.[3]

In the third part of this chapter I examine the investigation of Iraq's BW program by the United Nations Special Commission from 1991 to 1998. The

2. Gordon M. Burck, "Chemical Weapons Production Technology and the Conversion of Civilian Production," *Arms Control* 11, no. 12 (1990): 122–63; and Office of Technology Assessment (OTA), *Technologies Underlying Weapons of Mass Destruction* (Washington, DC: GPO, 1993), 15–55.

3. On the influence of the offense-defense balance on the security dilemma, see Robert Jervis, "Cooperation under the Security Dilemma," *World Politics* 30, no. 2 (1978): 167–214; and Stephen Van Evera, *Causes of War: Power and the Roots of Conflict* (Ithaca: Cornell University Press, 2000), 135–37.

UNSCOM experience represents the most important effort by the international community to verify biological arms control and disarmament. UNSCOM was the most intrusive arms control regime ever devised and had access to an unprecedented range of inspection techniques and technologies. Although UNSCOM was successful in uncovering aspects of Iraq's past BW activities, a comprehensive account of Iraq's biological agent research, production, testing, and weaponization only emerged following the defection of a high-level Iraqi official in August 1995. The UNSCOM experience provides insight into how the multiple uses of biological technologies complicates verification and the extraordinary measures that were required to overcome Iraq's attempts to retain an offensive BW capability based on multiuse technologies.

The chapter concludes with an analysis of the applicability of the UNSCOM experience to strengthening the BWC. While UNSCOM amply demonstrated the utility of a number of technologies and techniques for verifying biological arms control, the conditions required for UNSCOM's success cast serious doubt on the ability of an international organization to achieve similar results in the context of a multilateral BW verification treaty.

The Biological Weapons Convention

The Biological Weapons Convention, formally known as the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, entered into force on March 26, 1975. As of July 2008, 162 nations had become parties to the treaty and another 13 had signed but not ratified it.

The BWC had its origin in an August 1968 British proposal to separate chemical and biological weapons in international disarmament negotiations and to focus international efforts on banning biological weapons.[4] Until this point, negotiators in Geneva had sought an agreement to prohibit both chemical and biological weapons. International interest in such an agreement had intensified during the mid-1960s in response to the use of tear gas, herbicides, and defoliants in Vietnam by the United States. Negotiations over the British proposal quickly bogged down due to the controversial nature of the U.S. intervention in Vietnam and attempts by Communist nations to use the forum for propaganda purposes.

4. For a summary of the negotiations leading to the BWC, see Susan Wright, "Geopolitical Origins," in *Biological Warfare and Disarmament: New Problems/New Perspectives,* ed. Susan Wright, (Lanham, MD: Rowman and Littlefield, 2002), 313–42; and Marie Isabelle Chevrier, "The Politics of Biological Disarmament," in *Deadly Cultures: Biological Weapons since 1945,* ed. Mark Wheelis, Lajos Rózsa, and Malcolm Dando, (Cambridge: Harvard University Press, 2006), 304–28.

The British reasoned that because biological weapons had not been previously used in battle, were not useful for deterrence, and had not yet spread beyond the great powers, it would be easier to negotiate a ban on them then on chemical weapons.[5] The British proposal, however, faced stiff resistance from other states that objected to the exclusion of chemical weapons and the lack of any verification provisions in the draft treaty. Two breakthroughs were required to overcome this logjam and enable the superpowers to reach an agreement on a treaty banning biological weapons.

The first breakthrough came on November 25, 1969, when President Nixon announced that the United States was terminating its offensive BW program. Nixon also announced that the United States would support the British draft convention despite the lack of verification provisions. Although verification had long been a key stumbling block for strategic arms control initiatives during the cold war, the United States was willing to accept this treaty without any verification measures for four reasons. First, the military was convinced that these weapons had little utility and therefore they were not concerned if another country was developing them. Second, the United States had already terminated its offensive BW program—and did not plan on rearming with biological weapons even if others violated the treaty. Third, it was hoped that the norm established by the treaty would deter other nations from developing biological weapons. Finally, the Soviets were opposed to on-site inspections.[6]

The second breakthrough occurred on March 30, 1971, when the Soviet Union, after having long opposed separating chemical and biological weapons in disarmament negotiations, reversed itself and submitted its own draft biological weapons treaty. At the time, the United States concluded that the Soviets were using the treaty to signal its interest in arms control and engage the Nixon administration in strategic nuclear issues.[7] After several months of negotiations, the United States and the Soviet Union jointly introduced a draft convention on biological weapons to the United Nations' Conference of the Committee on Disarmament. The BWC opened for signature on April 10, 1972, and entered into force on March 26, 1975. In recognition of the important roles they played in the negotiation of the BWC, the United States, the United Kingdom, and Russia (originally the Soviet Union) serve as the depositories for the treaty.

5. UK Foreign Office, Arms Control and Disarmament Research Unit, "Arms Control Implications of Chemical and Biological Warfare," report written by Hedley Bull, ACDRU (66) 2 (2nd Draft), 4 July 1966, FO 371/187448, National Archives, Kew, United Kingdom.

6. Tom Mangold and Jeff Goldberg, *Plague Wars: The Terrifying Reality of Biological Warfare* (New York: St. Martin's Press, 1999), 55–57, 402 n. 26; and Alan F. Neidle, "The Rise and Fall of Multilateral Arms Control: Choices for the United States," in *Arms Control: The Multilateral Alternative,* ed. Edward C. Luck, (New York: New York University Press, 1983), 13.

7. Ambassador James Leonard, cited in Mangold and Goldberg, *Plague Wars,* 59.

Key Features of the BWC

The BWC was the first international treaty to outlaw an entire class of weapons. In contrast, the recently completed Treaty on the Non-Proliferation of Nuclear Weapons (or Nuclear Non-Proliferation Treaty) allowed the five states that possessed nuclear weapons at the time the treaty was written to keep them. The preamble of the BWC highlights the importance the drafters of the treaty gave to capitalizing on the preexisting stigma against using disease as a weapon and their hope that the treaty would further reinforce this norm. The preamble states that the use of biological weapons is "repugnant to the conscience of mankind" and that the prohibition of these weapons is "for the sake of all mankind."

The heart of the treaty is Article 1, which states:

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

The language in this article walks a fine line between the aspirations of the drafters to achieve a clear and unequivocal prohibition against biological weapons and the reality of the multiuse nature of biological agents and biological research. As a result, while state parties are obligated "never in any circumstances" to develop, produce, or possess biological weapons, the borders demarcating prohibited and legitimate activities are either vague or undefined. The convention does not prohibit research on biological weapons in recognition of the great difficulty in determining whether such activities are being undertaken for permitted or prohibited purposes.[8] Furthermore, the convention does not define what activities are considered research, and therefore fall outside the scope of the treaty, and what activities constitute development, and therefore subject to the treaty's provisions. In addition, the treaty allows the development, production, and stockpiling of biological agents of appropriate "types and quantities" so long as they have "prophylactic, protective or other peaceful purposes." However, the types, quantities, and purposes that are permitted are not further defined in the treaty.[9] This ambiguous wording and lack of definition was required

8. Barend ter Haar, *The Future of Biological Weapons* (New York: Praeger, 1991), 64–65.

9. The United States has interpreted "protective, prophylactic, or other peaceful purposes" to include the prevention, diagnosis, or treatment of disease in humans, plants, and animals; the protection of humans, plants, and animals through vulnerability studies and the development of protective masks,

to allow states to continue conducting medical, scientific, public health, commercial, and defensive work with organisms that could also be used as BW agents. The multiuse dilemma resulted in a treaty that places a heavy burden on interpreting the intent of an activity to determine whether or not it is in compliance with Article I.

Although the BWC was written before the advent of the biotechnology revolution, its drafters were aware of the amazing advances that had already taken place in the life sciences and fully expected further such advances in the future. The inclusion of the phrases "other biological agents" and "whatever their origin or method of production" in Article I was intended to provide as broad as possible coverage of biological threats. The parties to the BWC have reaffirmed at each of the treaty's review conferences that Article I covers all recent developments in science and technology relevant to biological weapons.[10]

The other major obligations for state parties to the BWC are to destroy any BW agents and weapons in their possession (Article II), not to transfer biological weapons or provide assistance to others in producing biological weapons (Article III), to put in place domestic legislation implementing the treaty (Article IV), to reaffirm the Geneva Protocol banning the use of biological weapons (Article VIII), and to provide assistance to states threatened by BW (Article VI). Under Article X, states are encouraged to engage in the fullest possible exchange of biological knowledge and materials and to implement the treaty in a way that does not hamper economic development or international cooperation in the life sciences.

The BWC has two notable differences from the other international WMD nonproliferation treaties: the Nuclear Non-Proliferation Treaty, the Chemical Weapons Convention, and the Comprehensive Test Ban Treaty. First, the BWC does not contain any verification provisions. If a state suspects another state of violating the treaty, it has two options. Under Article V, it can engage in consultations and attempt to resolve compliance concerns in a cooperative manner.[11] Under Article VI, it can lodge a complaint with the United Nations Security

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filtration systems, detection, warning and identification devices, and decontamination systems; the development of means for detecting violations of the treaty; biomedical research and biological processing technology for nonweapon purposes; and activities to protect or enhance the use of agriculture and the environment. "Memorandum from Brent Scowcroft, National Security Advisor, to Heads of Executive Departments and Agencies, Subject: U.S. Compliance with the Biological Weapons Convention, December 23, 1975," *CBW Conventions Bulletin* 57 (September 2002): 2.

10. British Medical Association, *Biotechnology, Weapons, and Humanity* (Amsterdam: Harwood Academic, 1999), 37–41.

11. Article V has been invoked only once, in response to allegations by Cuba in 1997 that the United States had spread agricultural pests on the island. Raymond A. Zilinskas, "Cuban Allegations of Biological Warfare by the United States: Assessing the Evidence," *Critical Reviews in Microbiology* 25, no. 3 (1999): 173–227.

Council, which is authorized to initiate an investigation of the allegation. Due to the veto power of the five permanent members of the Security Council, this mechanism has not proven to be of any value. An alternative means of addressing compliance concerns emerged in 1982 when the UN Secretary-General gained the authority to investigate allegations of CBW use brought to its attention by member states.[12] Although this mechanism has never been used to investigate the alleged use of biological weapons, the Secretary-General dispatched several teams to investigate alleged cases of CW use during the Iran-Iraq War, as well as in Mozambique and Azerbaijan in the early 1990s.[13]

The second major difference between the BWC and these other treaties is that the BWC lacks an international organization to support its implementation. When the Nuclear Non-Proliferation Treaty was signed in 1968, the International Atomic Energy Agency (IAEA) was charged with ensuring that nonnuclear states did not divert nuclear material into a weapons program. When the CWC was signed in 1993, the Organization for the Prohibition of Chemical Weapons was created to oversee the destruction of existing chemical weapons and to monitor civilian chemical facilities to ensure that they were not utilized for military purposes. The Comprehensive Test Ban Treaty Organization was created in 1996 to oversee a global verification regime for the test ban treaty including an international monitoring system. Given the absence of an international organization to act as an advocate for the BWC or to serve as a forum for state parties to discuss the treaty's implementation and improvement, the review conferences held every five years have served as the primary venue for discussing measures to strengthen the treaty.

Evolution of the BWC

Since its entry into force in 1975, the BWC has evolved in fits and starts.[14] For the first sixteen years of the treaty, efforts to strengthen the treaty made incremental progress through the adoption of voluntary confidence-building

12. Additional General Assembly and Security Council resolutions in 1987 and 1998 empowered the Secretary-General to launch sucb investigations on its own authority.

13. These episodes demonstrated the ability of international investigations to confirm or disprove allegations of CW use, but only if they were dispatched soon after the attack allegedly took place and the host country provided its full cooperation. Jonathan B. Tucker, "Multilateral Approaches to the Investigation and Attribution of Biological Weapons Use," in *Terrorism, War, or Disease? Unraveling the Use of Biological Weapons,* ed. Anne L. Clunan, Peter R. Lavoy, and Susan B. Martin (Stanford: Stanford University Press, 2008), 269–92.

14. For detailed descriptions of the evolution of the BWC, see Nicholas A. Sims, *The Evolution of Biological Disarmament* (Oxford: Oxford University Press, 2001); and Jez Littlewood, *The Biological Weapons Convention: A Failed Revolution* (London: Ashgate, 2005).

measures (CBMs) intended to improve the transparency of civilian and defensive biological activities. Beginning in 1991, state parties began a process to devise stronger mandatory measures to further improve transparency and provide greater confidence that all state parties were in compliance with the treaty. Negotiations on a compliance protocol for the treaty came to an end in 2001 when the United States announced it would not support the draft protocol (discussed in more detail below). A new process began in 2002 that featured regular exchanges of ideas and proposals on a wide array of voluntary national measures to strengthen the BWC.

At the second review conference in 1986 and at the third review conference in 1991 states adopted a number of voluntary CBMs to increase the transparency of facilities and activities of special relevance to the treaty. In the absence of verification measures built into the BWC, state parties developed these CBMs to enhance their confidence that other parties to the treaty were in compliance. In 1986 the state parties agreed to provide information on maximum containment biological labs on their territory, unusual outbreaks of infectious diseases or illnesses due to toxins, publications on biomedical research, and efforts to promote contact between scientists conducting research related to the BWC. In 1991 the state parties adopted four new CBMs that required states to exchange information on past offensive and/or defensive biological programs, ongoing national biological defense research-and-development programs, human vaccine production facilities, and the implementation of national legislation relevant to the BWC. The lack of widespread and consistent participation in these CBMs and the uneven quality of the submitted information has been a consistent disappointment and a motivating factor in the pursuit of more robust measures to strengthen the treaty.[15]

The third review conference in 1991 also established the Ad Hoc Group of Government Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint (or Ad Hoc Group of Verification Experts—VEREX) to evaluate twenty-one possible on-site and off-site measures to strengthen the BWC. The group submitted a consensus report to the state parties in 1993 that found that a combination of both types of measures could increase transparency and enhance confidence in compliance with the treaty.[16] In 1994 a special conference of signatories to the BWC authorized the negotiation of a legally binding protocol to the BWC to enhance compliance.

15. Marie Isabelle Chevrier and Iris Hunger, "Confidence Building Measures for the BTWC: Performance and Potential," *Nonproliferation Review* 7, no. 3 (2000): 24–42.

16. Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, *Report,* BWC/CONF.III.VEREX/9 (Geneva: United Nations, 1993).

The newly created Ad Hoc Group began meeting regularly in January 1995, and in July 1997 the chairman of the group introduced a rolling text based on the negotiations to date. In January 1998, after a bruising battle over U.S. Senate ratification of the CWC, the United States announced its support for a protocol to strengthen the BWC based on declarations and on-site inspections administered by an international organization.[17]

By fall 2000, progress on the rolling text had stalled. The chairman of the talks judged that the remaining issues were too interdependent to be resolved individually and would instead require compromises across the entire body of the text. After extensive consultations with the delegations in Geneva, the chairman introduced a composite text of a draft compliance protocol in March 2001. This draft protocol was intended to forge a compromise on contentious issues that were stalling the negotiations, such as the scope of required declarations, the extent and intrusiveness of inspections, the degree of protection afforded to proprietary information, and restrictions on trade in biotechnology.

This text almost immediately encountered opposition. In May a group of developing nations from the Non-Aligned Movement rejected the chairman's text and demanded a return to negotiations.[18] The Non-Aligned Movement's opposition to the protocol revolved around the issue of export controls. The Australia Group, an informal group now consisting of forty-one Western nations (including all OECD members except Mexico, the European Commission, all EU member states, Argentina, Croatia, and Ukraine) that was created with fifteen members in 1985 to strengthen export controls on CW-related materials and equipment, had extended its mandate in 1991 to technology and materials relating to BW.[19] While these nations justified their action under terms of Article III of the BWC to prevent the proliferation of biological weapons, developing nations viewed the arrangement as discriminatory, an impediment to their economic development, and a violation of Article X. The tension between Article III and Article X created by the Australia Group's export controls had been a key issue of contention throughout the protocol negotiations.

In July 2001 the United States announced that it would not accept the draft protocol because it was not intrusive enough to detect clandestine BW activities, but it was invasive enough to compromise proprietary and classified

17. The U.S. opposed routine or random visits. White House Press Secretary, "The Biological Weapons Convention," *Fact Sheet,* January 27, 1998.

18. China, Cuba, Islamic Republic of Iran, Indonesia, Libyan Arab Jamahiriya, Pakistan, and Sri Lanka, *Joint Statement on the Process of the BTWC Ad Hoc Group Negotiations,* BWC/AD HOC GROUP/WP.451, May 4, 2001.

19. Robert J. Mathews, "The Development of the Australia Group Export Control Lists of Biological Pathogens, Toxins and Dual-Use Equipment," *CBW Conventions Bulletin* 66 (December 2004): 1–4.

information.[20] Several factors contributed to this decision. The George W. Bush administration that took office in January 2001 was opposed to multilateral treaties, which it viewed as imposing unnecessary limitations on U.S. power and autonomy. Based on this ideology, the Bush administration opposed not only the BWC protocol but also the Kyoto Protocol on greenhouse gases, the Comprehensive Test Ban Treaty, and the Anti-Ballistic Missile Treaty. Aside from these foreign policy considerations, the United States had two substantive concerns about the draft protocol that predated the George W. Bush administration. First, since the late 1990s the United States had dramatically expanded its biodefense program, including classified threat assessment programs, to counter the threat posed by states and terrorists. By 2001 the United States had the largest biodefense program in the world, and it feared that the protocol might compromise intelligence sources and methods associated with the threat assessment programs and reveal vulnerabilities in U.S. defenses against biological weapons.[21] Second, the United States was home to the largest and most dynamic pharmaceutical and biotechnology industries, including ten of the top twenty pharmaceutical companies in the world. U.S. pharmaceutical firms are the biggest spenders on R&D, and they have introduced the most new drugs, including the most popular ones.[22] The United States also leads the world, by a large margin, in the number of biotechnology firms, private biotechnology R&D expenditures, and the number of biotechnology patents filed.[23] These industries, and the government, were wary of declarations and on-site inspections that might compromise proprietary information in these increasingly global and competitive businesses. Industry executives were already wary of BW inspections due to their negative experience with Russian visits to a U.S. pharmaceutical company in the early 1990s as part of the Trilateral Agreement. As part of the Trilateral Agreement signed by the United States, the United Kingdom, and the Russian Federation in September 1992 to address U.S. and British concerns about Russia's compliance with the BWC, the parties agreed to reciprocal visits to nonmilitary biological facilities. In 1993, after Anglo-American visits to Biopreparat facilities in Russia, a Russian delegation visited a pharmaceutical production plant owned by Pfizer and Pfizer's main research center in the United States. After the visit, a Russian newspaper published allegations by an unidentified Russian government official that

20. Ambassador Donald Mahley, "Statement by the United States to the Ad Hoc Group of Biological Weapons Convention States Parties," Geneva, Switzerland, July 25, 2001, http://www.state.gov/t/ac/rls/rm/2001/5497.htm.

21. Interview with Ambassador Donald Mahley, Cambridge, Massachusetts, April 3, 2003.

22. European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry In Figures: 2002* (Brussels: EFPIA, 2002), 6, 13, 21.

23. Brigitte van Beuzekom and Anthony Arundel, *OECD Biotechnology Statistics—2006* (Paris: Organization for Economic Cooperation and Development, 2006), 14, 17, 44.

the United States was violating the BWC and implicated Pfizer in maintaining BW research and production facilities. No official from the Russian government refuted the report.[24]

At the end of the fifth review conference in December 2001, the United States surprised the other state parties by demanding an end to the Ad Hoc Group. Instead of acceding to this demand, the conference was suspended until 2002. On the resumption of the review conference in November 2002, the state parties agreed to hold a series of annual meetings leading up to the next review conference in 2006. These meetings examined new mechanisms to strengthen the treaty, such as national implementing legislation, pathogen security, investigations of BW use and disease outbreaks, disease surveillance, and codes of conduct for scientists.[25] The negotiation of a legally binding compliance protocol was effectively put into abeyance.

At the sixth review conference in 2007, a new agenda was adopted to address the following issues over the next five years: national implementation and regional cooperation on BWC implementation; biosafety and biosecurity; oversight, education, and codes of conduct; assistance with surveillance, detection, diagnosis, and containment of infectious disease; and assistance to states in case of BW use. This meeting also established the Implementation Support Unit (ISU), the treaty's first dedicated organizational capacity, to administer the CBMs, the annual meetings, and the review conferences. While the creation of a dedicated organization to assist with the implementation of the BWC was a long overdue measure, the authority and capability of the ISU are severely limited.[26]

The BWC remains the cornerstone of the BW nonproliferation regime. The treaty has been vital for reinforcing the norm against the use of disease as a weapon. The treaty's CBMs increase transparency of BW-related activities and facilities and help states demonstrate their compliance with the treaty. The perennial shortcoming of the treaty has been its lack of verification provisions. Although efforts to strengthen the treaty through a legally binding compliance protocol have halted, parties to the treaty are continuing to explore other means of reducing the threat posed by biological weapons during the ongoing intersessional meetings.

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24. Mangold and Goldberg, *Plague Wars,* 203–7; and Will D. Carpenter and Michael Moodie, "Industry and Arms Control," in *Biological Warfare: Modern Offense and Defense,* ed. Raymond Zilinskas (Boulder, CO: Lynne Reinner, 2000), 191.

25. Jonathan B. Tucker, "The BWC New Process: A Preliminary Assessment," *Nonproliferation Review* 11, no. 1 (2004): 4–8.

26. The ISU has a staff of three while the IAEA has 2,200 employees, the Organization for the Prohibition of Chemical Weapons has 500, and the Comprehensive Test Ban Treaty Organization has 260.

Obstacles to Verification of Biological Arms Control

As indicated in the introduction, the difficulty in verifying that a state is complying with its commitment to use biotechnology for peaceful purposes is due to: (1) the multiuse nature of biotechnology, (2) the overlap between offensive and defensive activities, (3) the need for secrecy to protect commercial and national security information, and (4) the lack of signatures of an offensive program. These characteristics make biological arms control and disarmament agreements dramatically harder to verify than similar arrangements regarding nuclear and chemical weapons.

The Multiuse Nature of Biotechnology

Biotechnology is multiuse in the sense that it can be applied to civilian endeavors as well as defensive and offensive military programs. Although chemical weapons technology is commonly characterized by a high degree of multiple uses, there is in fact a range of materials, equipment, production processes, and facilities that have no civilian application.[27] In contrast, many of the raw materials and equipment required for the research, development, production, and weaponization of biological weapons are used in civilian industries.[28] The multiuse nature of biology exacerbates the difficulty in determining the true purpose behind suspicious activities or facilities.

In some cases, the biological agents themselves are multiuse. Botulinum toxin, ten thousand times more lethal than the nerve gas VX, is marketed under the name Botox to treat spastic eye-muscle disorders and migraine headaches and to smooth facial wrinkles.[29] The number of multiuse agents is likely to become more pronounced as the use of toxins in medical research and therapy continues to grow.[30] Even innocuous agents with civilian applications can be used as part of an offensive BW program. The use of nonpathogenic organisms, such as *B. subtilis* and *B. thuringiensis* as simulants for the closely related *B. anthracis,* was integral to the Iraqi BW program.[31]

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27. Burck, "Chemical Weapons Production Technology," 122–63.

28. OTA, *Technologies Underlying Weapons of Mass Destruction,* 84–87.

29. Jonathan B. Tucker, "Dilemmas of a Dual-Use Technology: Toxins in Medicine and Warfare," *Politics and the Life Sciences* 13, no. 1 (1994): 52–53; and Eric A. Johnson, "Clostridial Toxins as Therapeutic Agents: Benefits of Nature's Most Toxic Proteins," *Annual Review of Microbiology* 53 (1999): 551–75.

30. Alan P. Zelicoff, "The Dual-Use Nature of Biotechnology: Some Examples from Medical Therapeutics," Director's Series on Proliferation 4 (Livermore, CA: Lawrence Livermore National Laboratory, May 1994), 82–83.

31. These simulants were used at every stage of Iraq's BW program: determining the best growth media to use, testing production equipment, scaling up production, developing spray-drying techniques,

Research conducted for scientific or commercial purposes could also potentially be used for military purposes. Many of the BW threat agents are naturally occurring diseases that are endemic in certain parts of the world and periodically cause epidemics for people and animals. Thus, the medical and public health authorities in many countries have legitimate reasons for conducting research on the virulence, pathogenicity, immune-response avoidance, and antibiotic resistance of dangerous pathogens. This research is facilitated by the sequencing of the genomes of more than one hundred microbial pathogens, including *Y. pestis* and *B. anthracis,* with the results posted on the Internet.[32] This information will allow researchers to develop better drugs and improve our understanding of the evolution of microorganisms as well as making it possible modify these pathogens to make them more efficient killers. Likewise, techniques developed for the microencapsulation of pharmaceuticals to improve drug delivery could also be applied to the development of more stable biological weapons.

The field of genetic engineering is rife with examples of multiuse research. Research on gene therapy is aimed at perfecting the art of inserting foreign genetic material into viruses and using them as vectors that can avoid the human immune system.[33] Scientific research may also devise new ways to create dangerous pathogens by accident. In 2001 Australian scientists inserted a gene for the immune regulatory protein interleukin-4 (IL-4) into mousepox, which inadvertently resulted in a virus that could kill all of the mice exposed to it, including those immunized against ordinary mousepox.[34] This experiment demonstrated a possible method for engineering a highly virulent and vaccine-resistant form of variola, the virus that causes smallpox.

The Soviet Union actively sought to apply advances in genetic engineering to the development of new biological weapons.[35] Milton Leitenberg has identified several examples of the same techniques and pathogens being utilized in civilian

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studying conditions suitable for storing organisms, assessing the viability of these organisms in an aerosol, testing munitions to determine dispersion patterns and dissemination efficiency, and training personnel. United Nations Monitoring, Verification and Inspection Commission (UNMOVIC), *Unresolved Disarmament Issues: Iraq's Proscribed Weapons Programmes* (New York: United Nations, 2003), 131–32.

32. National Research Council, *Seeking Security: Pathogens, Open Access, and Genome Databases* (Washington, DC: National Academies Press, 2004), 3.

33. Steven M. Block, "Living Nightmares: Biological Threats Enabled by Molecular Biology," in *The New Terror: Facing the Threat of Biological and Chemical Weapons,* ed. Sidney D. Drell, Abraham D. Sofaer, and George D. Wilson (Stanford, CA: Hoover Institution Press, 1999), 60–65.

34. Ronald J. Jackson, et al., "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox," *Journal of Virology* 75, no. 3 (2001): 1205–10.

35. Interview with Serguei Popov, former Soviet biological weapons scientist, Manassas, Virginia, July 25, 2002; and Ken Alibek, *Biohazard: The Chilling True Story of the Largest Covert Biological Weapons Program in the World—Told from the Inside by the Man Who Ran It,* with Stephen Handelman (New York: Random House, 1999), 231.

biomedical research, in defensive programs within the United States and United Kingdom, and in the former Soviet Union's offensive program. For example, in the 1980s the U.S. Army developed techniques to insert foreign genetic material into vaccinia, the virus used as a vaccine for smallpox, to develop new vaccines. Soviet scientists took advantage of this research and the genetic similarities between vaccinia and variola to develop an improved smallpox weapon.[36]

Biotechnology's multiuse nature is also evident in the equipment used in the production, weaponization, and dissemination of biological agents. The same fermenters, egg incubators, and tissue-cell cultures found in the pharmaceutical, dairy, and brewery industries can also produce biological warfare agents. According to a former UNSCOM inspector, all of the equipment and supplies Iraq used for research and development, testing, pilot plant trials, and production of biological weapons were dual-use.[37] After the 1991 Gulf War, Iraq was able to gain considerable experience in the production of dry bulk bacterial agents under the cover of biopesticide production at Al Hakam. The same equipment and processes could also be applied to the production of *B. anthracis* in dry powder form. The equipment required to dry and mill a pharmaceutical product for aerosol delivery does not differ greatly from equipment needed to produce an easily aerosolized BW agent. The centrifuges used in the Soviet program to purify and concentrate liquid slurries of bacteria were similar to those used to make milk and butter and were produced at a civilian dairy-equipment plant. Even the machines used by Iraq and the Soviet Union to fill munitions with biological agents were commercially available and had civilian uses. Finally, in some cases, civilian equipment can be used to disseminate biological agents. In the 1980s, Iraq modified and successfully tested domestic and imported agricultural sprayers for the dissemination of biological agents.[38]

The multiuse property of biotechnology allows a nation developing biological weapons to hide its activities in civilian institutes that appear to be, or actually are, conducting legitimate pharmaceutical or medical research. Most countries believed to have worked on or be working on biological weapons, including Iran, Iraq, the Soviet Union, and South Africa, have exploited the multiuse nature of biotechnology to conduct the research, development, and production of BW agents in ostensibly civilian facilities.[39] The Soviet Union created Biopreparat

36. Milton Leitenberg, "Distinguishing Offensive from Defensive Biological Weapons Research," *Critical Reviews in Microbiology* 29, no. 3 (2003): 232–34; and Alibek, *Biohazard,* 259–60.

37. Raymond A. Zilinskas, "Verifying Compliance to the Biological and Toxin Weapons Convention," *Critical Reviews in Microbiology* 24, no. 3 (1998): 198.

38. Alibek, *Biohazard,* 98–99; Tim Trevan, *Saddam's Secrets: The Hunt for Iraq's Hidden Weapons* (London: HarperCollins, 1999), 314; and UNMOVIC, *Unresolved Disarmament Issues,* 57–60, 132.

39. Gregory Koblentz, "Countering Dual-Use Facilities: Lessons from Iraq and Sudan," *Jane's Intelligence Review* 11, no. 3 (1999): 48–53.

as a civilian research organization in the 1970s to exploit the emerging field of molecular biology for military applications. According to Ken Alibek (formerly Kantajan Alibekov), deputy director of Biopreparat, "ostensibly operating as a civilian pharmaceutical enterprise, the agency could engage in genetic research without arousing suspicion. It could participate in international conferences, interact with the world scientific community, and obtain disease strains from foreign microbe banks—all activities which would have been impossible for a military laboratory."[40] A similar logic led South Africa to conduct its secret CBW program in front companies that concealed the role of the military, granted scientists free access to the international scientific community, and assisted with the procurement of multiuse equipment and materials from abroad.[41] The remarkable progress of Iraq's BW program before the 1991 Gulf War from research to production in only five years was due in part to its exploitation of civilian vaccine facilities for the production of BW agents.[42]

Overlap between Offensive and Defensive Activities

A second phenomenon that further undermines the ability of states to reliably distinguish between activities prohibited and permitted under the BWC is the substantial overlap between these types of activities. Although biological weapons (munitions designed to disseminate biological agents) and biological defenses (such as syringes filled with vaccine) can be readily distinguished when placed side by side, the research, development, production, and testing activities used to develop these capabilities are similar, if not identical, in many ways. The overlap between offensive and defensive activities provides states with another means of masking an offensive program and complicates efforts to assess compliance with biological arms control and disarmament agreements.

At the research-and-development stage, it is extraordinarily difficult to differentiate between research conducted solely for defensive purposes and research that is undertaken for the development of weapons. The same equipment, materials, technologies, and techniques are used for both types of research. For example, experiments to manipulate an organism's virulence are staples of both defensive and offensive programs and generate similar types of knowledge.

40. Alibek, *Biohazard,* 22.

41. Chandré Gould, and Peter Folb, "The South African Chemical and Biological Warfare Program: An Overview," *Nonproliferation Review* 7, no. 3 (Fall/Winter 2000): 14.

42. The fermenters at the civilian facilities were either transferred to the biological weapons production plant at Al Hakam or converted on-site to the production of biological warfare agents. UNMOVIC, *Compendium of Iraq's Proscribed Weapons Programmes in the Chemical, Biological and Missile Areas* (New York: United Nations, 2007), 780–85 [hereafter *Compendium*].

Defensive programs conduct such research to identify ways to decrease an organism's virulence in order to create a better vaccine, while offensive programs explore ways to heighten an organism's virulence. Russian scientists have portrayed research conducted under the former Soviet program on enhancing the virulence of *B. anthracis* and conferring multiple antibiotic resistance to *B. anthracis* as efforts to develop improved defenses against this agent.[43]

The production processes for some vaccines and BW agents are also similar. In 1990–91, when the United States sought to stockpile botulinum antitoxin, it first had to grow large quantities of the toxin, which was then treated with formalin to inactivate it while preserving its immunogenic properties. Killed vaccines go through a similar process that results in the production of large quantities of the pathogen until the organisms are chemically treated and killed.[44]

Both offensive and defensive programs also need to engage in generating and testing aerosols of infectious agents and simulants in both the laboratory and the field. Defensive programs conduct such experiments to develop animal models for studying the pathogenesis of disease, evaluating the effectiveness of vaccines and treatments, and testing detection systems and decontamination procedures. Offensive programs engage in aerosol testing to determine the effectiveness of different strains and preparations of an agent, the optimal environmental parameters for disseminating the agent, and the performance of biological munitions. Both types of programs are also interested in understanding the behavior of aerosols in order to predict the effects of a biological attack. Although the scale of testing and nature of agents employed would differ between these types of programs, such differences would not be readily apparent to outside observers.[45]

Even apparently benign defensive activities such as immunizing soldiers against anticipated biological warfare threats can have an offensive connotation. It would be reasonable to infer that an aggressor contemplating the use of a biological weapon would want to ensure that its own troops are protected in the event of blowback. During the cold war, the United States viewed Soviet chemical and biological defensive preparations as evidence of intent to initiate the use of these weapons.[46] According to press reports, the U.S. government viewed the immunization of Iraqi and North Korean soldiers against smallpox

43. A. V. Stepanov, et al., "Development of Novel Vaccines against Anthrax in Man," *Journal of Biotechnology* 44 (1996): 155–60; and A. P. Pomerantsev, et al., "Expression of Cereolysine AB Genes in *Bacillus Anthracis* Vaccine Strain Ensures Protection against Experimental Hemolytic Anthrax Infection," *Vaccine* 15, no. 17/18 (1997): 1846–50.

44. Tucker, "Dilemmas of a Dual-Use Technology," 56; and Leitenberg, "Distinguishing Offensive from Defensive Biological Weapons Research," 246.

45. Haar, *Future of Biological Weapons,* 66–67.

46. Stockholm International Peace Research Institute (SIPRI), *The Problem of Chemical and Biological Warfare,* vol. 2, *CB Weapons Today* (New York: Humanities Press, 1973), 163–64.

as evidence that these countries possessed variola virus, planned on using it as a weapon, and wanted to protect their own forces. As one anonymous Department of Defense official put it: "The vaccinations are as close to a smoking gun as you can come."[47] This inference, however, is not always warranted. After Operation Iraqi Freedom, it was determined that Iraq did not in fact possess variola virus.[48] Likewise, the vaccination of U.S. soldiers against anthrax and smallpox are not indicators of intent to use these agents as biological weapons.

Perhaps the most vexing challenge to distinguishing between offensive and defensive programs is the need for defensive programs to engage in offensive research to prepare for current threats or to anticipate new ones. This type of research goes beyond that described above in that the goal is to create a limited offensive capability in order to assess vulnerabilities and evaluate the effectiveness of current and planned defenses. As with any other form of warfare, understanding the threats posed by others is a prerequisite for developing an effective defense. In 1969, when the United States terminated its offensive BW program, it was recognized that "maintenance of a defensive RDT&E [research, development, test, and evaluation] program inherently requires some offensive RDT&E effort."[49] Although the new policy limited the United States to conducting only defensive biological research, it was recognized that "this does not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required."[50] These types of activities fall into a grey area of the BWC that does not prohibit research on biological and toxin agents. This ambiguity has been exploited by Russian and South African officials who have claimed that their past offensive activities were motivated by external threats and that their sole purpose was to assess these threats and develop countermeasures.[51]

This lack of a clear boundary between offensive and defensive programs has been a source of continuing controversy for the United States' biodefense program. In the 1980s, the U.S. Army increased its spending on defensive biological

47. William Broad and Judith Miller, "Government Report Says 3 Nations Hide Stocks of Smallpox," *New York Times,* June 13, 1999, A1.

48. Charles Duelfer, *Comprehensive Report of the Special Advisor to the DCI on Iraq's WMD,* vol. 3, *Biological Warfare* (Langley, VA: CIA, 2004), 3 [hereafter Duelfer Report].

49. Report to the National Security Council, *U.S. Policy on Chemical and Biological Warfare and Agents,* submitted by the Interdepartmental Political-Military Group in response to NSSM 59, November 10, 1969, p. 27, released under the Freedom of Information Act [hereafter FOIA].

50. National Security Council, "United States Policy on Chemical Warfare Program and Bacteriological/Biological Research Program," *National Security Decision Memorandum 35,* November 25, 1969, p. 3, FOIA.

51. "Valentin Yevstigneyev on Issues Relating to Russian Biological Weapons," *Kaderny Control Digest* 11 (Summer 1999); and Marléne Burger and Chandré Gould, *Secrets and Lies: Wouter Basson and South Africa's Chemical and Biological Warfare Programme* (Cape Town, S. A.: Zebra Press, 2002), 183.

research in response to intelligence that Soviet Union had an active BW program, including the application of genetic engineering. The military's research on genetically modified organisms and exotic diseases, as well as construction of a new aerosol test facility were subsequently criticized and restricted due to their perceived association with offensive activities.[52] After September 11, 2001, the United States established a new facility, the National Biodefense Analysis and Countermeasures Center (NBACC), to conduct research on the physical and biological properties of traditional, genetically modified, and emerging BW agents as part of a threat assessment program.[53] Critics have pointed out that the research necessary to characterize biological threats as described by NBACC scientists could cross the line into activities prohibited by the BWC. Without greater transparency into the facility, its activities, and the measures it was taking to ensure that it remained in compliance with the BWC, U.S. biodefense research might be misinterpreted as being for offensive purposes or provide justification for other states to conduct such work in the context of an offensive program.[54]

Secrecy to Protect National Security and Proprietary Information

Facilities engaged in defensive and civilian activities frequently have legitimate needs for a limited degree of secrecy to protect national security and proprietary business information. This secrecy makes it more difficult for outside observers to determine the intent behind a program or capability and can foster suspicion and mistrust. Furthermore, the safeguards for protecting sensitive information demanded by states uninterested in developing biological weapons make it easier for states pursuing these weapons to hide their illicit activities. Even advocates of strengthening the BWC acknowledge that a verification regime that is sensitive to national security and commercial concerns will likely be unable to reliably detect violations of the treaty.[55]

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52. Charles Piller and Keith R. Yamamoto, *Gene Wars: Military Control over the New Genetic Technologies* (New York: Morrow, 1988); and Susan Wright and Stuart Ketcham, "The Problem of Interpreting the U.S. Biological Defense Research Program," in *Preventing a Biological Arms Race,* ed. Susan Wright, (Cambridge: MIT Press, 1990), 169–96.

53. James B. Petro and W. Seth Carus, "Biological Threat Characterization Research: A Critical Component of National Biodefense," *Biosecurity and Bioterrorism* 3, no. 4 (2005): 295–308.

54. Milton Leitenberg, James Leonard, and Richard Spertzel, "Biodefense Crossing the Line," *Politics and the Life Sciences* 22, no. 2 (2004): 1–2; and Lois R. Ember, "Testing the Limits," *Chemical and Engineering News* 83 (August 15, 2005): 26–32.

55. Marie Isabelle Chevrier, "Verifying the Unverifiable: Lessons from the Biological Weapons Convention," *Politics and the Life Sciences* 9, no. 1 (1990): 99; Zilinskas, "Verifying Compliance," 211; and Barbara Hatch Rosenberg, "U.S. Policy and the BWC Protocol," *CBW Conventions Bulletin* 52 (June 2001): 2.

States developing defenses against biological weapons may need to keep certain aspects and characteristics of these activities secret to ensure the effectiveness of their preparations. Intelligence on foreign biological threats, specific vulnerabilities, and the range of medical countermeasures available have been cited as "obvious examples where secrecy would be advisable."[56] Making such information publicly available could enable an adversary to identify and exploit weaknesses in defensive preparations and intelligence gathering. Given the diversity of biological warfare agents, an adversary could select an agent for which it knows the target state lacks any or adequate defenses. In addition, the advent of genetic engineering makes it possible to modify pathogens to be resistant to antibiotics, circumvent vaccine-induced immunity, or evade diagnostic and detection systems.[57]

When the United States abandoned its offensive program in 1969, it committed itself to conducting its defensive program as openly as possible. Nonetheless, an interagency group determined that the performance of detection systems, threat assessments, and vulnerability studies may require classification.[58] Although this policy is not believed to have changed, the number and nature of classified biodefense programs has increased since the mid-1990s. These secret biodefense projects have included the construction of a small biological agent production facility, the production of dried *B. anthracis* spores, the testing of copies of a Soviet-designed biological bomblet, and the replication of a genetically engineered strain of *B. anthracis* developed by the Soviet Union that was able to circumvent some vaccines.[59] The United States claimed that the purpose of these research projects was defensive and legal under the BWC, but the combination of capabilities under development and the secrecy of the work raised questions at home and abroad about the commitment of the United States to enforcing the

56. Malcolm Dando, *Biological Warfare in the 21st Century: Biotechnology and the Proliferation of Biological Weapons* (London: Brassey's, 1994), 190. In addition, SIPRI has listed methods of dissemination, results of field tests, studies of tactical and strategic implications based on this information, and the nature of countermeasures that an aggressor could bypass as examples of information that should be classified under a defensive program. SIPRI, *The Problem of Chemical and Biological Warfare,* vol. 6, *Technical Aspects of Early Warning and Verification* (New York: Humanities Press, 1975), 25.

57. Department of Defense, *Biotechnology and Genetic Engineering: Implications for the Development of New Warfare Agents* (Washington, DC: DOD, 1996), 4–7; and Block, "Living Nightmares," 39–75.

58. Interdepartmental Political Military Working Group, *Annual Review of United States Chemical Warfare and Biological Research Programs as of 1 November 1970,* December 5, 1970, 23–24, FOIA.

59. Judith Miller, Stephen Engelberg, and William J. Broad, "U.S. Germ Warfare Research Pushes Treaty Limits," *New York Times,* September 4, 2001, A1; Judith Miller, Stephen Engelberg, and William Broad, *Germs: Biological Weapons and America's Secret War* (New York: Simon and Schuster, 2001), 290–98, 308–10; and Scott Shane, "Army Confirms Making Anthrax in Recent Years," *Baltimore Sun,* December 13, 2001.

BWC.[60] In contrast, some officials involved in biodefense activities believe that there is already an excessive amount of publicly available information on the U.S. biodefense program that exposes current shortfalls and gaps in defensive preparedness.[61] Indeed, the original design of NBACC called for it to be a classified facility requiring a security clearance to enter.[62]

The pharmaceutical and biotechnology industries, which have the greatest concentration of multiuse technological capabilities to research, develop, produce and test biological weapons, rely on secrecy to protect their intellectual property. This secrecy is necessary due to the long, costly, and risky process of developing new drugs, the limited duration of patent protection, and the incentives for rivals to engage in corporate espionage.

The pharmaceutical and biotechnology industries are knowledge intensive and invest heavily in research and development to generate new products.[63] The drug discovery and development process is also a risky one. The pharmaceutical industry estimates that for every 25,000 to 50,000 compounds discovered and investigated by researchers, only one will successfully make it to market and earn a positive return on its R&D costs.[64] The escalating costs of R&D, clinical trials, and regulatory review have boosted the average cost of developing a new drug to between $800 million to $1.2 billion.[65]

Firms seeking to protect their investment in a promising organism or compound must rely on secrecy and security until their discovery has been patented. Since the R&D process for a new drug can take ten to twelve years and drugs are protected by patents for seventeen years, companies typically have only five to seven years to make a profit before a drug is available for generic production.

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60. Judith Miller, "When Is a Bomb Not a Bomb? Germ Experts Confront U.S.," *New York Times,* September 5, 2001, A5; Elisa Harris, "Research Not to Be Hidden," *New York Times,* September 6, 2001; Barbara Hatch Rosenberg and Milton Leitenberg, "Who's Afraid of a Germ Warfare Treaty?" *Los Angeles Times,* September 6, 2001; and Mark Wheelis and Malcolm Dando, "Back to Bioweapons," *Bulletin of the Atomic Scientists* 59, no. 1 (2003): 40–46.

61. Robert P. Kadlec and Randall J. Larsen, "Passive Defense," in *Countering the Proliferation and Use of Weapons of Mass Destruction,* ed. Peter L. Hays, Vincent J. Jodoin, and Alan R. Van Tassel, (New York: McGraw-Hill, 1998), 232.

62. Joby Warrick, "The Secretive Fight against Bioterror," *Washington Post,* July 30, 2006, A1.

63. These industries invest a far higher percentage of their revenue in R&D than the chemical industry and even more than other high-technology industries such as aerospace. Office of Technology Policy, *U.S. Corporate R&D Investment, 1994–2000 Final Estimates* (Washington, DC: Department of Commerce, 2002), 7; and Department of Commerce, *A Survey of the Use of Biotechnology in U.S. Industry* (Washington, DC: Department of Commerce, 2003), 73, 76–77.

64. Gillian R. Woollett, "Industry's Role, Concerns, and Interests in the Negotiations of a BWC Compliance Protocol," in Marie I. Chevrier, et al., *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, 1998), 41.

65. Joseph A. DiMasi and Henry G. Gabrowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469–79.

Firms can extend the window of profitability by delaying the application for a patent and relying instead on trade secrecy to protect their discovery. Once patent protection does expire, a firm's advantage in competing against generic versions of its product may result from customized production equipment and processes that are also held as trade secrets.[66]

The 1990s saw a boom in the rise of blockbuster drugs, the sales of which are over $1 billion a year.[67] Historically, the first drug to market for a particular disease or condition has been the most profitable.[68] This first-mover advantage places enormous pressure on companies to safeguard their drug-development process and for unscrupulous rivals to seek proprietary information on promising drug candidates. As a result, the pharmaceutical industry has experienced a number of corporate espionage cases in recent years.[69] The industry estimates that corporate espionage in the mid-1990s cost firms over $3 billion in lost sales.[70]

Offensive BW Programs Lack Unique Signatures

The paucity of unique signatures associated with offensive BW programs makes them difficult to detect. Detecting facilities utilized in the production of BW agents is challenging. First, pathogen production facilities can be externally identical to a pharmaceutical facility or double as a pharmaceutical facility during peacetime. High levels of biocontainment are not necessary or sufficient for a plant to produce BW agents. Iraq produced *B. anthracis* and botulinum toxin without these precautions.[71] Meanwhile, modern pharmaceutical facilities have begun incorporating multipurpose containment features in plants to ensure quality control.[72] The physical characteristics of a facility such as heavy security, storage bunkers, and incinerator stacks may look suspicious, but they are not direct evidence of an offensive program. Second, large facilities or stockpiles of agent

66. Dane Zabriskie, "Strengthening the Biological Weapons Convention and Implications on the Pharmaceutical Industry and Biotechnology Industry," *Current Opinion in Biotechnology* 9 (1998): 313; and Al Homberg, "Industry Concerns Regarding Disclosure of Proprietary Information," Director's Series on Proliferation 4 (Livermore, CA: Lawrence Livermore National Laboratory, May 1994), 93–97.

67. Robert F. Service, "Surviving the Blockbuster Syndrome," *Science* 303 (March 19, 2004): 1796–99.

68. Homberg, "Industry Concerns," 94.

69. Sharon Mollman Elliott, "The Threat from Within: Trade Secret Theft by Employees," *Nature Biotechnology* 25, no. 3 (2007): 293–95; Douglas Pasternak, "In the DNA Vials, Secrets to Steal," *U.S. News & World Report,* May 21, 2001, 42; and Richard Behar, "Drug Spies," *Fortune,* September 6, 1999, 230–41.

70. Woollett, "Industry's Role, Concerns, and Interests," 41.

71. Raymond A. Zilinskas, "Iraq's Biological Weapons: The Past as Future?" in *Biological Weapons: Limiting the Threat,* ed. Joshua Lederberg (Cambridge: MIT Press, 1999), 138–40.

72. These systems can also be used to prevent the leakage of pathogens into the environment. Haar, *Future of Biological Weapons,* 88; and Peter Hambleton, et al., "A High Containment Polymodal Pilot-Plant Fermenter: Design Concepts," *Journal of Chemical Technology Biotechnology* 50, no. 2 (1991): 167–80.