Florida Journal of International Law

Volume 17 | Issue 1 Article 7

March 2005

Ill at Ease: The Precarious State of the Biological Weapons Convention's Proposed Enforcement Regime

Nahal Kazemi

ILL AT EASE: THE PRECARIOUS STATE OF THE BIOLOGICAL WEAPONS CONVENTION'S PROPOSED ENFORCEMENT REGIME

*Nahal Kazemi**

I. INTRODUCTION

In the current environment, the scourge of biological and chemical weapons is more prescient than ever. The anthrax attacks in 2001, following closely after the events of September 11th, as well as the fears

---

* Harvard Law School, J.D., 2004, Harvard College, A.B., 2001. All opinions stated herein are solely those of the author. The author thanks Peter Barton Hutt, David Mrazik, and Shannon Vivian for their invaluable assistance.

regarding the potential use of smallpox as a weapon, have cast in sharp relief the threat of biological toxins and the difficulty in preventing and preparing for an attack. The fruitless search for biological and chemical weapons in Iraq has also contributed to our understanding of how difficult it is to gather reliable intelligence on the development of these weapons and to locate and destroy them.

Contrary to the belief that anyone can possess and disseminate a biotoxin capable of killing thousands, biological weapons remain too difficult, expensive, and dangerous for many substate actors to produce successfully.[1] Until the emergence of the Aum Shinrikyo cult, terrorists seemed wedded to much more traditional implements of violence — guns and bombs.[2] The Aum Shinrikyo cult in Japan had at its disposal over a billion dollars, state of the art facilities, and prominent nuclear scientists and biochemists among its membership. Nonetheless, the Shinrikyo cult still failed several times in its attempt to produce and launch a biological weapons attack before its attack on the Japanese subway system in March 1995.[3]

Terrorists are still likely to get more devastating results from explosives than from germs, but while limited, the attempts to develop and deploy these weapons are very real and very frightening.[4] While substate actors still have trouble producing and using chemical and biological weapons, these unconventional weapons remain the poor nation's nuclear weapons,[5] cheaper and easier to develop than atomic weapons and justified by those who would develop them as the only way to counteract the asymmetry of power between nuclear and nonnuclear states.[6] The development and proliferation of these weapons by less powerful nations

---

1. *See, e.g.*, BRUCE HOFFMAN, INSIDE TERRORISM 121 (1998); John Lauder, Testimony to the House Permanent Select Committee on Intelligence (Mar. 3, 1999), *available at* http://www.fas.org/irp/congress/1999_hr/acda106.htm (last visited Feb. 24, 2005); Doctor Barbara Hatch Rosenberg, Remarks to the Nonproliferation Policy Education Center's Twelfth Nonproliferation Policy Reform Task Force Meeting (Aug. 10, 2000) [hereinafter Policy Reform Meeting], *available at* http://www.npec-web.org/projects/summary12.htm (last visited Feb. 24, 2005).

2. *See* HOFFMAN, *supra* note 1, at 121.

3. *See id.* at 121-27.

4. *See id.* at 198, 201-02.

5. Chemical and biological weapons are often referred to as the "poor man's nuclear weapons," but perhaps "poor nation's nuclear weapons" is a more accurate description. *See, e.g.*, Hillel W. Cohen et al., Bioterrorism Initiatives: Public Health in Reverse?, American Public Health Association, *available at* http://www.apha.org/journal/editorials/editcoh.htm (last visited July 24, 2005).

6. *See* Mohammed El Baradei, Editorial, *Preemption is not the Model*, WASH. POST, Apr. 23, 2003, at A35.

and by powerful substate actors is known in the military intelligence world as an instance of "asymmetric warfare."[7] In 1999, the Central Intelligence Agency stated that approximately a dozen nations either possessed or were pursuing biological weapons capabilities.[8]

Another dimension of bioterrorism that adds to the magnitude of the threat is the difficulty in detecting their presence. Small and easily hidden in legitimate research facilities, biological weapons are exceptionally difficult to detect. Claims made by the U.S. government to the Security Council in February 2003 regarding the Iraqi weapons program proved to be unfounded, despite repeated assertions by the Bush administration that these agents would be discovered.[9] Inspectors combed Iraq in search of biological weapons — the purported existence of which was proffered as justification for the U.S. invasion — but the head of the U.S. inspection team, David Kay, ultimately concluded that no such weapons would be found.[10] In his testimony to the Senate Armed Services Committee on January 28, 2004, Mr. Kay stated that with regard to the Iraqi weapons program, "we were all wrong."[11]

While Kay's January report, his resignation, and his testimony to the Senate Armed Services Committee were portrayed as political bombshells, they were not entirely unexpected. Kay's interim report of October 2003 suggested that Saddam Hussein's chemical and biological weapons capabilities had largely been destroyed by the 1991 Persian Gulf War, the work of U.N. inspectors, and the air strikes ordered by President Clinton in 1998.[12] The interim report does provide evidence that Hussein's regime

---

7. *See* Lauder, *supra* note 1.

8. *See id.*

9. *See, e.g.*, HANS BLIX, DISARMING IRAQ (2004); *see also* Richard W. Stevenson, *Head of Iraqi Arms Search May Be Ready to Step Down*, N.Y. TIMES, Dec. 19, 2003, EA, at 15 (citing Donald Rumsfeld's statement to reporters on Dec. 16, 2003 that a hole the size of the one Saddam Hussein was found in could hold enough biological weapons to kill tens of thousands of people and that it could be some time before the United States managed to find the hiding places of such weapons).

10. *See* Telephone Interview by Reuters with David Key (Jan. 23, 2004), *available at* http://www.peaceredding.org/Text%20of%20 Reuters%20Interview%20with%20David%20Kay.htm (last visited Feb. 24, 2005).

11. David Kay, Testimony Before the U.S. Senate Armed Services Committee (Jan. 28, 2004), *available at* http://cerdipity.no-ip.com/verbatim/archives/000286.html (last visited Feb. 24, 2005).

12. *See* David Key, Statement on the Interim Progress Report on the Activities of the Iraq Survey Group (ISG) Before the House Permanent Select Committee on Intelligence, The House Committee on Appropriations, Subcommittee on Defense, and the Senate Select Committee on Intelligence 6 (Oct. 2, 2003) [hereinafter Kay Interim Report], *available at* http://cia.gov/cia/public_affairs/speeches/2003/david_kay_10022003.html (last visited July 24, 2005).

failed to cooperate with the United Nations and failed to disclose information about long-range weapons and attempts at creating illegal weapons,[13] but no evidence could be found to suggest that these programs resulted in any weapons of note.[14] Indeed, Hussein's regime was attempting to create weapons of mass destruction (WMDs).[15] Instead of a massive chemical and biological weapons program that produced stockpiles of deadly agents, however, it appears (as other political and intelligence experts have suggested)[16] that Hussein had been effectively thwarted by U.N. inspections and by prior military action. As the U.S. government begins its inquiries into the work of the intelligence community, the question presented to us is whether continued reliance on current intelligence gathering methods and the use of force are effective methods of combating the scourge of biological and chemical weapons. Instead of force, can the law be used to control the use of biological agents and prevent the manufacturing and proliferation of biological weapons?

In May 2002, the U.S. Congress adopted the Public Health Safety and Bioterrorism Preparedness Act of 2002 (Bioterrorism Act), to improve readiness for a biological terror attack.[17] Section 201 of the Bioterrorism Act codifies and amends provisions of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996, which regulated defined biotoxins, called "select agents," by the Secretary of Health and Human

---

13. *See id.* at 1.

14. *See id.* at 6 (stating that Iraq did not have mustard gas or sarin, and that they could be developed within two to six months and two years, respectively. Incidentally, it would likely take any moderately developed country about these amounts of time to produce such weapons); *id.* at 7 (stating no steps were taken to actually produce nuclear weapons or fissile materials); *id.* at 4-5 (reference is made to *resuming* Biological Weapons programs and to furthering Biological Weapons applicable research, but no reference is made to actual biological weapons (emphasis added)).

15. *See id.*

16. Australian intelligence officer Andrew Wilkie, who resigned from his post at the Office of National Assessments over this issue, stated in March 2003: "Iraq's weapons of mass destruction program is, I believe, genuinely contained. There is no doubt they have chemical and biological weapons, but their program now is disjointed and limited. It's not a national WMD program like they used to have." Laurie Oakes, *The Insider*, THE BULLETIN, Mar. 12, 2003, *available at* http://bulletin.ninemsn.com.au/bulletin/EdDesk.nsf/All/01A33C10272BF7A2CA256CE500837A10 (last visited Feb. 24, 2005). Jane's Chemical-Biological Defense Guidebook lists Iraq's desires to retain and create CB weapons as very high, but cited the work of UNSCOM and the U.N. sanctions regime as having significantly frustrated Iraq's ability to actual pursue such weapons programs. JAVED ALI ET AL., JANE'S CHEMICAL-BIOLOGICAL DEFENSE GUIDEBOOK 281, 398-99 (1999).

17. *See, e.g.*, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. NO. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 7, 21, 29, 42 U.S.C.) [hereinafter Bioterrorism Act].

Services (Secretary).[18] Section 201 of the Bioterrorism Act gives the Secretary the regulatory power to determine which agents are a threat to public health and safety.[19] Regulation of the transfer,[20] possession and use,[21] registration and identification of agents and possessors of agents,[22] safeguard and security requirements,[23] and inspections[24] all fall within the powers and responsibilities of the Secretary.[25]

Yet while the United States has moved to strengthen domestic control and regulation of biotoxins, it has opposed similar efforts at the international level. Just months before the terror attacks in September 2001, the U.S. delegation at the Geneva negotiations to create an enforcement protocol for the Convention on the Prohibition of Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons (BWC) declared the draft enforcement protocol (Draft Protocol) useless and too weak to be effective.[26] A significant point of contention between the supporters of the Draft Protocol and the U.S. government was the question of inspections of private research facilities.[27] The Draft Protocol called for both challenge inspections (those based upon complaints or intelligence that suggest that a facility is in violation of the BWC) and non-challenge inspections (those undertaken at random without suspicion of violation) of both government and private research facilities.[28]

---

18. *Id.* § 201, 116 Stat. at 637-46.

19. *Id.* § 201, 116 Stat. at 637-38.

20. *Id.* § 201, 116 Stat. at 638.

21. *Id.*

22. Bioterrorism Act § 201, 116 Stat. at 638-39.

23. *Id.* § 201, 116 Stat. at 639-42.

24. *Id.* § 201, 116 Stat. at 642.

25. *Id.* § 201, 116 Stat. at 637-46.

26. Barbara Hatch Rosenberg, FAS Comments on U.S. Rejection of the BWC Protocol, Address Before the NGO Seminar for the Ad Hoc Group, (July 25, 2001), *available at* http://www.armscontrolcenter.org/cbw/papers/wg/wg_2001_us_rejection_bwc_protocol.pdf(last visited Feb. 24, 2005).

27. It is important to note that the United States is not the only party which is blocking progress on the adoption of an enforcement protocol. In May 2001, during the 23rd session of the Ad Hoc Group, a small group of countries (China, Cuba, Indonesia, Pakistan, Iran, Sri Lanka, and Libya) submitted a working paper in opposition to the use of the Chairman's composite draft of the protocol. This opposition likely would have proved a significant obstacle to continuing work on the protocol had attention not been diverted to the U.S. opposition to the protocol in July 2001. *See* Nicholas A. Sims, *Route-Maps to the OPBW: Using the Resumed BWC Fifth Review Conference*, 56 CBW CONVENTIONS BULL. 2, 4 (June 2002). Work on the protocol is done on a consensus basis and the U.S. opposition was enough to derail the process. As such, these nations, whose positions are at odds with the vast majority of States Parties, have been able to avoid scrutiny. *See id.*

28. *See* Procedural Report from the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological)

In this case, it was not a recalcitrant dictator fighting the imposition of intrusive and unwanted inspections, it was the U.S. pharmaceutical industry that opposed the use of inspections (except in very limited cases) to monitor compliance with the BWC. The Bioterrorism Act exempts research facilities, including those of the pharmaceutical industry, from inspections under section 201.[29] Before avoiding heavy burdens associated with inspections within domestic legislation, the pharmaceutical industry had earlier lobbied to avoid facing inspections under international control.[30] The concerns of the pharmaceutical industry were largely based on issues of protecting confidential business information (CBI) and protecting the reputations of American pharmaceutical companies.[31] On the other side of the balance were scientists and policymakers who claimed that no enforcement mechanism would have any hope of preventing the development and proliferation of biological weapons without a robust inspection process.[32]

This Article examines briefly, in Part II, the history of biological weapons control (including the unique challenges posed by biological weapons) and the move toward a Draft Protocol on enforcement and verification. In Part III, this Article then turns to the different positions taken with regard to nonproliferation and the role of the Draft Protocol, including the positions taken by the States Parties and relevant substate actors and the political and legal arguments for and against the Protocol. Part IV reviews the Chemical Weapons Convention (CWC) for comparison. It will then draw upon the comparison to the CWC and the recommendations of involved parties to suggest solutions that take into account the characteristics of biological weapons that make them profoundly different from other WMDs. Finally, in Part V, this Article shows that the concerns of the U.S. government and the pharmaceutical industry can be sufficiently mitigated though these suggested solutions and that the benefits of supporting the international enforcement of the BWC far outweigh any associated costs.

---

and Toxin Weapons and Their Destruction (Mar. 1, 2001), Annex I, 39-40, 90 [hereinafter Draft Protocol].

29. *See* Bioterrorism Act § 201, 116 Stat. at 642-32.

30. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHRMA POSITION ON A COMPLIANCE PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION (1997) [hereinafter PHRMA].

31. *Id.*

32. *See, e.g.*, FEDERATION OF AMERICAN SCIENTISTS, PROPOSALS FOR U.S. IMPLEMENTING LEGISLATION FOR THE BIOLOGICAL WEAPONS CONVENTION PROTOCOL (2000) [hereinafter FAS Implementation Proposals].

II. BACKGROUND

A. *The History of Biological Weapons and Attempts to Prohibit Them*

The first recorded intentional uses of biological agents in warfare date to 1346 and the catapulting of plague ridden corpses into the city of Kaffa in Crimea by the Tartars laying siege to the city. The plague spread throughout the population of the city, which was then surrendered. Survivors of Kaffa, carrying the bacteria, returned to Italy, where the plague quickly spread, killing 20 million people over the next four years.[33] Another early use of biological weapons occurred during the French and Indian wars (1754-63), when Colonel Henry Bouquet and Lord Jeffrey Amherst, commanding general of British forces in North America, devised a strategy of delivering smallpox infested blankets to the American Indian populations.[34]

In 1868, the Imperial Cabinet of Russia assembled an International Military Commission to establish the limits "at which the necessities of war ought to yield to the requirements of humanity."[35] The resulting Declaration of St. Petersburg proclaimed that the employment of arms which needlessly aggravated the suffering of disabled soldiers or rendered their deaths inevitable would be contrary to the laws of humanity.[36] The Declaration of St. Petersburg, however, only applied among contracting or acceding parties.[37] If a contracting party fought against a nonmember, no prohibition was assumed. Also, once a nonmember joined in the hostilities on the side of any contracting or acceding party, the Declaration would cease to be obligatory.[38] The St. Petersburg Declaration did not specifically single out biological or chemical weapons as prohibited. The first explicit reference to chemical or biological weapons in an international declaration

---

33. Adrienne Mayor, *Dirty Tricks in Ancient Warfare*, 10 Q.J. OF MIL. HIST. 1, 32 (1997).

34. *See* Letter from Colonel Henry Bouquet, to General Jeffery Amherst (July 13, 1763), *available at* http://www.nativeweb.org/ pages/legal/amherst/34_40_305_fn.jpeg (last visited Feb. 24, 2005); Letter from General Jeffery Amherst to Colonel Henry Bouquet (July 16, 1763), *available at* http://www.nativeweb.org/pages/legal/amherst/34_41_114_fn.jpeg (last visited Feb. 24, 2005).

35. 1868 ST. PETERSBURG DECLARATION, Nov. 29, 1868, pmbl., *available at* http://www.yale.edu/lawweb/avalon/lawofwar/decpeter.htm (last visited July 24, 2005).

36. *See id.*; *see also* ALEXANDER KELLE & JIRI MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, 33 (Alexander Kelle et al. eds., 2001).

37. 1868 DECLARATION OF ST. PETERSBURG, *supra* note 35.

38. *Id.*

was in the Declaration on Laws and Methods of Conducting Wars, which prohibited *inter alia* the use of poisons and poisoned weapons.[39] This declaration, signed in Brussels on August 27, 1874, never entered into force for lack of ratification.[40]

The same prohibition, however, was incorporated into the Convention on the Laws and Customs of Land Warfare, drafted and signed by the great powers of Europe (no nations outside of Europe participated in the process) in July 1899.[41] The Fourth Hague Convention on the Laws of War, which was drafted by the European powers and without the U.S. participation, also banned the use of specified types of weapons, including poisons and arms calculated to cause unnecessary suffering.[42]

During World War I, although no biological agents were used by the belligerent parties, chemical weapons were used extensively and are estimated to have resulted in over a million casualties, including 100,000 deaths.[43] The Hague Convention completely failed to prevent the use of chlorine and mustard gas by the belligerents, perhaps because the Hague Conventions only applied to conflicts in which all belligerents were parties to the Convention.[44]

In response to the horrors of chemical warfare in World War I, the great powers signed the 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases and of Bacteriological Methods of Warfare (Geneva Protocol), although again, the United States was not a party and did not become a party to the convention until 1975.[45] The Geneva Protocol addresses solely the use of chemical and biological agents in war and does not directly discuss the

---

39. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 34.

40. Howard S. Levie, *History of the Law of War on Land,* 838 INT'L REV. RED CROSS, 339–50 (2000), *available at* http://www.icrc.org/Web/eng/siteeng0.nsf/iwpList304/114E245DA2286D1BC1256B66005E8ACC (last visited Feb. 24, 2005).

41. LAWS AND CUSTOMS OF WAR ON LAND, July 29, 1899, Annex to the Convention, art. 23, *available at* http://www.yale.edu/lawweb/avalon/lawofwar/hague02.htm#art23 (last visited Feb. 24, 2005).

42. LAWS AND CUSTOMS OF WAR ON LAND, Oct. 18, 1907, Annex to the Convention, art. 23 [hereinafter HAGUE IV], *available at* http://www.yale.edu/lawweb/avalon/lawofwar/hague04.htm#art23 (last visited Feb. 24, 2005).

43. STOCKHOLM INTERNATIONAL PEACE RESEARCH INSTITUTE, The Chemical Weapons Convention Fact Sheet (Apr. 1997) [hereinafter SIPRI], *available at* http://projects.sipri.se/cbw/research/ssf-cwc-fs-eif.html (last visited Feb. 24, 2005).

44. HAGUE IV, *supra* note 42, art. 2.

45. *See* SIPRI, Contracting Parties to the Geneva Protocol, *available at* http://www.sipri.org/contents/cbwarfare/bw_research_doc/cbw_historical/cbw-hist-geneva-parties.htm.

production, stockpiling, or destruction of these agents.[46] The Geneva Protocol was the first international instrument that distinguished between chemical and biological agents, which had previously been lumped together in the category of "poisonous weapons."[47]

Despite the extensive usage of chemical weapons by all sides in World War I, these weapons were largely unused by the belligerents in battle in World War II. The Axis powers did not show such restraint against civilian populations. Chemical agents were used by the Nazis in extermination camps, most infamously, Zyklon B, the commercial name for hydrocyanic acid used in the gas chambers.[48] Japanese forces occupying China used biological agents on a limited scale in gruesome experiments.[49] Considering the fact that the U.S. deployment of atomic weapons was also against civilian targets, it was not armies, but civilians, who bore the entirety of the costs of the use of WMDs during World War II. Kelle and Matousek argue that the nonuse of chemical and biological weapons in battle in World War II was based on three factors: reciprocal warnings of in-kind retaliation by the belligerents; lack of preparation by the militaries to use such weapons; and a "general feeling of abhorrence on the part of the governments for the use of CB [chemical-biological] weapons."[50]

While the taboo against the use of chemical and biological weapons was clearly not enough to prevent the use of such agents against concentration camp prisoners, the combined threat of in-kind retaliation by opposing forces and the uncertain military value of deploying such weapons rendered chemical and biological agents a non-issue on the battlefield in World War II. In a war known for its cruelty toward civilians and soldiers alike, this battlefield chivalry and refusal to employ cruel weapons seems perversely out of place. Nonetheless, World War II

---

46. *See, e.g.*, Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571, 94 L.N.T.S. 65 [hereinafter Geneva Protocol].

47. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 34.

48. Kyle R. Jacobson, *Doing Business with the Devil: The Challenges of Prosecuting Corporate Officials Whose Business Transactions Facilitate Ware Crimes and Crimes Against Humanity*, 56 A.F. L. REV. 167, 193-95 (2005).

49. Harald Müeller, *Dealing with a Headache: Three Scenarios and Two Dilemmas*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 1.

50. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 35 (quoting ALMQVIST & WIKSELL INTERNATIONAL, THE PROBLEM OF CHEMICAL AND BIOLOGICAL WARFARE 4 (1971)).

signaled growing international consensus in humanitarian law on the prohibition of chemical and biological weapons.

The development of this sentiment was by no means completed at the end of the World War II. In looking at the evolving consensus against the use of both biological and chemical weapons, it is helpful to make the distinction between chemical and biological agents first made in the Geneva Protocol. Since World War II, chemical weapons have been used in war and otherwise. The United States employed chemical agents during the Vietnam War,[51] and chemical weapons were used extensively during the Iran-Iraq war in the 1980s.[52] Hussein's regime also used chemical weapons against domestic populations including the Kurds in northern Iraq and the Shi'a in the south.[53] The use of biological weapons, on the other hand, has generally been limited to terrorist attacks such as the anthrax and ricin mailings in the United States.[54] Differences in the potency of chemical and biological weapons, their ease of development, and their latency periods (all of which will be discussed in Part III) led the international community to regulate them differently in the post war period.[55] While the Geneva Protocol covering both chemical and biological weapons, is still in force, separate conventions on biological and chemical weapons have since been promulgated.[56]

The decision to bifurcate the debate on chemical and biological weapons and deal with each type of weapon separately was a contentious one. In 1968, the Eighteen Nation Disarmament Committee of the United Nations put the question of chemical and biological weapons on its agenda under the heading of nonnuclear measures.[57] The United Kingdom suggested that the issues presented by chemical and biological weapons could be better addressed if the two methods of warfare were dealt with separately.[58] The following year, the United Kingdom presented to the

---

51. For a discussion on the U.S. use of chemical agents in southeast Asia, see VICTOR A. UTGOFF, THE CHALLENGE OF CHEMICAL WEAPONS, 67–74, 88–90, 94–97 (St. Martin's Press ed., 1991).

52. *See id.* at 80–86.

53. *See generally* RICHARD BUTLER, SADDAM DEFIANT (2000).

54. *See* Dana A. Shea, Terrorism: Background on Chemical, Biological, and Toxin Weapons and Options for Lessening Their Impact, Congressional Research Service, Dec. 1, 2004, *available at* www.fas.org/irp/crs/rl31669.pdf.

55. UNITED NATIONS, U.N. INSTITUTE FOR DISARMAMENT RESEARCH, THE THIRD REVIEW OF THE BIOLOGICAL WEAPONS CONVENTION: ISSUES AND PROPOSALS, at 2, U.N. Doc. 91/17 (1991) [hereinafter U.N. Doc. 91/17].

56. Draft Protocol, *supra* note 28; CWC, *infra* note 109.

57. ERHARD GEISSLER, STRENGTHENING THE BIOLOGICAL WEAPONS CONVENTION 5 (Oxford Univ. Press ed., 1990).

58. U.N. Doc. 91/17, *supra* note 55.

Convention of the Committee on Disarmament (the Eighteen Nation Disarmament Committee's successor), a draft convention prohibiting biological methods of warfare. The Convention of the Committee on Disarmament also had before it a draft convention submitted previously to the General Assembly by the Soviet Union and other socialist countries on the prohibition of the development, production, and stockpiling of biological and chemical weapons.[59]

At the 1970 session of the Convention of the Committee on Disarmament, the main question for discussion was whether the two types of weapons should be dealt with separately or in conjunction. The United States supported the U.K. position on the grounds that chemical weapons had been used in modern warfare and getting states to abandon their chemical weapons programs would prove more difficult than banning biological weapons, which had largely remained unused in modern warfare.[60] As a consequence of this difference between the two types of weapons, the United States argued that the Committee of the Convention on Disarmament should turn its attention to biological weapons first so that the more complicated issues involved with chemical weapons would not hold up the prohibition on biological weapons.[61] The United States claimed no preference for banning one type of weapon before the other — it was merely the issue of ripeness that pushed the U.S. position.[62]

In 1971, the socialist states in the Convention of the Committee on Disarmament agreed to the approach put forward by the United States and the United Kingdom.[63] On August 5, 1971, the draft text of the Biological Weapons Convention (BWC) was submitted to the committee.[64] After some revisions, it was annexed to the committee's report to the General Assembly. The General Assembly commended the Convention in its Resolution 2826 (XXVI) of December 16, 1971, to which the BWC was annexed.[65]

The BWC was opened for signature in 1972 and entered into force in 1975. The BWC was not a response to any particularized threat or use of biological weapons, but was instead drafted in response to the fact that biological weapons are relatively easy and inexpensive to develop, produce, stockpile, and conceal and they have a potentially devastating

59. *See* GEISSLER, *supra* note 57, at 6.
60. *Id.*
61. *Id.*
62. *Id.*
63. *See* U.N. Doc. 91/17, *supra* note 55, at 2.
64. *See* GEISSLER, *supra* note 57, at 6.
65. G.A. Res. 2826, U.N. GAOR, 26th Sess., art. XXVI, U.N. Doc. A/2826 (1971).

impact.[66] The BWC calls upon States Parties: to refrain from developing such weapons, to destroy any dangerous biological agents that do not have peaceful purposes, and to prevent the proliferation of such agents.[67] It also requires that States Parties ban delivery systems for such agents.[68] The BWC does not explicitly prohibit the use of biological weapons. Instead it affirms the 1925 Geneva Protocol and all duties stemming from that agreement.[69] It was anticipated that Review Conferences of the States Parties would be held periodically.[70] With the exception of a handful of nations, all countries in the world are States Parties to the BWC.[71]

While the BWC calls for cooperation among its States Parties to ensure compliance, like the Geneva Protocol before it, the BWC lacked provisions for enforcement and monitoring. States Parties assumed and envisaged that complaints regarding noncompliance would be lodged with the U.N. Security Council.[72] Concerns over the inadequacy of verification measures were expressed at the First Review Conference held in March 1980 in Geneva.[73] In the unanimously adopted Final Declaration of the conference, it was agreed that the Article V provisions for consultation and cooperation were broad and flexible enough to allow States Parties to use various international procedures to effectively and adequately ensure the implementation of the BWC.[74] The Final Declaration also reiterated that States Parties could request consultations with other States Parties to ensure compliance and that States Parties could lodge complaints with the Security Council.[75] No other concrete progress was made in clarifying Article V, or in formulating more robust compliance measures.[76]

During the 1980s, changes in biotechnology meant that prior military apathy toward biological weapons as an effective tool of warfare could not

---

66. MÜELLER, *Dealing with a Headache: Three Scenarios and Two Dilemmas*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 2.

67. Convention on the Prohibition of Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons, Apr. 10, 1972, arts. I, II, III, & IV, 1015 U.N.T.S. 163 (entered into force Mar. 26, 1975) [hereinafter BWC].

68. GEISSLER, *supra* note 57, at 7.

69. *See* BWC, *supra* note 67.

70. *See* GEISSLER, *supra* note 57, at 7.

71. *See* Biological and Toxin Weapons Convention Website, *at* http://www.opbw.org.

72. *See id.*

73. Biological Weapons Convention, First Review Conference, Final Declaration, Mar. 3-21, 1980, (adopted Mar. 21, 1980),*available at* http://projects.sipri.se/cbw/docs/bw-btwc-reviewconf-1.html, BWC/CONF.I/10 (last visited July 24, 2005).

74. *Id.*

75. *Id.*

76. *See* GEISSLER, *supra* note 57, at 8.

be expected to continue into the future.[77] The key assumption that had led states to believe it would be easier to ban biological weapons first had been dramatically undercut. Biological weapons were previously considered impractical because of the danger to handling personnel.[78] They were also considered relatively difficult to manufacture.[79] These weapons are also difficult to direct in warfare and linger for considerable periods of time, putting at risk civilians and the forces deploying the weapons as well as the intended targets.[80] As a result of these problems, biological weapons had been considered too unpredictable and uncontrollable to be effective tools of warfare.[81] In 1986, however, the U.S. Department of Defense declared in its Biological Defense Program that biotechnology had made biological warfare much more feasible and effective.[82] As a result of advances in biotechnology, germs were being produced that were consistent, highly contagious, and effective in low dosages.[83]

The Second Review Conference was held in September 1986 in Geneva. Concerned about advances in biotechnology, the States Parties agreed to a series of confidence building measures (CBM) to promote openness and the exchange of information.[84] The States Parties also agreed that the BWC covered new developments and advances in biotechnology.[85] This question had arisen due to the fact that the prohibition in the BWC on weapons "whatever their origin or method of production"[86] only modifies toxins and not other biological agents according to a strict reading of the text.[87] While this interpretation of the text by the States Parties is not technically binding, it represents subsequent practice agreed to by the parties as defined by Article 31, paragraph 36 of the Vienna Convention on the Laws of Treaties.[88] Biological agents were defined authoritatively by the World Health Organization (WHO) in its 1970 report on the health

77. *Id.*

78. *See id.* at 18.

79. *Id.*

80. *See id.*

81. GEISSLER, *supra* note 57, at 18.

82. *See id.* at 8.

83. *See id.*

84. Biological Weapons Convention, Second Review Conference, Final Declaration, Sept. 8-26, 1986, (adopted Sept. 26, 1986) [hereinafter Second Review Conference], *available at* http://projects.sipri.se/cbw/docs/bw-btwc-reviewconf-2.html,BWC/CONF.II/13/II (last visited July 24, 2005).

85. *Id.*

86. *See* Second Review Conference, *supra* note 84.

87. Draft Protocol, *supra* note 28.

88. Vienna Convention on the Laws of Treaties, art. 31, ¶ 36, 115 U.N.T.S. 331 (entered into force Jan. 27, 1980).

aspects of biological and chemical weapons.[89] Biological agents are those that depend for their effects on multiplication within the target organism and are intended for use in war to cause disease or death in humans, animals, or plants.[90] Toxins are poisonous products of organisms and, unlike biological agents, are inanimate.[91]

Several of the States Parties at the Second Review Conference suggested that an amendment to the BWC, while outside the purview of the Review Conference, might be necessary to enhance compliance.[92] Others, including the United States, held that no amendment was necessary.[93] All parties agreed that the possibility of an amendment could not be considered until after the conclusion of negotiations for the CWC.[94]

Strengthening measures designed to work within the BWC's already existing framework, which were considered, fell into two categories — those concerned with implementation issues and those designed to build confidence and foster the exchange of information.[95] The Final Declaration clarified procedures for calling for consultation (but did not give a formal role to the U.N. Secretary General, despite the fact that the Secretary General is called upon to aid in the dissemination of relevant information).[96] In terms of fostering information exchanges and increasing transparency, the Final Declaration called for the exchange, among States Parties, of information on research facilities and labs that met very high international or national safety standards for handling high-risk agents or had biological programs related to the BWC.[97] The Final Declaration called for: exchange of information of all abnormal outbreaks of infectious diseases; publication of relevant research in widely-available scientific journals; and contact among scientists in the field.[98] The States Parties also agreed to have meetings of scientific and technical experts to facilitate the information exchange called for in the Final Declaration.[99] These

89. World Health Organization, Health Aspects of Chemical and Biological Weapons (1st ed. 1970), *available at* www.who.int.

90. U.N. Doc. 91/17, *supra* note 55, at 5.

91. *Id.*

92. *See* GEISSLER, *supra* note 57, at 10.

93. *See id.*

94. *See id.*

95. *See* Second Review Conference, *supra* note 84.

96. *See id.*

97. *Id.*

98. *See id.*

99. *See id.*

exchanges took place in 1987, 1988, and 1989 in the lead up to the Third Review Conference in 1991.[100]

Reviewing the history of the BWC and the various attempts to strengthen it, it becomes evident that the success of this rather toothless convention has been dubious. In 1992, President Boris Yeltsin admitted that the Soviet Union had an offensive biological weapons program despite the fact that the Soviet Union (and later its successor, the Russian Federation) had acted as an official depository state of the BWC.[101] Despite the fact that it was readily known that Saddam Hussein used unconventional weapons against domestic and foreign enemy groups, Iraq did not admit to its offensive biological weapons program until 1995, and it was not until the defection of Hussein's son-in-law, General Hussein Kamel to Jordan on August 7, 1995, that it became clear that Iraq could deliver biological agents by aerial bombs and SCUD missiles.[102]

The consultation and complaint system of enforcement is further hindered by the expectation that nations making complaints to the Security Council in accordance with Article VI include in the complaint all possible evidence confirming the validity of the complaint.[103] Few states have the means to collect such evidence against supposed violators.[104] The likely result of this system would be, at best, inaccurate and vague complaints, and at worst, politically motivated ones. This was indeed, the actual result of the system of reporting noncompliance.[105] Two of the most famous claims regarding noncompliance were brought by the United States against the Soviet Union.[106] The first dealt with claims that anthrax spores had been released from a Soviet Biological facility in the city of Sverdlovsk.[107] The second was a claim that the Soviet Union used a poisonous material known as yellow rain in military campaigns in Laos, Kampuchea, and

---

100. *See* GEISSLER, *supra* note 57, at 13.

101. GRAHAM S. PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 9, 13. The United States had made other claims about the Soviet Union employing biological and chemical weapons during the 1980s, though these claims are disputed. For a discussion of the allegations made that an illegal biological weapons facility exploded in Sverdlovsk in 1979, that the Soviets used "yellow rain" in Southeast Asia and Afghanistan, and that the Soviets were creating biological weapons through genetic engineering, see LEONARD A. COLE, *Sverdlovsk, Yellow Rain, and Novel Soviet Bioweapons: Allegations and Responses*, *in* PREVENTING A BIOLOGICAL ARMS RACE (1990).

102. *See* PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 13-14.

103. SIPRI, *supra* note 43.

104. *See* U.N. Doc. 91/17, *supra* note 55, at 9.

105. *Id.*

106. *Id.*

107. *Id.*

Afghanistan, beginning in 1978. Neither of these reports of alleged noncompliance was settled satisfactorily.[108] From the very early days of the BWC, it was clear that the enforcement provisions were flawed. Numerous attempts have been made over the years to address these flaws, but without significant success.

In contrast, the CWC is relatively new, having entered into force in 1997 complete with a Verification Annex.[109] The Verification Annex includes procedures for monitoring, site inspections, destruction of chemical weapons, a database registry for agents that can be used as precursors for the creation of chemical weapons, and a Confidentiality Annex to protect sensitive information gathered in the verification and monitoring process.[110] The CWC was promulgated largely in response to the use of chemical weapons during the Iran-Iraq war, as opposed to the vague threat of potential use of such weapons behind the BWC.[111] The Verification Annex of the CWC met with much less resistance from private industry than the Draft Protocol to the BWC. While the pharmaceutical industry was viewed as an opponent to the Draft Protocol to the BWC, the chemical industry played a constructive role in creating the CWC.[112]

Real differences between chemical and biological agents that can be used as weapons are a significant cause for this difference in approach between the pharmaceutical industry and the chemical industry regarding enforcement mechanisms. Nonetheless, dollar for dollar, biological weapons are by far the most devastating WMDs, and yet, they are the least strictly regulated under international law.[113] The weakness of international prohibitions on biological weapons has not escaped worldwide notice.

B. *The Move Toward Enforcement*

The gap between law and practice has led the experts and the states parties to the BWC themselves to consider thoroughly the subject of enforcement. From the very early history of the BWC, it was clear that the

---

108. *See id.* at 13-14.

109. *See* Convention on the Prohibition of Development, Production and Stockpiling of Chemical Weapons and Their Destruction, Jan. 13, 1993, 32 I.L.M. 800 (entered into force Apr. 29, 1997) [hereinafter CWC].

110. *See id.* Chemical Annex, Verification Annex & Confidentiality Annex.

111. Müeller, *Dealing with a Headache: Three Scenarios and Two Dilemmas*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 1.

112. RENÉ VAN SLOTEN, *Biotechnology and the Strengthening of the BTWC*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 47.

113. PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 9.

enforcement and verification mechanisms were lacking and in need of clarification and strengthening. As stated above, at the Second Review Conference in 1987, the States Parties agreed to politically binding information exchanges as CBM to ensure compliance with the BWC, including meetings of scientific experts in the years between the Second and Third Review Conferences.

This approach proved inadequate, and the States Parties began searching for legally binding measures of compliance. At the 1991 Third Review Conference, the States Parties launched VEREX, a two-year study by the verification experts of the States Parties to determine the feasibility of verification measures.[114] The verification experts' report was presented in 1994 at a special conference, which established an Ad Hoc Group to negotiate a protocol to strengthen the BWC.[115]

Negotiations on a rolling text of the Draft Protocol began in 1997 and were generally met with enthusiastic responses from States Parties. In 1997, the North Atlantic Council meeting welcomed "improving protections against biological weapons."[116] In 1998, the European Union, the G8 countries, Australia, and the Nonaligned Movement all expressed their support for the Draft Protocol and its adoption.[117] President Bill Clinton made the adoption of the Draft Protocol a policy priority that year.[118]

The members of the Ad Hoc Group negotiated individual articles one at a time, and after general agreement on the wording of an article developed, the article was incorporated into the text of the Draft Protocol. Areas of contention were divided into three categories — Category I: "Little Controversy, relatively easy to resolve;" Category II: "Medium level of disagreement;" Category III: "Strong conceptual differences in views."[119] As these issues were resolved, the Draft Protocol moved closer and closer to completion. The ad hoc group presented its Draft Protocol at a special conference in 2001. Despite strong commitment by the United

---

114. FAS Implementation Proposals, *supra* note 32.

115. *Id.*

116. Press Release, NATO, Meeting of the North Atlantic Council in Defence Ministers Session, Final Communiqué (June 12, 1997).

117. *See* PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 16.

118. *See id.* at 17.

119. Graham Pearson et al., The BTWC Protocol: Proposed Complete Text for an Integrated Regime 1-2 (Sept. 2000), *available at* http://www.brad.ac.uk/acad/sbtwc/evaulation/evalu19.pdf (last visited July 24, 2005).

States to fighting bioterrorism and preventing the proliferation of WMDs, the United States opposed the Draft Protocol.[120]

Interestingly, the United States was very supportive of the Draft Protocol during the process of its creation, and only expressed significant reservations beginning July 25, 2001, when the Draft Protocol was presented at a special conference. Given the rolling nature of the text of the Draft Protocol, information about the contents of the protocol and the debated provisions were made available as each round of negotiations by the Ad Hoc Group was completed. During the 1998 rounds of negotiations, the United States subscribed to the rolling text of the Draft Protocol presented, "including declarations, visits (non-challenge, or routine inspections), investigations (challenge inspections), and an implementing organization."[121]

There is, in fact, a noticeable divide between U.S. positions prior to 2001 and after. In his State of the Union Address of January 27, 1998, President Clinton stated:

> now we must act to prevent the use of disease as a weapon of war and terror. The Biological Weapons Convention has been in effect for twenty-nine years. The rules are good, but the enforcement is weak and we must strengthen it with a new international system to detect and deter cheating.[122]

In 1998, the United States expressed the view that declarations should cover a range of facilities and activities of potential relevance under the Convention, and in March 2000, suggested a compromise package of declaration triggers.[123] In May 1998, Clinton announced a major U.S. initiative against biological weapons:

> [w]e must strengthen the international Biological Weapons Convention with a strong system of inspections to detect and prevent cheating. This is a major priority. It was part of my State of

120. FAS Implementation Proposals, *supra* note 32.

121. Federation of American Scientists, U.S. Public Positions on the BTWC Protocol (2001) [hereinafter U.S. Public Positions], *available at* http://www.fas.org/bwc/news/USPublicPositions OnProtocol.htm (last visited Feb. 24, 2005).

122. President William Jefferson Clinton, State of the Union Address Before a Joint Session of Congress (Jan. 27, 1998).

123. U.S. Public Positions, *supra* note 121.

> the Union address earlier this year and we are working with other nations and our industries to make it happen.[124]

In 2001, the U.S. position was that the declaration triggers covered an almost randomly-selected set of facilities rather than establishing a systematic approach to inspections.[125] On the issue of random visits, the United States made several proposals in 2000, most of which weakened the provisions of the Draft Protocol to limit visits to the status of CBM, not as a method of verifying declarations. The United States proposed non-adversarial visits, not inspections, and suggested that teams not draw any conclusion or make any finding in their reports.[126] In a July 25, 2001 statement made to the Ad Hoc Group, the United States claimed that random visits served no purpose, not even as CBM, and that they would do more harm than good.[127] The United States then withdrew its support for the Draft Protocol. This is ironic given the fact that in 1971, the United States opened up its biological facilities for public inspection and international visitors following the destruction of its stocks of biological agents — a voluntary act.[128]

Among the reservations expressed by the U.S. government regarding the Draft Protocol were the concerns of the American pharmaceutical industry regarding the protection of trade secrets.[129] The Draft Protocol called for both challenge and non-challenge inspections of sites registered to possess biological agents,[130] which the pharmaceutical industry in the

---

124. President William Jefferson Clinton, Remarks at the U.S. Naval Academy Commencement (May 22, 1998) *available at* http://www.pub.whitehouse.gov.

125. U.S. Public Positions, *supra* note 121.

126. *Id.*

127. Graham S. Pearson et al., The U.S. Rejection of the Composite Protocol: A Huge Mistake Based on Illogical Assessments, Bradford Evaluation Paper No. 22, at 1 (Aug. 2001), *available at*: http://www.brad.ac.uk/acad/sbtwc/evaluation/evalu22.pdf (last visited Feb. 24, 2005).

128. *See* U.N. Doc. 91/17, *supra* note 55, at 8.

129. For the purpose of U.S. law and for this Article, trade secret means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

> (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
> (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

UNIF. TRADE SECRETS ACT § 1(4) (amended 1985).

130. Draft Protocol, *supra* note 28.

United States vigorously opposes.[131] The U.S. pharmaceutical industry, represented by the industry group, PhRMA, published a position paper calling for no non-challenge visits and limited scheduled inspections, calling these steps necessary for the protection of CBI and facility reputations.[132] The pharmaceutical industries outside the United States were more amenable to on-site inspections and to the Draft Protocol generally.[133]

While many nations and many substate interest groups have stressed the need for an enforcement protocol for years, the progress toward such a protocol has been halting. The Fifth Review Conference in November 2002 launched a new process toward strengthening the BWC through both national and international procedures, since the Draft Protocol has fallen from favor.[134] The much more recent CWC included a Verification Annex and was vigorously supported in the United States by both parties and by industry. This paradox is at least in part because biological weapons pose a unique set of difficulties. The verification procedures of the CWC cannot simply be transplanted onto the BWC. While the two types of weapons have historically been grouped together, there are serious differences between them that must be accounted for in any attempt to control biological weapons. These differences go a long way in explaining why the chemical industry and the pharmaceutical and biotechnology industries have approached the respective enforcement mechanisms in very different ways. We must examine the differences between these types of weapons to determine where common solutions are possible and where the unique properties of biological weapons require novel approaches.

C. *The Different Challenges Posed by Chemical and Biological Weapons*

While similar concerns regarding CBI and on-site inspections existed with the CWC, the situation at hand is complicated by the nature of biological agents. Unlike chemical weapons, many of the components of which are banned outright as having no useful, peaceful purposes, most biological agents covered by the BWC have harmless and even beneficial

131. *See* PHRMA, *supra* note 30.

132. *See id.*; *see also* FAS Implementation Proposals, *supra* note 32.

133. *See, e.g.*, SLOTEN, *Biotechnology and the Strengthening of the BTWC*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36.

134. *See* Biological Weapons Convention, Fifth Review Conference, Final Declaration, Nov. 11-22, 2002, ¶ 18 (adopted Nov. 22, 2002), *available at* http://www.opbw.org/rev_cons/5rc/docs/final_dec/BWC-CONF.V-17-(final_doc).pdf (last visited Feb. 24, 2005).

uses.[135] As Henry Kelly, President of the Federation of American Scientists (FAS), wrote in an editorial in the *New York Times*, "it is possible to imagine a malicious use for virtually any biological research or production site. The difference between a lab for producing lifesaving vaccines and one capable of making deadly toxins is largely one of intent."[136] Kelly further stated that the problems of monitoring the use of biological agents is exacerbated by the fact that techniques suitable to controlling nuclear and chemical weapons are being transplanted onto the fight against bioterrorism. The substances and equipment necessary to build an atomic bomb may be easy to organize into a short list of contraband materials, but "putting this sort of emphasis on materials and labs will not suffice on the bioterrorism front where everyday equipment could be used to create horrors."[137]

Most materials that could be used to create biological weapons fall into the category of dual use materials, that is, they have both malicious and benign applications.[138] The perverse truth regarding biological agents is that the very research and procedures that make bioterrorism possible were likely created in the process to protect against the agent.[139] Research to prepare vaccines and countermeasures to these biological agents requires the use of these same dangerous materials and the same procedures to create, cultivate, and test them. As a result, inspections for biological agents would not be limited to a search for the presence of such agents, but instead must be much more involved inspections into the proper use, maintenance, and storage of biological agents in order to insure that they are not used for improper purposes.[140]

Also unlike chemical weapons components, many different entities and sites are permitted to possess and use biological components for research purposes, from university labs to private pharmaceutical companies.[141] The number of sites that would be subject to inspection would be larger, as

---

135. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 36.

136. Henry Kelly, Editorial, *Terrorism and the Biology Lab*, N.Y. TIMES, July 2, 2003, at 25.

137. *Id.*

138. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 40.

139. Kelly, *supra* note 136, at 25.

140. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 40.

141. *See* Malcom R. Dando, The Strengthened BTWC Protocol: Implications for the Biotechnology and Pharmaceutical Industry, Briefing Paper No. 17 ¶¶ 9-13 (Mar. 2000), *available at* http://www.brad.ac.uk/acad/sbtwc/briefing/bp17.htm (last visited Feb. 24, 2005).

would the number of sites subject to preparing declarations.[142] Only a limited number of sites are permitted to have the type of chemical agents that could be used to produce most chemical weapons. Many chemical weapons have no peaceful uses, and as such, these agents and their precursors can be placed on lists of automatic trigger agents.[143] There are no legitimate civilian purposes for VX gas, and the presence of any VX at a site should result in an automatic response under the CWC. As was stated previously, the list of dual use biological agents is coextensive with the list of dangerous biological agents.

Today's chemical weapons technology is very low-tech for the most part and remains from early twentieth century development.[144] Biological weapons concerns, on the other hand, cover the very low-tech, naturally occurring agents such as botulism and anthrax, to cutting edge, such as genetically modified agents designed to be more virulent.[145] A 1993 survey of the field by Bartfai, Lundin, and Rybeck identified three types of potential misuse of cutting edge biotechnology: the enhancement of bacterial and viral virulence, heterologous gene expression, and protein engineering of toxins and genetic weapons.[146] In a more recent study, Malcom Dando points out that:

> the gap between theoretical possibility and practical reality seems to be closing steadily. Significant new successes in the application of gene therapy, in particular, should be carefully monitored and assessed. While it can be hoped that ethnically specific weapons will never become a reality, it would be foolish to imagine that they are an impossibility or that incredibly precise targeting might not become possible.[147]

Attacks utilizing chemical weapons will be easier to detect and terminate preemptively because it takes a much larger amount of the chemical agent to kill the same number of people compared to a biological agent. A biological weapons attack will be much harder to detect, but

---

142. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 39.

143. *See id.*

144. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 36.

145. *See id.*

146. *See* Tamas Bartfai et al., *Benefits and Threats of Developments in Biotechnology and Genetic Engineering*, 1993 SIPRI Y.B.: WORLD ARMAMENTS & DISARMAMENT 293–305.

147. Malcom Dando, *Benefits and Threats of Developments in Biotechnology and Genetic Engineering*, 1999 SIPRI Y.B.: ARMAMENTS, DISARMAMENT & INT'L SECURITY 596–611.

given the fragility of most biological agents, the existence of vaccines, and protective measures such as masks and hazardous materials suits, a biological weapons attack is easier to contain than prevent.[148]

Nonetheless, as experts such as Rosenberg and Pearson have suggested, a "web" of preventive and containment defenses needs to be created to deal with the threat of biological weapons.[149] Pearson looks at arms control, export controls, protective measures, and a determined international and national response to development or use as being the key elements of such a defensive web.[150] Rosenberg similarly looks at the failure to respond to the use of chemical weapons usage in the Iran-Iraq war as a failure of the defensive web to protect against chemical weapons usage and to create a norm against the use of WMDs.[151] Both see a need for greater response to the threat by the international community, both in preparation for attacks and for prevention of them.[152]

III. THE DRAFT PROTOCOL

The Draft Protocol included enforcement measures, each of which is considered in turn in this section. These mechanisms included: declarations by States Parties of a range of facilities and activities that are relevant to the BWC to enhance transparency; visits to promote accurate and complete declarations (non-challenge visits); investigations into concerns of noncompliance including both field and facility investigations (challenge visits); and the creation of a permanent organization with staff to implement the Draft Protocol.[153]

The mandate of the Ad Hoc Group required that measures should be formulated and implemented in a manner designed to protect sensitive CBI and legitimate national security needs, and that: "measures shall be formulated and implemented in a manner designed to avoid any negative impact on scientific research, international cooperation and industrial

148. *See* KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS *supra* note 36, at 37-38.

149. *See* Rosenberg, *supra* note 1; PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 9.

150. PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 9.

151. *See* Rosenberg, *supra* note 1.

152. *See* PEARSON, *Countering Biological Warfare: An Overview*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 9; Rosenberg, *supra* note 1.

153. *See* Dando, *supra* note 141.

development."[154] Representatives of the pharmaceutical industry and supporters of the Draft Protocol disagreed as to whether the Ad Hoc Group succeeded in drafting provisions in accordance with its twin goals of strengthening the BWC and protecting legitimate research and cooperation. The remainder of this part looks at each major enforcement mechanism considered and the arguments made by supporters and opponents of the mechanism. This part looks at the positions taken by the European bioindustry as well as FAS and PhRMA on these issues.

A. *Industry Concerns Regarding CBI*

The pharmaceutical industry's concerns regarding the effects of the Enforcement Protocol are real and legitimate. Compared to other industries, the pharmaceutical industry relies very heavily upon research and development and the value in its CBI. Given the immense investments by the pharmaceutical industry into research and development, it is clear that the products of this research and development must be protected from industrial espionage and unfair business practices.[155] Most pharmaceutical products are very easy to mass produce once the information regarding their production becomes available.[156] Companies attempting to recoup investments in research and development would see their revenues dramatically undercut if they were forced to compete immediately with companies able to exploit the first-mover's research without bearing any of the costs.[157] If everyone is able to free ride and benefit from the investments of the first-mover, there will be no incentive to invest in research and development. This would, no doubt, have a chilling effect on the entire pharmaceutical industry by keeping potentially vital drugs from ever coming to market. In order to promote investment in research, patent and trade secret law protects first-movers for a limited period of time with a monopoly over their information and processes.

---

154. Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (VEREX), Sept. 19–30, 1994, Final Declaration (Sept. 1994).

155. *See* Barry Kellman et al., *Disarmament and Disclosure: How Arms Control Verification Can Proceed Without Threatening Confidential Business Information*, 36 HARV. INT'L L.J. 71, 75 (1995).

156. *Id.*

157. *See id.* at 74–75.

Despite the legal protections provided by patent and trade secret law,[158] concerns remain for pharmaceutical companies. Firstly, in order for trade secret protection to exist, whatever is being protected must obviously be a secret.[159] Once the information becomes public, it is can no longer be protected as a trade secret and the owner of that information no longer has the ability to stop others from using that information for commercial gain.[160] Employees at companies that rely upon the confidentiality of their intellectual property are often required to sign confidentiality agreements in order to protect the information.[161] Companies, however, are still concerned with threats such as industrial espionage and attempts by competitors to induce employees or former employees of the holder of a trade secret to violate confidentiality agreements.[162] Further, despite the requirements of the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement), different countries have different levels of domestic protection for CBI.[163]

While we hope that international inspectors acting under the authority of a hypothetical BWC enforcement protocol would not be corruptible and would not exploit or sell the CBI of inspected sites, there are still reasonable grounds for companies to be concerned that inspections could compromise trade secrets. Along with the concern that information will be intentionally and maliciously exploited by inspectors, is the possibility that declarations made to the U.S. government in conjunction with national declaration requirements could result in the loss of CBI.[164] U.S firms, leading the world in cutting edge research and development, have particular concerns regarding the protection of CBI.[165] Given the relative weight of the concerns of the industry and the importance of getting the cooperation of private actors in the enforcement of the prohibition of biological weapons, concerns of the pharmaceutical industry regarding confidentiality and the protection of intellectual property must be taken

158. Protection for trade secrets in U.S. law is guaranteed. UNIF. TRADE SECRETS ACT 14 U.L.A. 437 (1990); Food Drug and Cosmetics Act of 1938 (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended 21 U.S.C. §§ 301–397 (2000)); Federal Trade Secrets Act, 18 U.S.C. § 1905 (2000); Freedom of Information Act (FIOA) 5 U.S.C. § 552 (2000); RESTATEMENT (FIRST) OF TORTS § 757 (1939).

159. *See id.*

160. *See* John C. Janka, *Federal Disclosure Statutes and the Fifth Amendment: The New Status of Trade Secrets*, 54 U. CHI. L. REV. 334, 348 (1987).

161. Kellman et al., *supra* note 155.

162. *Id.*

163. *See id.* at 76.

164. *See id.*

165. PHRMA, *supra* note 30.

seriously by proponents of an enforcement regime. Any enforcement methods considered must include significant measures to safeguard CBI, both to protect valuable intellectual property and to empower methods of arms control.[166] There are several types of CBI which must be protected by any enforcement regime: confidential information about valuable research microorganisms and information about their biological makeup; information about proprietary process technology; confidential economic information;[167] and test results and test protocols.

Both the U.S. industry group, PhRMA, and the European bioindustry expressed concerns relating to the Draft Protocol.[168] The European bioindustry, however, took a position that was more moderate than PhRMA.[169] As the Ad Hoc Group began its work to create a Draft Protocol, the industry's coordinating group, the Forum for European Bioindustry Coordination (FEBC), prepared to play a role in the process.[170] It created the FEBC Task Force Against Biological Weapons in 1996.[171] The group published its first position paper in 1997.[172]

FEBC's position on enforcement included the observation that the CWC shows that it is essential for industry to be able to provide input to the negotiation process and provided good examples of how to strike a fair balance.[173] The European bioindustry's concerns regarding an enforcement protocol are as follows:

- Scope of declarations and inspections;
- Protection of commercial and proprietary; confidential business information;
- Costs of likely disruptions to their activities from inspections; and

166. *See id.*

167. LYNN C. KLOTZ, *Working Group on BW Verification, Confidentiality Can Be Protected During Sampling and Analysis, in* BWC COMPLIANCE REGIME (Sept. 1997), *available at* http://www.armscontrolcenter.org/cbw/papers/wg/wg_1997_confidentiality_bwc_compliance_regime.htm.

168. FAS Implementation Proposals, *supra* note 32; SLOTEN, *Biotechnology and the Strengthening of the BTWC, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36; PHRMA, *supra* note 30.

169. SLOTEN, *Biotechnology and the Strengthening of the BTWC, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36.

170. *Id.*

171. *Id.* at 47.

172. *Id.*

173. *See id.* at 48.

- Bureaucracy of dealing with complex declaration forms.[174]

The FEBC's official position regarding enforcement mechanisms is that controls are acceptable when they are instrumental to the object pursued.[175] The FEBC's recommendations for appropriate ways to address the aforementioned concerns are that controls must be:

- Administratively manageable;
- Not overly burdensome in terms of cost and manpower;
- Designed to safeguard confidential business information;
- Designed to respect the principle of a level playing field; and
- Applied on a universal basis.[176]

The concerns of industry apply to three enforcement mechanisms: declarations, challenge inspections, and non-challenge inspections.[177] Both industry and the FAS agree that the declarations should be explicitly and narrowly tailored so as to avoid revealing CBI.[178] With regard to site inspections, several specific concerns are presented by the industry, though proponents of the protocol are prepared with responses.[179]

B. *Declarations*

Under the Draft Protocol, nations would have been required to make declarations of certain facilities and activities that come under the purview of the BWC.[180] The purpose of such declarations is to increase transparency, clarify potential points of confusion, and build confidence in compliance.[181] As Dr. Hans Blix, the former Director-General of the International Atomic Energy Agency (IAEA) and the former executive director of the U.N. Monitoring, Verification and Inspection Commission (UNMOVIC), has stated:

---

174. *See* SLOTEN, *Biotechnology and the Strengthening of the BTWC, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36.

175. *Id.* at 48.

176. *Id.* at 48-49.

177. *Id.*; PHRMA, *supra* note 30.

178. SLOTEN, *Biotechnology and the Strengthening of the BTWC, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36; PHRMA, *supra* note 30; FAS Implementation Proposals, *supra* note 32.

179. SLOTEN, *Biotechnology and the Strengthening of the BTWC, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36; PHRMA, *supra* note 30.

180. Draft Protocol, *supra* note 28, art. III(D).

181. *See* Dando, *supra* note 141.

> [t]he idea of self-declaration is as basic to arms control as it is to income tax systems. The weapons inspectors or tax man should not need to go and find what you have. Rather, you know what information is required and you have it, so it is for you to collect all the relevant data and submit it for scrutiny. You declare and the inspector verifies.[182]

The declarations would have provided States Parties with an opportunity to properly document and describe peaceful uses of biological agents so that they might have been distinguished from pernicious uses of such agents; thus, explaining the nature of an issue would otherwise be a cause of concern for the convention.[183] These declarations, while the responsibility of the state party, would have required information about both public and private facilities and would require the disclosure of certain activities at these facilities.[184] Many facilities that are purely medical diagnostic and treatment facilities, and facilities that do not handle the most dangerous biological agents and toxins would have been exempt from declaration requirements.[185] The remaining facilities that would have fallen under the declaration requirements could have been numbered in the dozens, according to estimates done by Malcom Dando.[186]

With regard to declarations, the importance of which were recognized by both PhRMA and FAS,[187] the principal questions concerned the extent and level of detail of the declarations and the thresholds or triggers to establish for mandatory declarations. The types of activities and sites that were to be covered in such a declaration regime under the Draft Protocol were:

A. Past Offensive/Defensive Programs;
B. Current Defensive Programs — both activities and facilities;
C. Vaccine Production Facilities;
D. Maximum Biological Containment Laboratories — those with a World Health Organization rating of Biosafety Level 4 (BL 4) or P4 or equivalent;
E. High Biological Containment Laboratories — those with a World Health Organization rating of Biosafety Level 3 (BL 3)

---

182. BLIX, *supra* note 9, at 99–100.
183. Dando, *supra* note 141.
184. *Id.*
185. *Id.*
186. Dando, *supra* note 141, conclusion.
187. FAS Implementing Proposals, *supra* note 32.

and working with listed agents or toxins, but excluding purely diagnostic and medical facilities;

F. Plant Pathogen Containment Facilities;
G. Sites which work with listed agents — excluding purely diagnostic and medical facilities — and which meet certain production capacity minimums;
H. Non-vaccine production facilities — sites that do not produce listed agents, but that have a certain minimum production capacities and which possess aerosol test chambers for work with microorganisms or toxins; conduct research on microorganisms for determinants of pathogenicity or toxicity, conduct genetic modification to enhance pathogenicity, virulence, or resistance to antibiotics;
I. Transfers of Listed Agents;
J. Appearance of Outbreaks of Disease or Epidemics;
K. Declarations on the Implementation of Article X of the Convention and Article VII of the Protocol; and
L. National Legislation and Regulations.[188]

Several of these declaration triggers were of no concern to the biotech and pharmaceuticals industries. Nevertheless, those triggers that could have potentially affected industry were hotly debated as to the likelihood of over-inclusiveness or under-inclusiveness.

The FEBC task force recommended that the triggers for declarations be precise and narrowly defined so as not to capture too many facilities and prove an unnecessary burden on industry.[189] The European bioindustry understood the importance of declarations as CBM to increase transparency and prevent misunderstandings, but it feared excessive disclosure requirements and the burdens they would place on industry.[190] According to FEBC, the declarations should have been designed to protect CBI and there should have been no possibility of misunderstandings by the company or the institutions regarding what was required in a declaration.[191]

---

188. *See* Draft Protocol, *supra* note 28, Annex 1 (The Draft Protocol has two possible lists of declaration triggers, one which groups offensive and defensive programs together, the other has the two listed as separate triggers). *See also* FAS Implementation Proposals, *supra* note 32, ¶ 9.

189. SLOTEN, *Biotechnology and the Sterengthening of the BTWC*, *in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 47.

190. *See id.*

191. *See id.*

C. *Challenge Visits*

Once declarations are made, the next step involved is verification. Here, we are reminded of President Ronald Reagan's famous adage on arms control verification, "trust, but verify."[192] Blix's analogy to income taxation is also helpful here, as well.

> . . . [T]ax men often do more than just check the counting in your declaration. They look around in various ways to see if there were any items which should have been declared but were not. The same is true for arms inspectors. For instance, they may make inquiries of exporting countries, they may study satellite images for signs of new or expanded arms facilities, they may visit sites indicated not only by the inspected state but also by defectors or intelligence. Yet, the declaration is basic.[193]

The case Blix is describing is common to challenge inspections, where there is information that suggests a state party is not in compliance with its international responsibilities, or that it has not been truthful in its declarations. Challenge visits, or investigations under the Draft Protocol, could have been requested by any state party and would have been "carried out for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party."[194] These inspections could potentially take place at any where under the jurisdiction or control of the state party.[195] These challenge inspections could have been initiated by the complaint of another state party, or at the behest of the Secretary General of the United Nations or the U.N. Security Council.[196] States Parties would have been encouraged to engage in consultation to attempt to clarify suspected breaches before pursuing an investigation.[197]

The appropriateness of challenge visits was not contested by FAS, FEBC, or PhRMA. In the case of any site visit, FAS and PhRMA agreed that managed access rules should govern inspections. There was significant concern that on-site sampling and analysis during inspections

---

192. The saying is actually a Russian proverb, "doveryay, no proveryay," but one which President Reagan often repeated in terms of arms control verification. *See* Kellman et al., *supra* note 155, at 77.

193. BLIX, *supra* note 9, at 100.

194. Draft Protocol, *supra* note 28, art. IIIG(A)(1).

195. *Id.*

196. *Id.*

197. *See id.*

presents serious threats to the protection of CBI.[198] Steps could have been taken, mainly through the managed access vehicle, to protect all three types of CBI — information about microorganisms, information about proprietary process technology, and confidential economic information. FAS responded to concerns regarding the protection of these three types of information with the following five protective measures:

- Rigorous sampling procedures that utilize dead organisms;
- Restriction of analysis to procedures that can provide only generic information;
- Full use of the tools available under managed access;
- Strict chain-of-custody procedures;
- Watchful monitoring of the inspections team.[199]

Using only dead organisms would have protected proprietary information in the germ line of both traditional and recombinant strains against theft. The theft of a single live production strain microorganism would allow a competitor to begin producing the microorganism. Thus, the use of dead strains would be necessary to prevent such theft and exploitation of CBI.[200] In any inspection regime, FAS recommends that all testing should be done on-site and only tests that provide generic information about the tested substance should be permitted.[201] Managed access, monitoring of inspectors, and strict chain-of-custody procedures should prevent the illicit removal of CBI from the premises.[202] These steps would allow a site to maintain control over its CBI throughout the process.

Industry strongly supported the managed access approach to inspections.[203] The managed access rules were developed for the CWC with the assistance of the U.S. chemical industry to protect confidentiality. Almost identical managed access rules were incorporated into the BWC Draft Protocol. Managed access calls for negotiations between inspectors and the inspected party as to the nature of access to particular places and the scope and extent of inspections.[204] In the CWC case, it allows the inspected party a great deal of control to insure the protection of CBI and the integrity of the site during inspections.

198. *See* KLOTZ, *supra* note 167.
199. *Id.*
200. *See id.*
201. FAS Implementation Proposals, *supra* note 32.
202. *Id.*
203. *Id.*
204. *Id.*

Under a hypothetical enforcement regime, at the inspection of nongovernment facilities, site managers would have the right to make managed access decisions. The U.S. Constitution's Fourth Amendment protections against unreasonable search and seizure support the right of operators of private facilities in making these managed access decisions. Managers of private facilities should also be involved in reviewing the governmental declarations that cover their facilities and in the process of nominating and evaluating candidates for the position of inspector. Finally, all site inspectors should be required to sign confidentiality agreements to protect CBI.[205] Blix himself claimed that he threatened to fire any member of the UNMOVIC staff who failed to maintain confidentiality.[206]

Drawing upon the experiences of the UNSCOM team in Iraq when deciding upon the procedures for the UNMOVIC team in 1999, Blix placed significant emphasis on the principle that intelligence regarding inspections must flow only one way.[207] Whereas the UNSCOM inspectors were often seen as being too "cozy" with intelligence agencies, especially with those of the United States and the United Kingdom, Blix felt that the only way for UNMOVIC to be recognized as credible and legitimate was for it to report only to the United Nations.[208] As such, UNMOVIC requested, and was grateful for, intelligence and assistance from states interested in disarming Iraq, but it provided no intelligence information to these states or agencies in return. All information traveled only one way.[209] Similar steps would have to be taken under any enforcement regime for the BWC. In order for confidentiality to be respected and for the enforcement regime to be respected as legitimate, it must have strict procedures to guarantee that intelligence flows in only one direction, and that national intelligence agencies do not pressure the inspectors or secretariat of an enforcement regime to compromise the national security interests and the CBI interests of States Parties.

D. *Non-Challenge Inspections*

The most controversial of the recommended enforcement mechanisms is the non-challenge inspection — an inspection not based upon any preexisting expectation or suspicion of violation — of the facilities governed by the BWC. In the Draft Protocol, these were referred to as

205. *Id.*
206. BLIX, *supra* note 9, at 47.
207. *Id.* at 50.
208. *Id.* at 39–40.
209. *Id.* at 47.

randomly-selected visits or transparency visits.[210] The Draft Protocol called for a limited number of these each year and they would have covered either biodefense and BL 4 or all declared facilities.[211] These inspections would have been made on the research premises with little advanced warning (so as to prevent the inspected party from having the ability to destroy damaging evidence). In the example of the CWC, "the number, intensity, duration, timing, and mode of inspection of a schedule 1 facility will be based on the risk that facility poses to the objectives of the CWC and the characteristics of that facility."[212] If inspections are part of the enforcement regime under the BWC, a similar approach should be taken toward inspected sites — the scope of the inspections, while left to negotiations between the site managers and the inspection team, should be roughly proportional to the potential threat posed. This proportionality will ensure that inspections disrupt site activities as little as possible and only to the extent necessary.

Even with limitations for proportionality based on potential threat, there is still the possibility of threat to CBI. The call for these intensive inspections and verification procedures has caused significant trepidation among U.S. pharmaceutical companies. The industry, through PhRMA, expressed concern that these very intrusive inspections will lead to industrial espionage and the threatening of protected trade secrets.[213] PhRMA claims that surprise, non-challenge site inspections will make it exceedingly difficult for companies to guard protected techniques and processes.[214] Further, PhRMA suggests that the potential damage to the reputation of facilities that would result from being the subject of an inspection, even a non-challenge inspection, would be significant.[215]

The European industry's position is that routine inspections are not useful because of the ability to remove almost all traces of any development, manufacturing, or storage within a short period of time. Challenge inspections, instead, should be the crux of the enforcement mechanism.[216] Challenge inspections, organized through a program of managed access will be the best verification mechanism according to the FEBC.[217] When an allegation or suspicion is brought forward, questions and ambiguities should be resolved, whenever possible, by informal

210. Draft Protocol, *supra* note 28, Annex I.
211. *Id.*
212. Kellman et al., *supra* note 155, at 89–90.
213. *See* PHRMA, *supra* note 30; *see also* FAS Implementation Proposals, *supra* note 32.
214. *See* PHRMA, *supra* note 30.
215. *Id.*
216. *See id.*
217. *See id.* at 133.

consultations and other cooperative measures before a challenge inspection is considered. Clarification measures should be the principal method of settling misunderstandings and under full control of the site.[218]

The FAS strongly disagrees with the FEBC's and PhRMA's position that non-challenge inspections provide more costs than benefits and considers non-challenge inspections a vital part of any functioning enforcement mechanism.[219] The FAS position is that the same managed access program that would protect CBI in challenge inspections will function just as well in the non-challenge scenario.[220] The non-challenge inspections are vital, according to FAS, because of their surprise nature.[221] If inspections are random and are conducted with little warning, it will be far more difficult for those wishing to produce and stockpile biological weapons to do so on a significant scale.[222] Further, the inspections will safeguard good practices at innocent facilities and prevent the misuse of biological agents by those who might otherwise have access to them and who would use them to attempt to produce weapons.[223]

Pearson argues that these inspections under the Draft Protocol would have been far less frequent and less intrusive than routine inspections for the health and safety of employees and for the safety of pharmaceutical products carried out by national regulatory agencies.[224] The frequency of visits to facilities in the United States under the projected protocol was seven or fewer per year.[225] Pearson also points to the fact that protections for commercial proprietary information were stronger in the Draft Protocol than the similar protections in the CWC, which the United States supported and signed.[226]

IV. LESSONS FROM THE CWC

The Draft Protocol was effectively abandoned at the end of 2001 when the United States declared that it opposed the protocol and any continued

---

218. *See id.*

219. FAS Implementation Proposals, *supra* note 32.

220. *Id.*

221. *Id.*

222. *Id.*

223. *Id.*

224. Graham S. Pearson, *The U.S. Rejection of the Protocol at the Eleventh Hour Damages International Security Against Biological Weapons*, 53 CHEMICAL BIOLOGICAL WEAPONS CONVENTIONS BULL. 6, 7 (2001).

225. *Id.*

226. *Id.*

efforts by the AdHoc group to amend the BWC.[227] Discussions of strengthening the BWC by amending enforcement provisions have since been tabled and may be taken up again at the Sixth Meeting of the States Parties in 2006.[228] When the States Parties meet again in 2006, they will take up the recommendations made by expert committees that have met during the last few years to discuss codes of conduct and other non-binding attempts to improve compliance.[229] The creation of an enforcement regime for the BWC presents different and more complicated issues than the creation of the Verification and Confidentiality Annexes of the CWC. There are, however, lessons to be learned from the CWC model, especially with regard to managed access as a solution to questions of protecting CBI. This Article explores the lessons regarding weapons control that can be learned and applied from experiences with the CWC and with the search for WMDs in Iraq.

A. *The Annex on Chemicals*

The CWC Annex on Chemicals covers three types of chemical agents, which are organized into schedules by their lethality and potential uses.[230] This organizational structure resembles a proposal for regulation put forward by the United States in 1984, to categorize agents as "super-toxic lethal chemicals," "other lethal chemicals," or "other harmful chemicals."[231] Schedule 1 chemicals have little or no peaceful uses.[232] They are actual weapons, can be used as weapons, are precursors to weapons, or can be converted to weapons.[233] Among the thirteen schedule 1 chemicals are ricin and VX.[234] Schedule 2 chemicals are not produced in large commercial quantities for purposes not prohibited under the convention.[235] These chemicals also pose a significant risk to the

227. *See* Graham S. Person et al., The U.S. Statement at the Fifth Review Conference: Compounding the Error in Rejecting the Composite Protocol, Review Conference Paper No. 4 (Jan. 2002), *available at* http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_4.pdf.

228. *See* Graham S. Pearson & Nicholas A. Sims, Preparing for the BTWC Sixth Review Conference in 2006, Review Conference Paper No. 10 (Jan. 2005), *available at* http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_10.pdf.

229. *See, e.g.*, Biological Weapons Convention, 2005 Meeting of the Experts, Working Papers, June 13-24, 2005, BWC/MSP/2005/MX/WP.1, *available at* http://www.opbw.org/.

230. CWC, *supra* note 109, pt. A., Annex on Chemicals.

231. WALTER KRUTZSCH & RALF TRAPP, A COMMENTARY ON THE CHEMICAL WEAPONS CONVENTION 257 (1994).

232. CWC, *supra* note 109, pt. A., Annex on Chemicals.

233. *Id.* Chemical Annex pt. A1.

234. *Id.* pt. B.

235. *Id.* pt. A.

objects and purposes of the CWC[236] and include arsenic trichloride and PFIBs.[237] Schedule 3 chemical agents are dual-use chemicals; they can be used as weapons or as precursors to weapons, but they also have peaceful, legitimate uses for scientific and industrial purposes.[238] These chemicals may be produced in large commercial quantities for purposes not prohibited under the CWC[239] and among these chemicals are hydrogen cyanide and sulfur dichloride.[240]

In order to address the problem of development of new chemical weapons or potential weapons, the Annex on Chemicals is the only part of the CWC that can be amended under the change-procedure of Article XV; additions and deletions can be made to the schedules without the amendment procedure, thus providing flexibility to the CWC.[241] Along with adding new chemicals and deleting old ones from the schedules, chemicals can be transferred to a different category if the need arises.[242]

Any quantity of schedule 1 chemicals will trigger a violation for almost any declared facility (and for any undeclared facility), private or governmental.[243] Any schedule 2 chemicals above the amount listed in proper declarations will trigger violations, as will any amount of schedule 2 chemicals at sites not authorized to possess them. Schedule 3 — dual use — chemicals pose challenges similar to those with biological weapons.[244] Their presence should be expected at certain declared, private or governmental facilities, along with the machinery and technology to produce them.[245] As such, declaration forms and inspection protocols dealing with these schedule 3 chemical agents can be useful in tailoring declarations and protocols for biological agents under the BWC.[246]

B. *The Verification Annex*

The Verification Annex of the CWC has separate parts for the different schedules of chemicals.[247] Part VI addresses schedule 1 chemicals and includes stringent declaration requirements; the first declaration must be

236. *Id.*
237. CWC, *supra* note 109, pt. B.
238. *See id.* pt. A., Annex on Chemicals.
239. *Id.*
240. *Id.* pt. B.
241. KRUTZSCH & TRAPP, *supra* note 231, at 259.
242. *Id.*
243. *Id.*
244. *Id.*
245. *Id.*
246. KRUTZSCH & TRAPP, *supra* note 231, at 259.
247. CWC, *supra* note 109, Verification Annex.

received no later than 30 days after the CWC's entry into force, and subsequent annual declarations must be made no more than 90 days after the beginning of each year.[248] In the event that a new schedule 1 facility is to be opened, the declaration for that facility must be received no fewer than 180 days before the facility opening.[249] Part VI also limits the number of facilities that may possess these chemicals to one single small-scale facility and other very limited facilities.[250] The inspections of these facilities will be proportional to the risk the facility poses to the object and purpose of the CWC.[251]

Part VII of the Verification Annex addresses schedule 2 chemicals and includes minimum amounts of these chemicals needed to trigger the declaration requirement. Part VII also lists the declaration schedule for facilities declaring under schedule 2 (which is similar to the schedule for schedule 1 facilities — the initial declaration must be submitted within 30 days of the entry into force, annual declarations must be made within 90 days of the beginning of the year).[252] Unlike schedule 1 facilities, there are no express limits on the number of schedule 2 chemicals, no limits to small-scale facilities, and small quantities of schedule 2 chemicals do not trigger declaration requirements, while any amount of schedule 1 chemicals will trigger mandatory declarations.[253] Inspections for schedule 2 declarations have the general aim of ensuring that no undeclared schedule 1 chemicals are present, that the levels of production, processing, or consumption of schedule 2 chemicals are consistent with declarations, and that there is no diversion of schedule 2 chemicals to activities prohibited under the CWC.[254]

Schedule 3 chemicals are covered under Part VIII, and are subject to the same declaration timetable as schedule 2 chemicals.[255] Like those regulated under schedule 2, schedule 3 chemicals only trigger mandatory declarations when they are present in large enough quantities to pose a threat to the object and purpose of the CWC.[256] The amount of information required in the declarations varies among schedule 1, 2, and 3 chemicals, with schedule 1 declarations being more demanding and thorough than

248. *Id.* pt. VI.
249. *Id.*
250. *Id.*
251. *Id.*
252. CWC, *supra* note 109, Verification Annex. pt. VII.
253. *Id.* pt. VII.
254. *Id.*
255. *Id.* pt. VIII.
256. *Id.*

schedule 3 declarations.[257] As with schedule 2 facilities, those regulated under schedule 3 will not be the subject of a non-challenge visit more than twice per calendar year.[258] Non-challenge site visits for schedule 3 facilities will be randomized and based on equitable geographic distributions.[259]

Part IX of the Annex addresses other chemical production facilities and the triggers for mandatory declarations for those sites that do not work with any of the schedule 1 or 2 chemicals or significant quantities of schedule 3 chemicals.[260] This Part of the Annex was one of the last elements to enter the Convention and was designed as a compromise to the controversial issue of the extent of routine inspections for those facilities that do not produce schedule 1 or 2 chemicals.[261] Unlike the other Parts, which specify particular chemicals that trigger declarations, Part IX addresses "unscheduled discrete organic chemicals" and requires declarations that give approximations of the amounts of chemicals produced.[262] Inspection schedules for facilities covered by Part IX are similar to those for schedule 3 facilities.[263] Just as inspections and verification methods for the CWC are tailored to the level of threat posed by the facility to the object and purpose of the convention, so too should verification measures under the BWC be designed. The compromises over schedule 3 and other chemical production facilities can provide guidance for the governance of commercial facilities that will fall under the BWC regime.

Part X of the Verification Annex concerns challenge inspections pursuant to Article IX of the CWC.[264] A Challenge inspection is defined for the purpose of the CWC as "the inspection of any facility or location in the territory or in any other place under the jurisdiction or control of a State Party requested by another State Party pursuant to Article IX, paragraphs 8 to 25"[265] of the CWC. As was the case in the Draft Protocol, States Parties are encouraged to first take cooperative steps and consult in order to clarify any issues of suspected noncompliance.[266] If bilateral consultations are undesired or unsuccessful, a state party may request the

257. *Compare* CWC, *supra* note 109, Verification Annex, pt. VIII, *with id.* pts. VI, VII.
258. *Id.* pt. VIII.
259. *Id.*
260. *Id.* pt. IX.
261. KRUTZSCH & TRAPP, *supra* note 231, at 456.
262. CWC, *supra* note 109, pt. IX, Verification Annex.
263. *Compare id.*, *with id.* pt. VIII.
264. *Id.* pt. X.
265. *Id.*
266. *Compare id.* art. IX, *with* Draft Protocol, *supra* note 28, at 70.

Executive Council obtain clarification from another state party,[267] allowing a neutral, official organ of the Organisation of the Prohibition of Chemical Weapons (OPCW) to mediate the dispute.[268] While preference is given to non-adversarial proceedings, each state party has the right to request a challenge inspection.[269] Upon receiving the request for a challenge inspection, the Director- General of the OPCW must inform the state party to be visited of the timing, nature, point of entry, the nature of the complaint, and limits of the visit.[270] Specific rules are delineated for entry into the inspected facility, security, the course of inspections, and departure.[271] The inspection team shall be guided by the principle of conducting the challenge inspection in the least intrusive manner possible, consistent with the effective and timely accomplishment of its mission.[272] In order to achieve the balance between robust inspections and protection for CBI, the Verification Annex has significant managed access provisions to protect confidential information.[273]

The managed access procedures, which have been discussed above, were initially developed by the British in response to concerns of confidentiality, largely raised by the Soviet Union, during the early stages of work on the CWC.[274] In 1984, the Reagan administration put forward its position on chemical weapons inspections — "anywhere, any time, with no right of refusal" — in the fiscal 1986 Defense Department report: "[w]e realize that such a verification measure is unprecedented, but the risks of the status quo or of an unverifiable treaty are so severe that they far outweigh the risks of allowing international inspection teams into our sensitive facilities."[275] The U.S. position was rejected by the Soviet Union, at first, but when the USSR called the U.S. bluff, the United States found itself unable to back down from an untenable policy. The British managed access approach was one of anywhere, any time, but not completely unfettered access, and it rescued all parties from an impossible position.[276]

The managed access approach in the CWC includes protection for sensitive papers, displays, store equipment, electronic systems, and data

267. *Compare id.*, *with* Draft Protocol, *supra* note 28, at 70.
268. KRUTZSCH & TRAPP, *supra* note 231, at 179.
269. CWC, *supra* note 109, art. IX.
270. *Id.* pt. X, Verification Annex.
271. *See id.*
272. *Id.*
273. *Id.*
274. J. CHRISTIAN KESSLER, VERIFYING NONPROLIFERATION TREATIES 78 (1995).
275. *Id.*
276. *See id.*

indicating devices.[277] The approach also limits access to sensitive sites by limiting the number of inspectors who are given access, by using a sampling of sensitive sites for random inspections,[278] and through facility agreements negotiated by the state party, the site managers, and the Director-General. These same protections were incorporated into the BWC Draft Protocol.[279]

C. *The Confidentiality Annex*

Along with the managed access provisions, designed to minimize intrusions into sensitive work and information and to limit disruptions of legitimate facility operations, the CWC includes a Confidentiality Annex to promote the protection of sensitive information.[280] Under the Confidentiality Annex of the CWC, the Director-General maintains primary responsibility for the maintenance of confidentiality.[281] The Director-General and the States Parties are called upon to negotiate individual secrecy agreements.[282] The States Parties are called upon to cooperate with the Director-General in investigating breaches and alleged breaches.[283] The Director-General has discretion and authority to impose appropriate punitive and disciplinary measures on staff members who have violated their obligations to protect confidential information.[284] The OPCW, however, shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat.[285] The inspectors are granted the same types of privileges and immunities granted to diplomats under the Vienna Convention on Diplomatic Relations, but the Director-General can waive immunity for inspectors if the Director-General deems immunity would impede the course of justice.[286]

Kellman, Gualtieri, and Tanzman, in their review of the protection of CBI under the CWC, give a detailed analysis of various protective and remedial measures available under international and U.S. law.[287] Since the writing of their article, the United States has passed implementing legislation for the CWC, which includes guarantees of constitutional

277. CWC, *supra* note 109, pt. X, Verification Annex.
278. *Id.* pt. X; *see also* arts. IV, V, & VI.
279. Draft Protocol, *supra* note 28, art. III, Annex.
280. CWC, *supra* note 109, Confidentiality Annex.
281. *Id.*
282. *Id.*
283. *Id.*
284. *Id.*
285. CWC, *supra* note 109, Confidentiality Annex.
286. *Id.* pt. II, Verification Annex.
287. Kellman et al., *supra* note 155, at 135-36.

protections against unreasonable searches and seizures,[288] civil liability for the federal government for takings related to the implementation of the CWC,[289] and statutory protection under exemption 3 to the Freedom of Information Act for all confidential information collected in accordance with the CWC.[290] Under section 103, the United States has civil liability for takings and tort liability claims.[291] Section 103(a)(1), the U.S. Court of Federal Claims and the district courts of the United States have concurrent jurisdiction.[292] Section 103(e) provides for recoupment of damages paid by the United States from states or foreign agents if they knowingly caused the loss of the CBI.[293] Sanctions may also be applied under this provision against those companies and nations involved in the knowing violation of confidentiality.[294] These protections cover both the prevention of loss of CBI and redress for loss of CBI and apply to information lost in inspections and in declarations.[295] Similar protections should be incorporated into any implementing legislation for a hypothetical BWC enforcement regime.

D. *Industry Positions and Arguments for U.S. Ratification*

The chemical industry in the United States not only supported the CWC, it was involved in the process of negotiating the convention.[296] It was the position of the Chemical Manufacturers Association that the obligations under the CWC would not pose an undue burden.[297] Nevertheless, it would pose some significant costs on industry. Speaking for the industry, Will Carpenter stated that:

> [t]he inescapable conclusion, from our perspective, is that a useful treaty will have a negative impact on the chemical industry. The challenge to those participating in the process is to obtain that valid, verifiable document while minimizing that negative impact, which includes the cost of compliance and of meeting the reporting

---

288. Chemical Weapons Convention Implementation Act of 1998, § 102 [hereinafter CWC Implementation Act].

289. *Id.* § 103(d)(3).

290. *Id.* § 404.

291. *Id.* § 103.

292. *Id.* § 103(a)(1).

293. CWC Implementation Act § 103(e)(1).

294. *Id.* §§ 103(e)(2)–103(e)(3).

295. *Id.*

296. DONALD A. MAHLEY, *The CWC and the U.S. National Interest*, *in* RATIFYING THE CHEMICAL WEAPONS CONVENTION 20, 28 (Brad Roberts ed., 1994).

297. *Id.*

> requirements, as well as educating and assigning people to meet those requirements.[298]

To achieve this end, the U.S. government has worked with industry to educate and prepare industry for its responsibilities under the CWC. The U.S. Arms Control and Disarmament Agency (ACDA) sponsored a series of seminars across the United States to educate industry about its responsibilities under the CWC and to address industry questions and concerns.[299] According to Carpenter, Chairman of the board of Agridyne Tehcnologies, Inc. and representative of the Chemical Manufacturers Association to the U.S. government on the chemical disarmament negotiations, the CWC "achieved an adequate trade-off between the need for intrusive verification for a useful treaty, on the one hand, and minimizing the damage to industry on the other."[300]

According to Richard Clarke, it was the high level of cooperation between industry and the government that made negotiating the treaty and producing a satisfactory result possible.[301] The chemical industry's concerns were ably represented by the Chemical Manufacturers' Association and government was able to meet those concerns in negotiating the text of the CWC.[302] While pharmaceuticals are produced principally with chemicals, and not biological agents, PhRMA was not involved in the process of negotiating the CWC because the chemicals covered in the Chemical Annex of the CWC are not generally used in the production of pharmaceuticals or in the bioindustry.[303]

Experts in the field of disarmament listed several reasons why supporting the CWC was imperative for the United States. The CWC was called the only instrument available to establish, as the unqualified international norm, the position that chemical weapons are categorically banned as a means of warfare.[304] Further, the CWC would provide the United States leverage to compel other states to abide by this norm and the

---

298. WILL D. CARPENTER, *Understanding Chemical Industry Support for the CWC, in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 30.

299. JOHN D. HOLUM, *The Clinton Administration and the Chemical Weapons Convention: The Need for Early Ratification, in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 8.

300. CARPENTER, *Understanding Chemical Industry Support for the CWC, in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 30.

301. Interview with Richard Clarke conducted at Harvard University, Apr. 21, 2004.

302. *Id.*

303. *Id.*

304. *See* MAHLEY, *The CWC and the U.S. National Interest, in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 21.

CWC would allow for the imposition of penalties on those states that do not adhere to these standards of conduct.[305]

John Holum, the director of ACDA, argued that the CWC was necessary to create a categorical norm against either first-strike or retaliatory use of chemical weapons.[306] He further stated that arms control is becoming increasingly a multilateral endeavor,[307] and that the United States had to ratify the CWC in order to demonstrate international leadership.[308] Holum points to several aspects of the CWC as important, both for chemical weapons disarmament and for future disarmament treaties.[309] Among these is the nondiscriminatory nature of the CWC. There are no distinctions among classes of adherents; all parties are equally subject to all provisions.[310]

Donald Mahley, who served as the U.S. representative to the Preparatory Commission for the OPCW gave another argument for U.S. support of the CWC.[311] The reputation and efficiency of the CWC regime, he argued, would be built in its first few years.[312] Being among the original parties would enhance the confidence of the United States in the OPCW and give the United States a base for facilitating the capabilities of the organization.[313]

V. THE NEED FOR A STRONG ENFORCEMENT REGIME

We should turn back to the words of David Kay if we need convincing that an enforcement regime is necessary. In his final report to the Senate, Kay said: "[t]here's a long record here of being wrong. There's a good reason for it. There are probably multiple reasons. Certainly proliferation is a hard thing to track, particularly in countries that deny easy and free access and don't have free and open societies."[314] It is precisely because proliferation is so difficult to track and because transparency must often

---

305. *See id.*

306. HOLUM, *The Clinton Administration and the Chemical Weapons Convention: The Need for Early Ratification*, *in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 6.

307. *Id.* at 8.

308. *Id.* at 9.

309. *Id.* at 8.

310. *Id.*

311. MAHLEY, *The CWC and the U.S. National Interest*, *in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 25.

312. *Id.*

313. *Id.*

314. Kay, *supra* note 11.

be forced upon nations that an enforcement protocol is necessary. Kay himself has endorsed the creation of an enforcement mechanism with a credible inspection regime.[315]

Many international enforcement mechanisms grow in a deep, then broad manner, with like-minded nations agreeing to bind themselves and then allowing all other nations willing to accept the limitations and restrictions of the agreement to become full fledged parties by ratifying the agreement. The World Trade Organization functions under this assumption, with no junior members.[316] Instead, all members are expected to make similar concessions, which then apply to all other members on a Most Favored Nation basis.[317] Among political scientists who study international cooperation, there is also a theory that widespread cooperation can be done on a "broad, then deep" basis.[318] First steps in response to international problems often do not require substantial commitments from all parties binding only some states and encouraging others to voluntarily follow the requirements of the agreement. This is the case with the Kyoto Protocol, which did not require the developing nations to agree to any sort of limitations of greenhouse gas emissions.[319]

In order for an enforcement regime for the BWC to be truly successful, however, it must bind all nations equally. As Holum pointed out with regard to the CWC, its nondiscriminatory nature was an integral part of the Convention.[320] A legal approach to the enforcement of the ban on biological weapons cannot have different rules for the white hats and the black hats. The rogue states that the United States believes are producing biological weapons are unlikely to allow inspections if the United States does not submit to those same requirements. As with the International Criminal Court, protestations that Americans are different and should be exempted from inspections or enforcement are likely to fall upon deaf ears.

As Nicholas Sims argued — when encouraging other States Parties to go forward with the Draft Protocol despite American opposition — the deep then broad approach that binds all parties to all the legal requirements

---

315. David Kay, response to question posed by the author at Harvard University, Mar. 22, 2004.

316. GENERAL AGREEMENT ON TARIFFS AND TRADE art. 1 (1947).

317. *Id.*

318. For a discussion of the "broad then deep" approach in the global climate change field, see DAVID G. VICTOR, COLLAPSE OF THE KYOTO PROTOCOL (2001).

319. *See* KYOTO PROTOCOL TO THE UNITED NATIONS FRAMEWORK CONVENTION ON CLIMATE CHANGE, Dec. 11, 1997.

320. *See* HOLUM, *The Clinton Administration and the Chemical Weapons Convention: The Need for Early Ratification, in* RATIFYING THE CHEMICAL WEAPONS CONVENTION, *supra* note 296, at 8.

of the treaty has its advantages, even when the founding states are all like-minded nations, which are unlikely to be violators:

> [t]reaty relationships solidify an agreed norm of behaviour and make it harder to overturn. Each state party stands guard over the others, and the watchfulness of treaty partners discourages backsliding. The relevance of this to the Protocol is that the latter would have value even if initially confined to a core group of states most strongly committed to the BWC and least likely to be suspected of undermining it. They would be mutually supportive in reinforcing, and giving organised expression to, their shared commitment.
>
> They would bear the costs, of the Organisation, and of compliance more generally; but they would also be in charge. Governments want to be where key decisions are being taken. They would be in a strong position from the start to shape an OPBW which both served their own interests as a core group and turned an open face to the rest of the world so as to attract steadily widening participation.[321]

A political approach will allow for the distinction between white hats and black hats, preventing low-threat institutions, including U.S. and EU pharmaceutical industries, from being captured. Such a political approach taken by a single state to find specific risks and to react based on perceived threat will not be an effective approach to the problem of biological weapons. The intelligence gaps that create situations such as the one in Iraq are likely to remain indefinitely. An enforcement regime designed to increase transparency and eliminate misunderstandings will help reduce the uncertainty and close these intelligence gaps.

A further problem with the exceptionalist approach for the United States is an economic issue. Other states are unlikely to bind their bioindustries to costly declarations and inspection regimes if the U.S. pharmaceutical industry is not similarly bound.[322] Industry outside the United States can be expected to lobby national governments vigorously to avoid the inequitable application of costs associated with applying the BWC enforcement protocol to all but American companies. Given the immense market share the U.S. pharmaceutical industry enjoys, its exemption from the costs of enforcement can be expected to have a

321. Sims, *supra* note 27, at 6

322. *See id.* at 4.

significant impact on the worldwide industry and foreign pharmaceutical companies will work hard to avoid this scenario.

If the international community is serious about an enforcement mechanism for the BWC, there is no halfway. Some degree of sovereignty must be ceded to an international enforcement mechanism and real consequences must exist for failing to cooperate with the enforcement mechanisms. While the Verification Annex of the CWC calls for declarations, it provides no consequences for failure to cooperate.[323] As a result, many countries failed to produce the required declarations on time. Of the 130 declarations made, twenty-eight declarations were wrong.[324] Countries found to be in substantive violation of the CWC, do however, face consequences. Article XII of the CWC includes collective measures to redress a situation and ensure compliance, including sanctions.[325] The measures in Article XII include referral of a situation of violation to the Security Council as well as suspension of benefits and rights under the CWC.[326] The CWC not only includes obligations, it also provides its members with economic benefits — members of the CWC can engage in exchanges of scientific information and technology only with other members in good standing of the CWC.[327] Article XII measures in response to noncompliance includes a suspension of these benefits.[328] Similar economic incentives should be built into any enforcement regime for the BWC, along with the ability to refer noncompliance to the U.N. Security Council as an issue of concern to international peace and security.[329] Economic incentives may also be useful in encouraging timely and accurate declarations.

If past U.S. policy toward enforceable international conventions that limit sovereignty is any indication of likely future behavior, however, there is reason for concern. In the realm of international human rights law, the United States has mixed the legal and political approaches, claiming a sort of exceptionalism for the United States to justify the enforcement of legal obligations on other nations while refusing to submit to those same obligations. As Professor Andrew Moravcsik points out in *The Paradox of U.S. Human Rights Foreign Policy*, a confluence of political factors unique to the United States results in a deep commitment to norms and

323. KELLE & MATOUSEK, *Lessons of the Chemical Weapons Convention for the BTWC Protocol, in* THE ROLE OF BIOTECHNOLOGY IN COUNTERING BTW AGENTS, *supra* note 36, at 40.

324. *Id.*

325. CWC, *supra* note 109, art. XII.

326. *Id.*

327. *Id.* art. XII.

328. *Id.*

329. U.N. CHARTER ch. VII.

their enforcement abroad, as well flat rejection of any attempt to submit to international authority in the enforcement of these norms within the United States.[330]

With regard to U.S. human rights policy, the Lawyer's Committee on Human Rights has claimed that the view of the American government is that "one set of rules belongs to the U.S. and another to the rest of the world."[331] Both Human Rights Watch and the American Civil Liberties Union attacked the U.S. ratification of the U.N. International Covenant on Civil and Political Rights (ICCPR) because of the long list of reservations entered by the United States, resulting in what these groups termed a "half step" based on "the cynical view of international human rights law as a source of protection only for those outside U.S. borders."[332]

The notion of American exceptionalism to international law must give way in order for a strong enforcement mechanism to function properly. The failure of the United States to support the Draft Protocol to the BWC was costly. The failure of the international community to create an enforcement regime for the BWC has meant a great deal of time, effort, and political will was expended and we are still without any credible method of enforcing the norm against biological weapons. The "New Process" (as it has been dubbed by the Biological and Toxin Weapons Convention Web Site)[333] will hold week-long meetings each year in the lead up to the Sixth Review Conference in 2006. The agenda for these meetings will include discussions of both national and international measures to strengthen the BWC. Domestic measures alone will not be enough to strengthen the BWC. While domestic implementation of the BWC is imperative, without a strong international enforcement regime, the BWC will remain toothless.

---

330. ANDREW MORAVCSIK, *The Paradox of U.S. Human Rights Policy*, *in* AMERICAN EXCEPTIONALISM AND HUMAN RIGHTS (Michael Ignatieff ed., 2003), *available at* http://www.people.fas.harvard.edu/~moravcs/publications.html (last visited Feb. 24, 2005).

331. Letter from the Lawyer's Committee on Human Rights to Senator Claiborne Pell, 14 HUM. RTS. L.J. 129 (1992); TONY EVANS, U.S. HEGEMONY AND THE PROJECT OF UNIVERSAL HUMAN RIGHTS 189 (1996).

332. HUMAN RIGHTS VIOLATIONS IN THE UNITED STATES: A REPORT ON U.S. COMPLIANCE WITH THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS 2 (1993).

333. *See* The Biological and Toxin Weapons Convention Website, *available at* http://www.opbw.org (last visited Feb. 24, 2005).

VI. CONCLUSIONS

This Article has shown that the United States should support a strong enforcement regime because the threat of biological weapons is so great as to justify the expenses that may accompany an international enforcement mechanism. The U.S. dual concerns — protecting the legitimate interests of the pharmaceutical industry and the pressing need to prevent the production, stockpiling, and proliferation of WMDs — can be met, but only within an international framework. The Bioterrorism Act is a good start in the process of improving preparedness for an attack, but it is not enough. In order to prevent a biological weapons attack, the United States must work with the international community. Similar to concerns over environmental degradation and international trafficking, the production and use of biological agents is a truly global concern and it must be addressed globally.

The issue of biological weapons cannot be addressed in the international sphere on an ad hoc basis. Just as the International Criminal Court, (another international institution opposed by the United States), was formed to create a permanent forum for dealing with a significant international concern, the international enforcement mechanism for the BWC is being promulgated in order to capture the institutional knowledge and capabilities of experts needed in the field of biological agents inspection.

Currently, the only force capable of completing biological weapons inspections in the world is UNMOVIC, created to search for weapons in Iraq. If UNMOVIC is disbanded, gone with it will be the collective knowledge and experience of its leadership and its inspectors. While UNMOVIC has lost its primary purpose, like other international institutions, it can be adapted and incorporated into the BWC enforcement system in order to capture its experience and expertise. These institutions must be preserved to deal with concerns over noncompliance. The earlier claims made against the Soviet Union regarding Sverdlovsk and the use of yellow rain were never adequately addressed because no institution with the capacity or legitimacy to investigate such claims existed at the time.

The IAEA relies upon its ability to inspect and verify compliance among its members. The organization would be toothless without these powers. Today, we rely upon the IAEA to prevent the proliferation of nuclear weapons, and we accept its importance as one part in the web of nuclear nonproliferation. Growing concerns regarding Iran and North Korea's noncompliance with their duties under the Nuclear Nonproliferation Treaty have been dealt with using multiple tools, including IAEA inspectors and pressure placed on the nations to abide by their own international obligations. The BWC must have similar powers

to inspect and verify compliance if it is to be an effective part of the web of protection against biological weapons proliferation.

The ease with which biological agents can be hidden or transferred and the inherent difficulty in detecting them requires a standing institution to carry out inspections. It will not be feasible to pull together inspection teams ad hoc to deal with problems as they arise. Only an international entity will have the credibility and the legitimacy to complete this task. As recent efforts to disarm Libya and Iran have demonstrated, the apparent internationality and impartiality of inspection teams has been a point of contention. The ability to draw from a pool of inspectors, acting independently of their respective nations, and the ability of nations to challenge specific inspectors will enhance the legitimacy of an inspection program, which will lead to more transparency across the board.

The managed access provisions of the CWC can be successfully transferred to a BWC enforcement regime to protect confidential processes. For the elements of biological agents that make them distinct from chemical agents, and thus require separate protection, the provisions suggested by FAS can be used to complement protection of confidential property. Institutions should be involved in every step of the process of creating guidelines and methods of testing that will protect their confidential information while providing inspectors with the necessary information.

Industry and government should work together in creating the necessary implementing legislation, and in the process of vetting candidates for the international inspection teams and for leadership in the BWC enforcement program. Industry should be consulted in the creation of preparing declarations and in the negotiations between the state party and the inspection team in determining the scope of inspections and the steps necessary to protect CBI. The Bioterrorism Act provides for this type of cooperation in the domestic control of hazardous biological agents, and this same cooperation should be applied to the international enforcement of the ban on biological weapons.[334]

Unilateralism cannot serve the United States in the fight against biological weapons. As the hunt for Saddam Hussein's suspected weapons program has shown, using force to dismantle a biological weapons threat is a difficult and costly process with mixed results at best. In order to fight the scourge of biological weapons, a multilateral approach is best for the United States and for the international community. If the process goes forward without U.S. support, the results will be negative, both for the United States and for the enforcement institution of the BWC. Failing to

334. *See* Bioterrorism Act § 108.

participate in the process of creating an enforcement institution will prevent the United States from exerting any influence on the direction and structure of the institution, an argument that had been made to support U.S. involvement in the creation of the International Criminal Court[335] and to explain why remaining outside the EU for so long was counterproductive for Great Britain.[336] Similarly, the enforcement mechanism will suffer if it is not supported by the world's most powerful nation. The only way to deal with this threat effectively is through international cooperation.

The enforcement regime will not completely protect the world against the use of biological weapons. The prevention of the weapons proliferation is a complicated and difficult task. An enforcement regime to increase transparency and build confidence is an integral part of the web of defense that must be created to prevent and protect against a biological weapons attack. Biological weapons pose a huge threat to international security and the States Parties must use a multi-pronged approach. A key part of our strategy must be international cooperation to prevent the production of these weapons by governments and sub-state actors. No single nation can prevent the proliferation of these weapons alone. The potential costs of a biological attack are so great that it would be foolish for the United States to forego the enforcement regime and try to prevent the use of biological weapons unilaterally.

335. *See generally* KENNETH ROTH ET AL., TOWARD AN INTERNATIONAL CRIMINAL COURT? (1998).

336. *See generally* LAURENCE MARTIN & JOHN GARNETT, BRITISH FOREIGN POLICY: CHALLENGES AND CHOICES FOR THE 21ST CENTURY (1997); JOHN TURNER, THE TORIES AND EUROPE (2000).