

Policy Analysis

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Strengthening the Biological Weapons Convention Illusory Benefits and Nasty Side Effects

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Executive Summary

The Biological Toxins and Weapons Convention—signed in 1972—prohibits signatory nations from developing, possessing, employing, or transferring biological weapons. The convention does not contain any protocols for its enforcement, however. There is now an international effort under way to develop such protocols.

The proposed protocols have built-in features that essentially render inspections useless in demonstrating either compliance with or violation of the convention. The line between research and development for biomedical purposes and for biological weapons is very fine. It reflects a state of mind and intent. A state would be foolish to declare that a known pharmaceutical or biotech facility was performing bioweapons R&D and might even shy away from using such a facility for those purposes. Logic dictates that any bioweapons R&D areas and documents would be declared confidential and out of bounds to inspectors. Rogue states will certainly seek to conceal their activities behind rules on confidentiality.

Inspections under the proposed protocols would also provide the potential for compromise of valued U.S. proprietary and commercial secrets and critical data used for defense against bioweapons. Inspections of U.S. leading-edge biomedical and biotechnology companies may well put at risk the security of commercial secrets that are the life's blood of our economy and future prosperity. Trained, knowledgeable inspectors from other nations conversant with biotech and bioweapons R&D will instantly recognize any such information that comes before them. In short, the more people with access to biotech commercial secrets, the less secure they are.

The future of the people's right to be secure in their possessions and personal effects is placed in peril by the Biological Toxins and Weapons Convention protocols. Although an attack with biological weapons on the United States would be dangerous, an assault on U.S. constitutional rights in an effort to strengthen an international convention has little hope of stopping the spread of those weapons.

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Introduction

The specter of biological warfare (or terrorism) reared its head during the Gulf War.¹ Much concern existed that Iraq possessed such heinous weapons and would use them. That fear was legitimately predicated on Iraq's willingness to use chemical weapons against its Iranian foes in the Iraq-Iran war of the 1980s, as well as against Iraqi Kurds.

Although during the Cold War the United States had been confronted with an adversary—the Soviet Union—that possessed the means and the will to use unconventional weapons in war, Iraq's attempts to obtain weapons of mass destruction brought home the danger of the proliferation of such technologies. The prospect of the United States and its allies fighting disease as a weapon was a chilling thought to our national leaders and citizens. But the United States, the Russian Republic, and Iraq are far from the only actors with the technical know-how to develop and use biological weapons.

There is another possibly more disquieting prospect than that of nations' using bioweapons to achieve military or political ends. Renegade groups of transnational character are possible players in this grisly new twist to warfare and political pressure. Terrorist groups are believed to be seeking the agents and technology for the development of bioweapons. Their indiscriminate use of conventional and, in a few cases, chemical weapons argues that their use of bioweapons would probably exhibit no more moral restraint. A strengthened Biological Toxins and Weapons Convention (BWC), however, would have little effect on the proliferation of biological weapons to rogue states and terrorist groups.

Historical Biological Warfare

Although today we fear sophisticated and cunning bioweapons, historical bioweapons

included diseased bodies or parts catapulted over fortification walls, venomous snakes hurled from one ship to another, and livestock herded into ponds or streams and killed so their carcasses would foul the water.² More recently, during the Vietnam War, the Vietcong planted sharpened sticks—the tips of which were fouled with waste of one kind or another—along the sides of trails and depressions. Those *pungi* sticks were designed to pierce arms, legs, or torsos of troops seeking cover in an ambush.³ The resulting infections were potentially more horrifying than any Edgar Allan Poe plot.

Perhaps no better examples of the potential consequences for today's society of the use of a biological weapon can be cited than the results of "naturally occurring" epidemics. Major outbreaks of bubonic plague have struck human society several times through the centuries, and the results have always been catastrophic. In the 14th century about one-third of the European population was wiped out by this pestilence.⁴

Modern times have similarly been confronted with disease of unprecedented virulence. The outbreak of influenza at the end of World War I surprised Europeans—already reeling from a devastating war—and American servicemen returning to the United States. American soldiers brought home death on a grand scale.

The worldwide pandemic is believed to have begun on a U.S. military post in Kansas on March 11, 1918. That influenza outbreak, like many, is thought to have originated in birds or pigs and made the trans-species jump—by mutation—to humans. By April, with American troops being sent to Europe in the waning days of the "war to end all wars," the disease spread rapidly among French troops and civilians. Simultaneously, the infection reached China and Japan. As May approached, the virus found its way to Africa and South America. Returning troops brought the virus back home to the United States. Estimates place the number of deaths worldwide at between 20 and 40 million. In the United States alone, the death toll ranged

between 600,000⁵ and 700,000⁶—a number almost as high as the combined casualties suffered by both the North and the South during the American Civil War.

The added horror of that unique flu outbreak—and the implication of any use of man-made bioweapons in the future—was the nearly total devastation the pandemic had on the fabric of communities as a whole. Graves were not dug, and garbage collected in heaps along community streets—further aggravating the threat from bacterial disease. There were serious shortages of coffins, food, and utilities. Services and functions broke down as those who provided them—for example, medical, law enforcement, and fire-fighting personnel—fell victim to the virus. Those people who did not fall to the flu but were incapable of fending for themselves—such as children and the very elderly—risked starvation because primary caretakers died of the flu.⁷ A close study of the societal consequences at the time gives a terrifying picture of what biological warfare or terrorism could do to a people totally unprepared and unequipped—materially, medically, and socially—to deal with such an onslaught.

New Biological Agents

Nature may still offer afflictions just as daunting as the flu of World War I. As researchers probe deep into the tropical rain forests of South America or regions of equatorial Africa where few if any humans have ever walked, new and unknown microbial organisms will be discovered. Some microbes have already made their threat to human society known.

In recent years, viruses responsible for a range of diseases generically called hemorrhagic fevers have gained the attention of researchers at the Centers for Disease Control and Prevention (CDC) and the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID). Some of those viruses, the filoviruses, exhibit unprecedented virulence and lethality. Although

their origin is not in all cases clear, some of them—such as the *Ebola* virus—originated in the Congo.⁸ Such viruses exemplify the extreme risk to human life posed by microbes of unimagined lethality. For nature to unleash such afflictions on humankind is one thing; for man to deliberately do so to himself is nothing short of insanity.

The prospects of biological warfare also include the threat from strains of microbes resistant to antibiotics. In the past few years, resistant bacteria that viciously attack the skin or cause tuberculosis have given medical and pharmaceutical researchers some sleepless nights. Liberal, and effective, prophylactic use of antibiotics since the end of World War II has resulted in resistant strains of bacteria that are now untouchable by some of the most potent and reliable antibiotics. Resistant strains of bacteria appear faster than we can develop and put into service new replacement antibiotics. The tide of the war against infection—begun with the introduction of penicillin at the close of World War II—may be shifting in favor of the microbes. Bioengineering may also permit some renegade group or nation to develop a strain of pathogen that is resistant to our present antibiotic arsenal or exhibits characteristics that mask its identity or presence.

Imagine a hostile nation or terrorist group manipulating the genetic capabilities of microbes in order to make weapons. Bioweapons are a poor nation's substitute for nuclear weapons. Bioweapons are much less expensive to develop and can propagate themselves once released. Bioweapons potentially offer more death for the buck than does any other major weapon.

Unlike nuclear weapons, which generally are large, heavy, and quite difficult for even a few people to transport, bioweapons are small, compact, lightweight, and undetectable by current standard security systems. Any number of common and seemingly innocuous methods for delivering or releasing bioweapons are available. In addition, renegade nations are not necessarily the only players in the bioweapons game. Terrorist

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Concern exists throughout the world that bioweapons present a major threat to health, peace, security, and prosperity.

groups will be forced to become more sophisticated in their plans and operations to survive the increasingly sophisticated surveillance and countermeasures of their targeted nations' intelligence, law enforcement, and military agencies. As bomb "sniffer" devices become more prominent and effective at ports of entry, terrorists will require weapons that do not depend on traditional explosives for delivery and hence are undetectable by such instruments.

Biological agents offer the best alternative and have the added benefit of increased terror when employed. For these and other reasons, concern exists in the Western world, and indeed generally throughout the world, that bioweapons present a major threat to world health, peace, security, and prosperity. For all of those reasons, the world community embarked on an international effort to address the global threat presented by biological weapons and the technology that can spawn them. The purported solution is the BWC.

Present BWC

The BWC is the result of an international effort to address biological and medical research used for both peaceful purposes and the making of weapons. The convention was signed in 1972, was ratified by the U.S. Senate in 1974, and entered into force in 1975. However, the first official U.S. action on biological weapons occurred in November 1969 when President Richard Nixon renounced all biological weapons research and employment by the United States. He did not prohibit U.S. R&D of defenses against biological weapons, such as the production of vaccines. Although the United States was sincere in its renunciation of bioweapons research and employment, the motives of several of the many nations signing the BWC can be questioned. Those countries include Iran, Iraq, the People's Republic of China, North Korea, Libya, and Syria.

The BWC provides for signatories to exchange materials, equipment, and scientific

and technological information for the promotion of peaceful uses of biological R&D (Article X). But the treaty prohibits signatories from stockpiling bioweapons (Articles I-II) and requires those nations to proscribe bioweapons development or possession within their borders (Article IV). The BWC insists that signatories agree to cooperate in prohibiting the transfer, development, and employment of biological weapons, including toxins (Article III). The convention also requires that participating nations assist in investigating allegations of bioweapons R&D or use (Articles V-VII). The original treaty did not include any protocols or procedures for its enforcement. That omission and other concerns have been the focus of numerous international meetings since 1975.⁹

The major focus of the discussions on enforcement has been inspections and procedures. The proposed scope and mechanics of inspections are approaching consensus and final adoption. Many of the proposed details are beyond the scope of this study. The issues addressed in this paper are whether such inspections will ensure compliance with the BWC and whether the proposed inspection protocols are constitutional.

Strengthening the BWC Enforcement Measures

Proposals to strengthen the BWC have three main features. The first is a declaration process in which biotechnology companies and government laboratories provide information on such matters as their activities and equipment and the biological materials they use. The second feature is inspection and investigation regimes of varying levels of intrusiveness that arise from the declarations or from accusations of violation of the BWC. The third element consists of supporting documents collected from the inspected facility and in some cases retained by the inspecting team and the organization that administers the BWC.

Generally, the essential enforcement mechanisms of the BWC are mandatory dec-

larations about facilities and activities of greatest concern to the BWC signatories, including information on past and present activities, equipment, and types of biological organisms on site; “nonchallenge” visits that are either random (visits to declared facilities intended to verify, as needed, the declarations) or focused (visits to declared facilities to clarify inconsistent declarations); and facility and field investigations in response to any compliance concerns that may arise.¹⁰ The kinds and numbers of visits have been in some flux as the discussions on strengthening the BWC have proceeded. Possible triggers for visits may include past offensive or defensive biological programs, current defensive programs, vaccine production facilities, facilities with stringent safety requirements (Biosafety Level-4 facilities), any R&D programs with listed biological agents of concern, and nonvaccine production facilities.¹¹

Disadvantages of the Proposed BWC Enforcement Measures

Medicinal development, as a component of the biotech industry, relies heavily on the very technology that is critical to bioweapons R&D. Medicinal development entails the use and growth of various microbes including many dangerous—if not hyperlethal¹²—viruses, the use of DNA recombinant¹³ research techniques, and genetic marking and isolation technologies. Dual-use technology is not unique to biological R&D. The same problem exists in chemical and nuclear R&D. Despite attempts to limit nuclear weapons capability to the nations on the U.N. Security Council, more nations now have that capability (India and Pakistan demonstrated their full use of dual-use nuclear technology in 1998). If anything, commercial applications of biotechnology are even more interwoven with military applications than are applications in the chemical or nuclear industries. Any competent biological scientist with the knowledge, the equipment, and an acquiescent government can branch

out into bioweapons R&D. Biological technology is a double-sided technology, its dual-use nature serving either good or evil. The difference between medical use and use as a bioweapon may be a matter of the difference between a syringe and an aerosol dispenser. The difference also rests on which nation may be doing the R&D.

Inspections under the BWC Will Probably Be Ineffective

There are disadvantages to the seemingly well intentioned efforts to target lawless elements that are seeking to develop or may be developing bioweapons. The dual-use nature of the technology in the biomedical, biotechnology, and pharmaceutical industries can create a view of the industry that involves “guilt by association.” Certainly in undemocratic, rogue nations the suspicion that arises may be reasonably well founded. In some hostile countries weapons facilities may masquerade as civilian facilities—such as pharmaceutical plants. Arguments can be made that such facilities should be inspected. The inspections are intended to assure the international community that no bioweapon R&D programs are being conducted. Yet so fine a line exists between biomedical research for the development of medicines and that for the development of bioweapons that careful scrutiny—though reasonably sought—may be uninformative.

According to Amy E. Smithson of the Stimson Center, the detection and determination of violations are going to be very difficult.¹⁴ The very nature of dual-use equipment—equipment that can be easily converted from the production of commercial items to the production of bioweapons and back again—makes the success of short-notice inspections suspect. Routine, daily practices of cleanliness at pharmaceutical firms can, in a few hours, virtually erase any meaningful evidence of bioweapons activities. Those practices are often required by various government regulatory agencies—in the United States, at both the state and federal levels—for health and safety reasons. Thus, daily health and safety procedures are impediments to the inspection’s discovery of untoward activities. The problems encountered

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during the inspections conducted by the U.N. Special Commission (UNSCOM) in Iraq speak volumes about the problems of inspecting thousands of facilities worldwide.

Inspections Could Compromise Sensitive Business Information

To be sure that no untoward activities are occurring, inspection of the target facility's activities must be thorough and penetrating. Any exception compromises the inspection's intent and efficacy. Such rigorous inspections raise the potential for compromising confidential business information (CBI) that is needed to compete in the global biotechnology market. Thus, the potential exists for an inspector to also be an industrial spy. According to a briefing paper on the BWC by Malcolm R. Dando, "It also seems that the negotiators are most unlikely to propose anything other than a professional inspectorate with clear loyalty to the BTWC organization."¹⁵ But the allegations of national spying under the cover of UNSCOM inspections in Iraq seemed to indicate that the first loyalty of at least some inspectors was to their national governments. Dando further asserts, "Only by utilizing a professional inspectorate can maximum protection of confidential information be assured."¹⁶ But the spies in UNSCOM were professional weapons inspectors.

Inspections in Iraq: A Case Study in Ineffectiveness

The limited prospects of success of the protocols for inspections and investigations under the BWC can be seen by examining the UNSCOM inspections of Iraq's R&D programs for bioweapons. In April 1991 Iraq officially declared the absence of any biological weapons (a declaration required under the BWC). Between 1991 and 1995 UNSCOM inspection teams could not find any evidence of an Iraqi bioweapons program—despite fears and vague intelligence provided by suspicious governments.¹⁷

In 1995, after Saddam Hussein's son-in-law defected and revealed the existence of a bioweapons program, Iraq finally admitted

that such R&D was under way. As noted by Graham Pearson, "Biological investigations have, even after the admissions by Iraq and despite more than 35 inspections, never seen a filled BW weapon or bulk agent." Iraq then asserted that bioweapons had been destroyed but could offer no verifiable evidence.¹⁸ Yet, if agents were destroyed, none would probably remain for detection. In addition, the inspectors felt that the absence of paperwork was a problem. But even reams of paperwork recording destruction would not necessarily guarantee compliance.

Tripwire Concerns—Recipes for Industrial Espionage

In January 1999 reports surfaced that Saddam objected to U.S. inspectors on the UNSCOM inspection team because they were spies. That charge may have held more than a grain of truth.¹⁹ Subsequent press reports indicated that UNSCOM inspectors, or personnel passing as UNSCOM inspectors, were planting electronic eavesdropping devices in Iraqi facilities and gathering intelligence information on major Iraqi military and intelligence organs, such as the infamous Republican Guard. What was truth and what was fiction remains to be sorted out.

What is clear is that an inspector of nation X can—during the course of his inspections—also gather information useful to his home government or a company that wants to know what the competition is doing. Considerable sums of R&D money can be saved by agents simply asking the right questions, reading the right documents, or gathering the right samples—all under the guise of a legitimate internationally sanctioned inspection conducted to ensure peaceful biomedical R&D. For U.S. biotechnology and pharmaceutical companies, international on-site inspections under the BWC harbor major risks of compromising sensitive, but legitimate, industrial secrets. This problem is especially troublesome for U.S. firms because they are often the world's leaders in developing new biotech products. Certain declarations or events—that is, tripwires—would catalyze various BWC inspections or

investigations of a state or of one of the facilities on its territory.

Mass outbreaks of disease in a region or nation would serve as a tripwire for massive investigation and inspection of a state or of biotech facilities in the surrounding area. The assumption would be that such an outbreak was probably unnatural and could have arisen only as a result of noncompliant bioweapons R&D that was accidentally exposed. But that scenario is only one possibility. In this age of travel and mobility, particularly in the wealthy nations, outbreaks of disease may also be the result of rapid natural inoculation of the public. The influenza outbreak at the end of World War I would certainly be a tripwire under today's BWC. Because the pandemic occurred during a war at a time that a major combatant, Germany, was losing, the outbreak might be regarded today as a probable use of bioweapons. Alternatively, the fact that the pandemic started in the United States and spread rapidly around the world could be regarded as *prima facie* evidence that the United States was engaged in a bioweapons R&D program that went out of control. Yet the outbreak was seemingly natural in origin and scope.

Programs to develop vaccines also are proposed as tripwires for BWC inspections and investigations. Single-site, multiple-site, and large-capacity facilities for the production of large quantities of vaccines are automatically viewed as suspect and are subject to inspection. Given the large populations of many countries, extensive vaccination programs might be needed. Such large programs would come to the attention of the BWC organization through declarations. Thus, a comprehensive vaccination program initially could be viewed as suspect and justify inspections on an as yet undetermined level. The vaccination of American children against poliovirus in the 1950s would likely have triggered an investigation under the BWC.

Of the four levels of containment for biological agents, Biosafety Level-4 is the most secure and critical.²⁰ In the modern biotechnology era, BL-4 facilities understandably

raise eyebrows because they are where the most virulent, lethal, or contagiously airborne pathogens are studied. Any virus of significant virulence or lethality will no doubt be studied in a BL-4 facility. The unique biological characteristics of viruses make them the most potentially dangerous of all microbes. The declaration of a BL-4 facility (and perhaps in some cases a BL-3 facility) is a tripwire for automatic scrutiny under the proposed BWC protocols. Yet BL-4 facilities are of such a nature that not just anyone—not even an inspector—may have access to them. New personnel at those containment facilities require considerable extra training in the protocols for the site. Such training is not performed in one day or by reading a policy manual a few hours before entering the facilities. Given the extreme danger of sampling or examining the agents, equipment, and storage facilities, inspections would only increase the risks of serious accidents. BL-4 facilities are prominent features of U.S. government labs, such as those at the CDC and USAMRIID. The presence of BL-4 facilities at government or private research installations seems to subject them to instant “guilt by association” in any declaration process.

The U.S. Biotechnology Industry Has Much to Lose

Loss of corporate secrets has serious economic consequences for the United States, as well as the company involved. Table 1 gives the economic contribution made by the biotechnology industry to the U.S. economy and employment in 1996 and 1997. Although the economic contribution of the industry is significant, such statistics fail to reflect its contribution to American health and standard of living.

The pharmaceutical industry is hotly competitive. The investment of much money and time is required to develop a drug. According to figures released by the governing associations of the biotech and pharmaceutical manufacturers, the U.S. biotech

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Table 1
Selected Characteristics of the U.S. Biotechnology Industry

Year	Companies	Employees	R&D Expenses	Sales	Revenues	Capitalization
1996	1,287	118,000	\$7.9	\$10.8	\$14.6	\$83
1997	1,274	140,000	\$9	\$13	\$17.4	\$93
% change	-1%	19%	14%	20%	19%	12%

Source: Pharmaceutical and Manufacturers' Association, *1998 Industry Profile*, www.phrma.org.
 Note: Dollar amounts are in billions.

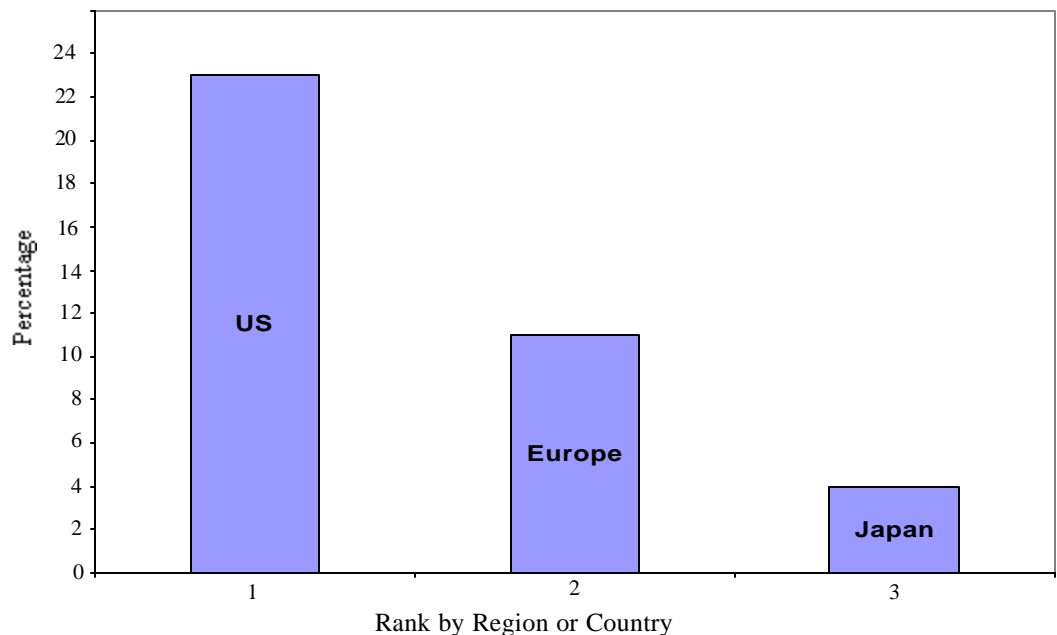
industry is by far the leading participant in the global industry of drug development. U.S. preeminence arises from U.S. patent laws and other safeguards for intellectual property. Given the importance of intellectual property in a modern economy, that property must be protected and defended as carefully as land and factories.

U.S. firms are the unquestioned leaders in bringing new drugs to the world market. Figure 1 shows the percentage of new drugs entering the international market from the

major regions of the world from 1980 to 1995. The United States claimed some 23 percent of the world market, Europe about 11 percent, and Japan about 5 percent. Figure 2 shows the distribution among major nations of worldwide company-financed R&D in the pharmaceutical industry. About 36 percent of all R&D conducted worldwide in 1995 was performed in the United States.

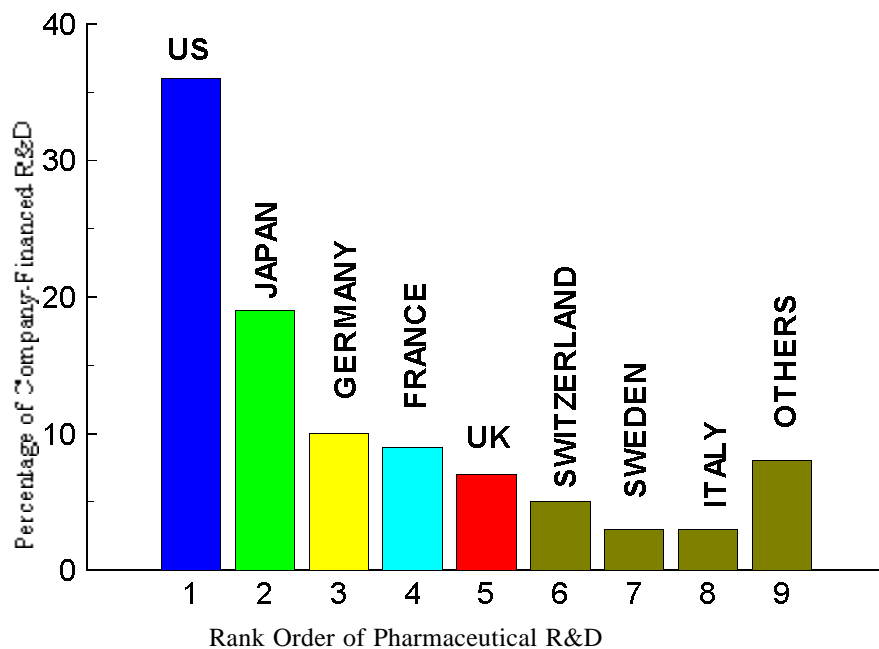
Some countries disregard the intellectual property rights of U.S. individuals and companies—for example, in the recording and

Figure 1
Percentage of New Medicinals Gaining International Standing, by Company Nationality, 1980–95



Source: Pharmaceutical Manufacturers' Association, *1998 Industry Profile*, www.phrma.org.

Figure 2
Percentage of Company-Financed Pharmaceutical R&D, 1995



Source: Pharmaceutical Research and Manufacturers' Association, *1998 Industry Profile*, www.phrma.org.

publishing industry. Foremost among those countries is China.

According to an industry profile issued by the Pharmaceutical Research and Manufacturers' Association (PhRMA), U.S. biotech and pharmaceutical companies are concerned about the security of their intellectual property rights and proprietary secrets. One hundred percent of U.S. firms replying to a question on the influence on business decisions of the confidentiality of business information consider intellectual property protections pivotal in any R&D investment decision (Figure 3).

The U.S.-based biotechnology business must retain the security of its corporate secrets and intellectual property. Thus, the security of CBI is a critically important consideration in any implementation of inspection protocols. Allowing inspections by international agents, who bear allegiance to the parochial interests of governments or companies of other nations, runs the risk that security within U.S. biotech corporations will be jeopardized. Assurances that no espionage-

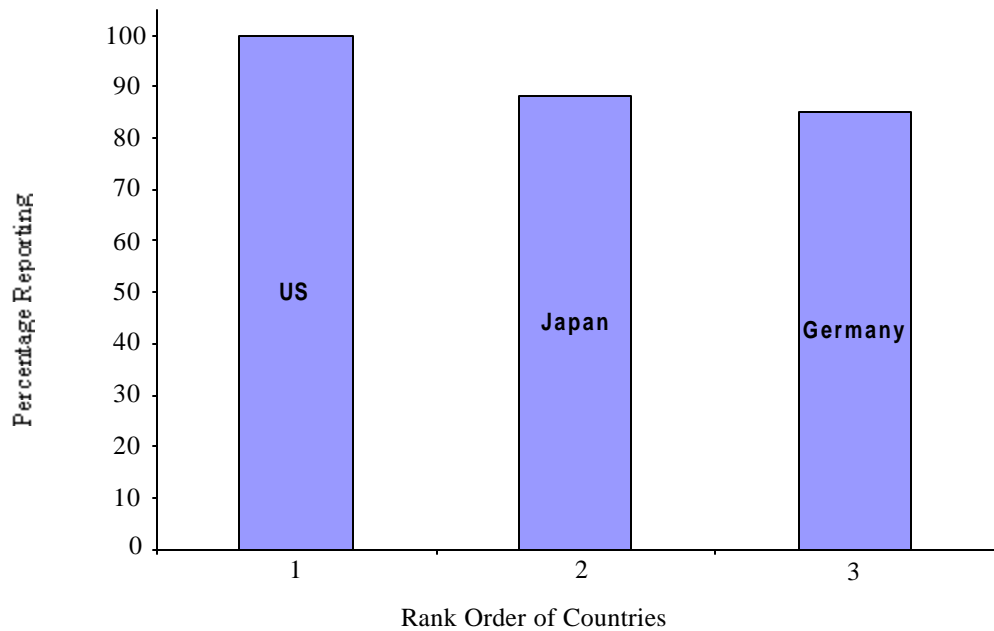
like activities will be a part of inspections for compliance with the BWC have no credibility, especially given the revelations of U.S. spying on Iraq during UNSCOM inspections.

Biotechnology Sector View of BWC Enforcement Measures

A position paper on BWC inspections issued by PhRMA seems to reflect political considerations. It begins by conceding, "The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty." But on the next page, the paper notes, "PhRMA is skeptical that any site inspection can detect a violation of the BWC."²¹ PhRMA acknowledges that inspections bring with them onerous implications. First, there is the very real risk of compromising the CBI on which corporate

For U.S. biotechnology and pharmaceutical companies, international on-site inspections under the BWC harbor major risks of compromising sensitive industrial secrets.

Figure 3
Influence of Intellectual Property Protection on Investment Decisions of Pharmaceutical Companies



Source: Pharmaceutical Research and Manufacturers' Association, *1998 Industry Profile*, www.phrma.org.

The consumer will pay a large part of the expenses for enforcing the BWC.

success rests. Second, accusations and resulting inspections place corporate reputations at risk. Third, compliance with inspection visits and all that attends them will result in increased regulatory costs borne by the business. And fourth, all those increased costs will be applied to the products sold in the marketplace. Thus, the consumer will pay a large part of the expenses for enforcing the BWC.

PhRMA asserts that any process that seeks to clarify declarations or omissions should not require on-site inspections or the production of CBI. (One proposed provision of the declarations process asserts that no CBI is required in the declarations.)²² Thus PhRMA opposes any form of nonchallenge visits. Yet it asserts that any unusual outbreak of disease, evidence of BWC violation, or evidence of bioweapons use may justify international on-site challenge inspections.

PhRMA's support for inspections under

some circumstances—coupled with its skepticism that any site inspection can detect a violation of the BWC and its insistence on safeguards to prevent capricious inspections and the disclosure of CBI—leads to the suspicion that PhRMA may be responding to U.S. government pressure to strengthen the BWC.

The Biotechnology Industry Organization (BIO) expresses concern about unjustified claims directed against U.S. facilities on politically motivated grounds and the harm to reputations that may follow. BIO also recognizes that inspectors most likely will have experience in the biotech field and will recognize CBI. But the source of any compromised CBI will be impossible to prove. Like PhRMA, BIO views routine visits as useless and ineffective for determining BWC compliance and international on-site challenge inspections as justified in the event of an unusual outbreak of disease.²³

U.S. Government Responsibilities

The U.S. government enters into treaties and agreements and enforces them as it would the domestic law of the land. Part of the government's responsibility is to ensure that international agreements do no harm to American interests—among them the economic fortunes of its people and businesses (including its growing biotechnology industry).²⁴ But how realistic is it to harbor confidence in U.S. resolve to adequately police international inspections of U.S. biotech firms and back strong measures designed to protect U.S. CBI from any potential abuses of access by BWC inspectors?

Although the Constitution does not use the words “company,” “business,” “corporation,” or “firm,” such entities generally enjoy many of the same protections as individuals do under the U.S. Constitution. Thus, the requirement for a warrant ordinarily applies if an American business is to be searched (although some heavily regulated businesses are supposedly protected by administrative procedures that serve as substitutes for warrants).²⁵

Problems with BWC Inspections

International inspections under the BWC present several problems:

- The basis of probable cause for a BWC inspection targeting a U.S. biotech company is unclear. A company that merely engages in R&D on microbes, recombinant DNA, or toxins could be targeted. The guilt by association principle may be sufficient and justifiable grounds for launching an inspection. An anonymous “tip” might be sufficient. Should an accusation by an informant nation be taken at face value? What constitutes credible evidence is in question. All of those issues lead to the conclusion that amorphous and ill-defined inspection power could pose a danger to U.S. firms.
- For the inspections to have any value in ensuring that no bioweapons-based R&D is practiced by any state or company, the inspectors must have unlimited and complete access to all records, labs, and personnel (as supposedly was the case in the UNSCOM inspections of Iraq).²⁶ That access could compromise legitimate CBI. An inspector could demand to see records that he insists—relying on the word of an “anonymous informant”—are on site and show covert bioweapons R&D.
- It may be hard for a company to protect legitimate secrets of product R&D from compromise by unauthorized people. BWC inspectors certainly would not be cleared by a corporation to have unbridled access to proprietary information. A company could not be confident that legitimate R&D information would not be transmitted deliberately or accidentally to foreign nations or competitors. The Chemical Weapons Convention (CWC) has no provisions holding inspectors or the Organization for the Prohibition of Chemical Weapons legally liable for damages pursuant to a compromise of CBI.²⁷ Although domestic law holds U.S. officials and agencies accountable for the compromise of CBI as a result of fulfilling reporting requirements of regulatory laws,²⁸ compromises in good faith cannot be legally challenged.²⁹ Disclosure of CBI to fulfill treaty or other international obligations is permissible.³⁰ Realistically, U.S. businesses are not protected from the compromise of CBI by foreign agents or international organizations because of the diplomatic status they enjoy.³¹
- A U.S. biotech firm may have little international recourse if it has reason to suspect or can show that BWC inspectors disclosed its R&D information to unauthorized parties. The U.S. firm may simply be out of luck when trying to obtain compensation for technology stolen during BWC inspections.

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If any inspections of U.S. companies are to be tolerated, they should be only compelled, challenge inspections.

- Inspections of U.S. firms under the BWC may be unconstitutional unless search warrants are required to be obtained. The Fourth Amendment to the U.S. Constitution protects individuals and businesses against unreasonable searches. Ordinarily, a search warrant is required, and it can be issued only on a showing of probable cause that illegal activity occurred. Each such warrant must describe the place to be searched and the persons or things to be seized.
- If inspections of domestic corporations are performed by U.S. nationals on behalf of international BWC agents, the first bullet is again applicable.

Recommendations to Address the Problems

To address those problems, the U.S. government should take the following actions:

- Closely examine existing U.S. laws and proposals for BWC enforcement protocols to ensure compliance with the Bill of Rights. The Supreme Court has never declared a treaty ratified by the U.S. Senate unconstitutional.³² But the recent CWC and the proposed BWC protocols may offer the first opportunities to do so on the basis of Fourth Amendment principles.

The CWC regime allows for inspections of business premises and of private residences.³³ Warrantless inspections are allowed with a minimum evidentiary burden.³⁴ In ratifying the CWC, the Senate imposed a requirement for warrants for all nonconsensual inspections.

If the protocols to enhance enforcement of the BWC are ratified by the Senate, the same requirements should apply to BWC inspections. Concern about the meaning of an inspection is important. Do inspections constitute searches?³⁵ Under the principle of expectancy of privacy, inspections may be regarded as searches—and thus require warrants. As Thurgood Marshall

opined, “The power to exclude has traditionally been considered one of the most treasured strands in an owner’s bundle of property rights.”³⁶

- Strengthen U.S. legal statutes concerning corporate CBI. A national commercial security version of the national security laws is needed to ensure that corporate CBI remains secure from foreign discovery and dissemination. In a global economy, secure CBI is every bit as critical to the national well-being as secure military information. CBI takes on great economic importance in today’s world.
- Prohibit routine, nonchallenged, or “soft public relations” inspections. If any inspections of U.S. companies are to be tolerated, they should be only compelled, challenge inspections. The inspections should be conducted by U.S. officials who are armed with warrants issued in accordance with the principles of the Fourth Amendment. Even then, strict adherence to CBI protections is a must.
- Improve U.S. human intelligence methods for detecting the development of unconventional weapons by terrorist groups or rogue states. Former director of central intelligence John Deutch effectively pointed out the importance of such intelligence: “In confronting proliferation, the first task of intelligence is to discover the hidden plans and intentions of countries of concern well before we have to confront the devastating power of the weapons themselves.”³⁷
- Exercise military restraint overseas. U.S. military intervention raises the profile of the United States as a target for attacks by rogue states or terrorists using biological weapons. The United States should intervene overseas only when its vital interests are at stake. Such military restraint would lessen the risks of a biological attack on the United States.³⁸

Conclusion

Fundamental problems exist with enforcement regimes proposed for the BWC. Rogue states (for example, Iraq, Iran, North Korea, and Syria) can easily thwart the enforcement regime. A rogue state is unlikely to declare that it has a bioweapons R&D program currently in place. U.S. laws concerning bioweapons R&D are cited as examples on which other countries may model their laws to comply with the BWC. But is one to assume that if Iraq enacted tough U.S.-style laws against bioweapons R&D, that would obviate any concern over Iraqi aspirations to have biological weapons and the need for closer scrutiny of Iraqi facilities?

If sensitive areas of a facility and sensitive or proprietary documents are opaque to inspection under the confidentiality provisions of the protocols, then inspectors essentially have only the word of the inspected facility. Logic dictates that any bioweapons R&D areas and documents will be declared confidential and out of bounds to inspectors. Rogue states will certainly seek to conceal their activities behind rules on confidentiality.

The membership of rogue states in the BWC regime is suspect in light of intelligence reports of their desires and efforts to pursue bioweapons R&D. One of their motives for remaining in the BWC may be to gather intelligence information on civilian biotechnology methods and technical know-how to complement their own ongoing bioweapons R&D efforts. George H. Quester of the Stimson Center made a statement about inspections of nuclear facilities that could easily be made about bioweapons: "Letting the world view nuclear facilities can help reassure nations that nuclear weapons are not being produced, but it also might help additional nations produce such weapons sooner and more easily, depending on the specific ground rules governing inspections."³⁹

The collection of data under the BWC could lead to excesses. The requirement that each participating state establish a "National Authority whose responsibilities will include

the collection of national data and information for declarations and submit these declarations to the BTWC Organization"⁴⁰ will necessitate yet another U.S. government bureaucracy. If a national authority is to be in the middle, why subject domestic companies to inspections by the BWC bureaucracy? In particular, the United States should oppose any compilation by the BWC bureaucracy of biotech staff, skills, education, and specialties. Such lists, which serve no compliance purpose, identify individuals for no legitimate reason. The compilation of such data further casts the researchers as suspect.

Also, inspections may be unfair. Designating BL-4 facilities (necessary for biomedical studies of very lethal, airborne pathogens) as suspect and subject to automatic inspections—routine or challenge—establishes guilt by association, an unreasonable basis for probable cause. Thus, inspections may also run afoul of the Fourth Amendment to the U.S. Constitution.

Since the early 1980s, public safety has been invoked many times by both state governments and the federal government as justification for abridging the Fourth Amendment rights of the people—for example, roadblock checks for drunk drivers, random (and not so random) drug testing, systematic searches of citizens in specific regions of New York City for weapons, increased warrantless searches at airports, and wiretaps to "thwart" airport terrorism. The courts seemed oblivious to the fact that there was no probable cause or suspicion (beyond personal appearance) that the people searched had committed crimes. As is the case with the CWC, the enforcement of the BWC portends routine violations of the Fourth Amendment rights of businesses. The proposed strengthening of the BWC, like that of the CWC, is being justified with the public safety incantation combined with the international security mantra.

The future of the right to be secure in one's possessions and personal effects is indeed in peril. As dangerous as an attack on the United States with biological weapons is, an assault on U.S. constitutional rights in an

Rogue states can easily thwart the enforcement regime.

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effort to strengthen an international convention that has little hope of stopping the spread of those weapons is even more worrisome. As Justice Louis Brandeis once said, "The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."⁴¹

The attempt to strengthen the BWC—like the CWC and the Nuclear Nonproliferation Treaty—is a feeble attempt to reconfine the loosed demons of Pandora's Box.⁴² The worldwide dispersion of scientific knowledge guarantees they will remain at large.

In the meantime, the government and the medical services community must address the level and severity of potential bioterrorist threats and the response to bioattack, and the general public must be educated. The February 1999 National Symposium on Medical and Public Health Response to Bioterrorism may have been a start in the right direction.⁴³ Instead of undertaking "feel-good" efforts to strengthen an international convention that will not stop the proliferation of biological weapons and will probably lead to the compromise of proprietary biotech information, the U.S. government should reduce its profile as a target for biological weapons by limiting overseas interventions and enhance domestic preparedness against attack.

Notes

1. Graham S. Pearson, *The Threat of Deliberate Disease in the 21st Century*, www.stimson.org/pubs/cwc/cbw2.pdf or www.brad.ac.uk/acad/sbtwc/other/disease.html, gives a listing of likely biological pathogens and characteristics.
2. Eric R. Taylor, *Lethal Mists: An Introduction to the Natural and Military Sciences of Chemical and Biological Warfare and Terrorism* (Commack, N.Y.: Nova, 1999), chap. 1.
3. Some writers on biological warfare argue that it was not practiced in Vietnam. I take exception to that view. The general definitions of biological warfare do not allow for a qualification of the delivery method as part of the definition. *Pungi* sticks were the delivery means and any septic material thereon was the weapon.
4. William H. McNeill, *Plagues and Peoples* (Garden City, N.Y.: Anchor/Doubleday, 1976), p. 168.
5. History Net, www.thehistorynet.com/cowles/link/picture/0721.html.
6. S. Sternberg, Science News Online, March 22, 1997, www.sciencenews.org/sn_arc97/3_22_97/fob1.html.
7. Eileen A. Lynch, *Pennsylvania Gazette*, www.upenn.edu/gazette/1189/lynch2.html.
8. Richard Preston, *The Hot Zone* (New York: Anchor Books, 1994), gives an excellent glimpse of the world of virus hunters and the methodology for tracking and dealing with very lethal viruses.
9. An excellent initial source for documents and working papers from the BWC Ad Hoc Group meetings is www.brad.ac.uk.
10. Graham S. Pearson, "The Protocol to Strengthen the BWC: An Integrated Regime," Department of Peace Studies, University of Bradford, U.K., reproduced with permission of the Sixth International Symposium on Protection against Chemical and Biological Warfare Agents, Stockholm, May 11–15, 1998, www.brad.ac.uk/acad/sb_twc/other/regime.html.
11. Graham S. Pearson, "Strengthening the Biological Weapons Convention," Briefing Paper no. 16 of the BTWC Protocol Implementation: Practical Considerations, Department of Peace Studies, University of Bradford, U.K., October 1998.
12. Examples of *hyperlethal* viruses are the filoviruses such as *Marburg* and *Ebola*—two of the known hemorrhagic viruses. These types of viruses may be studied only in Biosafety Level-4 facilities, such as those of CDC or USAMRIID.
13. DNA recombinant technology involves the localization of a particular fragment of DNA (or the entire gene of a cell), its surgical removal, and its introduction into the DNA of another totally different species of cell. This process is an example of genetic engineering.
14. Amy E. Smithson, *Man versus Microbe: The Negotiations to Strengthen the Biological Weapons Convention*, www.stimson.org/pubs/cwc/cbw6.pdf.
15. Malcolm R. Dando, "The Strengthened BTWC Protocol: Implication for the Biotechnology and Pharmaceutical Industry," Briefing Paper no. 17, Department of Peace Studies, University of Bradford, U.K., October 1998, para. 23, www.brad.ac.uk.

16. *Ibid.*
17. Graham S. Pearson, "Implementing Article X of the BTWC: Avoiding Duplication," *Chemical Weapons Convention Bulletin, Quarterly Journal of the Harvard Sussex Program on CBW Armament and Arms Limitation*, no. 32 (July 1996): 7.
18. *Ibid.*, p. 8.
19. BBC News, March 23, 1999, http://news.bbc.co.uk/hi/english/world/middle_east/newsid_
20. For a complete description of the four biosafety levels and their differences, see Centers for Disease Control and Prevention, www.cdc.gov/od/ohs/biosfty/bmbl/sectio3.html; National Institutes of Health, www.nih.gov/od/ors/ds/pubs/bmbl/sect2.html#part4; or University of California at San Diego, *Biosafety Handbook*, www.ehs.ucsd.edu/bio.html.
21. Pharmaceutical Research and Manufacturers' Association, "Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention," provided March 1999, pp. 1, 2.
22. Pearson, "Strengthening the Biological Weapons Convention," para. 5.
23. "U.S. Pharmaceutical and Biotechnology Industries White Paper on Strengthening Biological Weapons Convention," March 1999, personal correspondence from Alan R. Goldhammer, executive director of technical affairs, Biotechnology Industries Organization.
24. For a concise definition of "vested American interests," see Eric R. Taylor, "In the Name of the People: World Policing and Anti- and Counterterrorism," Paper presented at Fourth Annual Colloquium on Values, Graduate School of the University of Southwestern Louisiana, October 28, 1998.
25. Jonathan P. Hersey and Anthony F. Ventura, "Challenging Challenge Inspections: A Fourth Amendment Analysis of the Chemical Weapons Convention," *Florida State University Law Review* 25 (1998): 570-629; Robert F. Greenlee, "Comment: The Fourth Amendment and Facilities Inspections under the Chemical Weapons Convention," *University of Chicago Law Review* 65 (1998): 943-79; and Ronald D. Rotunda, "The Chemical Weapons Convention: Political and Constitutional Issues," *Constitutional Commentary* 15 (1998): 131-59.
26. In the final analysis, the degree of insistence and intrusion may be more a function of the target nation and its ability to militarily resist or challenge inspections and of the international composition of the inspection teams than of any specifically mandated BWC treaty provisions.
27. Barry Kellman, David S. Gualtieri, and Edward A. Tanzman, "Disarmament and Disclosure: How Arms Control Verification Proceeds without Threatening Confidential Business Information," *Harvard International Law Journal* 36 (1995): 71-126.
28. *Ibid.*; 18 U.S.C. § 1905 (Supp. V 1993); 7 U.S.C. § 136h(b)(1994); 15 U.S.C. § 2613(a) (1994); and 42 U.S.C. § 7414(c) (1994).
29. Kellman, Gualtieri, and Tanzman; and 28 U.S.C. § 2680(h).
30. Kellman, Gualtieri, and Tanzman; and 10 C.F.R. § 2.790(b)(5).
31. Vienna Convention on Diplomatic Relations and Protocols, April 18, 1961, Arts. 29, 30(2), 31(1)(2), 38(1), 39(1)(2).
32. Greenlee, p. 943.
33. *Ibid.*, p. 966; Kellman, Gualtieri, and Tanzman, p. 74; Rotunda, p. 142; and Hersey and Ventura, pp. 600, 615.
34. *Ibid.*, pp. 582, 607, 617; and Greenlee, p. 964.
35. *Ibid.*, pp. 944, 952, 958.
36. Quoted in Rotunda, p. 148.
37. John M. Deutch, "Worldwide Threat Assessment," Brief to the Senate Select Committee on Intelligence, March 22, 1996.
38. For more on this argument, see Ivan Eland, "Protecting the Homeland: The Best Defense Is to Give No Offense," *Cato Institute Policy Analysis* no. 306, May 5, 1998; and Ivan Eland, "Does U.S. Intervention Overseas Breed Terrorism? The Historical Record," *Cato Institute Foreign Policy Briefing* no. 50, December 17, 1998.
39. George H. Quester, "International Safeguards for Eliminating Weapons of Mass Destruction," Henry L. Stimson Center Occasional Paper no. 31, December 1996, p. 15, stimson.org/pubs/zeronuke/quester.pdf.
40. Pearson, "Protocol to Strengthen the BWC."
41. *Olmstead v. United States*, 277 U.S. 438, 479 (1928).
42. The Nuclear Nonproliferation Treaty did not thwart Pakistan's or India's development of the nuclear bomb from dual-use technology. Neither will the BWC or the CWC prevent development of chemical or biological weapons.

43. The National Symposium on Medical and Public Health Response to Bioterrorism, February 16–17, 1999, in Arlington, Virginia, was sponsored by the Johns Hopkins University, the U.S. Department of Health and Human Services, the Infectious Diseases Society of America, and the American Society of Microbiology.

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