

Biological Weapons Proliferation: Reasons for Concern, Courses of Action

Industry's Role, Concerns, and Interests in the Negotiation of a BWC Compliance Protocol

Gillian R. Woollett, M.A., D. Phil.

The companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) support reducing the threat of biological weapons. PhRMA, described in more detail in Box 1, is a trade association representing companies that develop over ninety percent of the new medicines used around the globe. For the past couple of years, PhRMA has been working with the US and other governments, as well as with colleagues in industry, to create a compliance protocol to the 1972 Biological Weapons Convention (BWC) that is based on sound and rational science. The research-based pharmaceutical industry is only too aware of the challenges in preparing medicines to cure devastating infectious diseases, and this industry is a strong proponent of the prevention of biological weapons use. A good compliance protocol will give legitimate confidence to the international community that the threat from biological weapons is reduced and, as such, will represent a valuable contribution to meaningful arms control worldwide. The technical expertise of PhRMA companies is available to facilitate this process wherever the negotiators need assistance.

An oft-heard refrain is that the pharmaceutical industry has nothing to fear from a BWC compliance protocol that is devised to find treaty violators. While no PhRMA company is making biological weapons, the industry recognizes that many of the technologies that it uses to develop new drugs and biologics could be used to make biological agents with little or no modification to equipment or processes. Of necessity, the pharmaceutical industry uses technology in a highly sophisticated manner, with processes designed to enhance the purity, consistency, and safety of medical products.

These dual-capability technologies, which include the rapidly emerging biotechnologies, are not unique to the pharmaceutical industry. To varying degrees, these technologies are found in such industries as brewing, industrial fuel manufacturing, cheese and yogurt production, baking, and also extensively in academic and government research laboratories. The production capacity of these other industries and establishments vastly exceeds that of the pharmaceutical industry. Capability is a legitimate requirement for the manufacture of biological weapons. However, PhRMA contends that this capability is so widely spread throughout many industries and other legitimate endeavors that it does not make sense to over-emphasize, and thereby over-implicate, the capability of the pharmaceutical industry in a new compliance protocol. In other words, capability will be necessary, but not sufficient, to identify an illegal biological weapons program.

On 16 May 1996, PhRMA's Board adopted the following statement of principle on the BWC:

Box 1: An Overview of PhRMA.

PhRMA is the leading trade group of the research-based, ethical pharmaceutical industry in America. A list of PhRMA's members can be found in Appendix 2. PhRMA represents the pharmaceutical companies that discover, develop, and manufacture prescription drugs and biologics. PhRMA companies develop over ninety percent of the new medicines worldwide. PhRMA's mission is to facilitate the industry's ability to successfully meet its goal of discovering, developing and bringing to market medicines to improve human health, patient satisfaction, and the quality of life around the world, as well as to reduce the overall cost of health care. Hence, PhRMA does represent the pharmaceutical industry and its contribution to the debate on a compliance protocol to the BWC.

While many PhRMA companies are American, many are also multi-national and have their headquarters overseas. The pharmaceutical industry is increasingly made up of large companies with a global presence for their research and development activities, for product manufacture, and also for their ultimate retail markets. The interests of the US pharmaceutical industry reflect similar opinions and concerns of sister companies in Europe and elsewhere.

PhRMA supports the international goals and objectives of the Biological Weapons Convention. Classical microbiology and the newly emerging biotechnologies have enabled, and will continue to enable, many new health care products to be developed. Their development should continue, while appropriate restrictions on the potential misuse of the technologies to create weapons is enforced in a manner which does not expose American industry to the loss of its legitimate competitive trade secrets and other confidential business information.

The challenges of monitoring the BWC are significant: Relatively small and simple facilities are adequate to make biological weapons. In order to fashion a workable monitoring regime, the negotiators of the BWC protocol will need to draw upon real-world experts to gain insight into the capabilities and processes of the biotechnology industry. Accordingly, the role of PhRMA and its member companies in the development of an effective protocol is to explain the possibilities and limitations of the technologies in a manner that can best answer the questions of the international negotiators.

The CWC: Not a Good Model for the BWC Protocol

The Chemical Weapons Convention (CWC), which bans the development, production, stockpiling, transfer, and use of poison gas, entered into force on 29 April 1997. The international community had a strong incentive to conclude this treaty in 1993 because there were no existing prohibitions on the acquisition and manufacture of chemical weapons. This landmark treaty also includes extensive verification measures. The US chemical industry strongly supported the

negotiation and ratification of the CWC. In fact, the US chemical industry offered extensive and constructive assistance to the CWC's negotiators. PhRMA also supported Senate ratification of the CWC, which occurred on 24 April 1997.¹

In contrast, the BWC's ban against the manufacture and stockpiling of biological and toxin agents has been in force since 1974 and has already been ratified or acceded to by 140 countries. With such prohibitions already established, the international community may not be as motivated to conclude a protocol to the BWC. Similarly, the pharmaceutical industry has reasons to perceive the task of negotiating a BWC protocol differently from the manner in which the chemical industry approached the drafting of the CWC. The ban against biological weapons is already in place, and since US pharmaceutical firms are not violating it, they understandably lack enthusiasm for intrusive monitoring procedures that could place their livelihoods at risk.

PhRMA's Position on a BWC Compliance Protocol

As already noted, PhRMA endorses the goal of catching violators of the BWC by creating a compliance protocol. For each monitoring measure proposed for the protocol, however, a cost/benefit analysis must be performed. The pharmaceutical industry and other enterprises around the world that would incur potential costs (e.g., other industries, universities, non-profit and government-funded research institutes) need to be given an opportunity to explain the limitations of any proposed measure and encouraged to suggest alternative means of achieving the specified compliance objective. Governments in various countries will engage industry, some inviting industry's participation more than others. Given the opportunity to contribute to this process, industry and the other affected organizations can offer constructive suggestions based upon their state-of-the-art knowledge. The negotiations could benefit greatly from such contributions.

Definitions

Before something can be looked for, it must be defined. While the definition of biological weapons should not be so precise that it cannot accommodate a minor change in the design or source of the organism, some common definition of what comprises a weapons-grade agent would greatly facilitate the development of a BWC protocol. The pharmaceutical industry is concerned that current definitions are so imprecise that the BWC protocol could become a vehicle to look for anything being done anywhere. These open-ended definitions would seriously complicate the ability of the pharmaceutical industry to protect CBI and the reputation of its companies.

Declarations

PhRMA does not currently support any expansion of the present declarations to encompass

¹ For an explanation of the US chemical industry's views, see Kyle B. Olson, "Why the US Chemical Industry Can Live With a Chemical Weapons Convention," *Arms Control Today* 19, no. 9 (November 1989): 21-5; Testimony of Will B. Carpenter, US Congress, Senate Foreign Relations Committee, *Hearings on the Chemical Weapons Convention*, 103d Cong., 2d. sess., S. Hrg. 103-869, (Washington, D.C.: Government Printing Office, 1994): 88-92. PhRMA joined the Chemical Manufacturers Association and several other industry trade associations advocating US ratification of the CWC.

a larger number of companies or to increase the detail that industry is now being asked to report. PhRMA will reconsider this position if other types of declarations are proposed. A full scientific justification should be the basis of any potential declaration requirement. Moreover, declarations should be unambiguous and administratively simple.

All declarations should be made public if they are to fulfill the aspirations for achieving transparency concerning the BWC. The dissemination of such information, perhaps on the Internet, can increase public confidence in the BWC. This approach also takes into account the fact that no security system can be effective if 140 governments have access to the data in these declarations. Hence, PhRMA does not believe any CBI should be included in any declaration.

On-Site Inspections

PhRMA considers inspections to have a legitimate but limited value in a compliance protocol. The nature and sophistication of current, widely used technologies undermine the ability of an international inspection team to enter a plant and catch the violators before the site has been effectively purged of any evidence of biological agent production. Some form of inspection, however, may be useful to deter potential cheaters. Therefore, inspections may have a role to play in the BWC protocol.

Routine inspections to confirm the accuracy of a facility's declaration would presumably be conducted according to a long-term schedule that enables both the inspectorate and the inspected facility to plan well ahead of the actual "visit." Only declared facilities would be inspected. Long notice could allow a facility's officials to prepare their site to reveal only what they wanted to show to inspectors. Minor infractions may be found, but these would be relatively insignificant to a BWC compliance assessment. For these reasons, PhRMA concludes that the most probable outcome of a routine inspection at one of its companies would be the loss of CBI and damage to a company's reputation. PhRMA believes that routine inspections would be expensive and extremely unlikely to catch significant violators. Therefore, PhRMA opposes the inclusion of routine inspections or visits in a BWC protocol.

Although PhRMA objects to the monitoring approaches that have been proposed thus far, PhRMA would encourage the negotiators in Geneva to develop an alternative to long-notice and validation inspections. One possible approach would have the inspectorate monitor everything coming out of a given facility for a determined period. As appropriate, sampling of final product could be conducted to confirm that these plants are indeed making legitimate peaceful products. If indeed the ultimate concern is to check that a company is really making what it declares, then the output of a facility should be the focus of inspections.

With certain constraints, short-notice challenge inspections are the only form of inside-the-fence inspection that PhRMA supports. Since the US pharmaceutical industry is not involved in the development or production of biological agents, PhRMA assumes that any allegation against a US firm will be politically motivated. Therefore, the BWC protocol must be structured to protect sites from frivolous or malicious challenge inspection requests. Specific safeguards are necessary to prevent the abuse of challenge inspections. For instance, the state requesting a challenge inspection

must provide substantial and convincing evidence to support a charge concerning the development, production, or stockpiling of biological agents or evidence of their alleged use. An unusual outbreak of disease that could represent inadvertent release of a biological agent could also be evidence of a contravention of the BWC. A “green light” process should also be instituted, wherein the requesting state must persuade a three-quarters majority of the BWC’s executive governing body of the validity of the allegation before a challenge inspection proceeds.² PhRMA considers the green light approach essential to protect industry from inherently damaging allegations. Finally, no representatives from the nation requesting the challenge inspection should be on the inspection team. PhRMA advocates the employment of full-time professional inspectors, not *ad hoc* inspectors chosen from a roster of consultants.

Technology Transfers

Some delegations at the BWC negotiations advocate the activation of mandatory provisions to share technology, equipment, and know-how under the auspices of Article X of the treaty.³ The US pharmaceutical industry does not support changes in import and export controls to facilitate the transfer of US biotechnology to other countries. Such transfers could require PhRMA companies to divulge CBI developed with substantial private investment capital. The secrecy of this CBI is essential to the competitiveness of the US pharmaceutical industry and to its ability to invest further in the development and production of medicines for sales in world markets.

PhRMA does, however, realize the problems associated with a lack of disease surveillance capabilities in some regions of the world. More technically advanced countries will need to provide assistance to support the epidemiological surveys to monitor unusual outbreaks of disease in these regions. The pharmaceutical industry does not anticipate being heavily involved in the provision of such assistance because disease surveillance expertise is the domain of the US government, particularly the Centers for Disease Control.

Conclusion

No one has yet suggested that any of PhRMA’s companies have ever made biological weapons, but the industry is acutely aware of the first principle in science: A negative can **never** be proved. In other words, if falsely accused a pharmaceutical company can never prove that it has not made biological weapons. Hence, PhRMA’s insistence that the BWC’s monitoring regime be founded on due process and the presumption of innocence.

PhRMA advocates a sound and reasonable compliance protocol to the BWC, but will not

² In contrast, the CWC has a “red light” approach. When a CWC challenge inspection is being launched, a three-quarters vote of the 41-member Executive Council is needed to halt the inspection.

³ Among other matters, Article X states that participating countries “undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.” For the full text, see US Arms Control and Disarmament Agency, *US Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: Government Printing Office, 1996): 99–100.

support a poorly conceived one that risks the legitimate and laudable aims of the pharmaceutical industry to use existing and emerging biomedical technologies to create medicines. An analysis of the costs and benefits of all aspects of the protocol will be critical to avoid unnecessarily sacrificing unmet medical needs and the general public health to overly ambitious or unrealistic concepts for a BWC protocol. PhRMA's principle concerns remain the loss of CBI, unwarranted damage to the reputation of pharmaceutical companies, and new, onerous, and expensive regulations. While not a principal force behind the development of such a protocol, as responsible corporate citizens PhRMA companies will provide expert assistance to clarify for the negotiators what can be achieved technically so that they can craft a BWC protocol based on solid science.