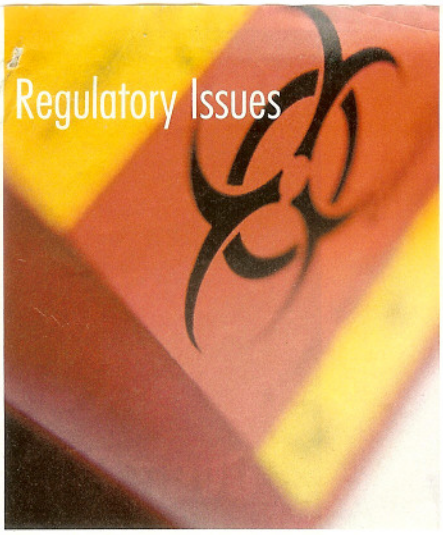

Lynn C. Klotz, Marie I. Chevrier, John J. Dingerdissen, Lynn Pritchard, Barbara Hatch Rosenberg, Mark Wheelis, and Gillian R. Woollett

Implementing the Biological Weapons Convention Protocol in the United States

What It Means to the Biopharmaceutical Industry

Early in the 1990s the chemical industry dealt with international scrutiny over the danger of chemical weapons. Now the biopharmaceutical industry faces similar questions about its products and processes. The industry must work with concerned officials to safeguard intellectual property while allowing access to those seeking to verify its peaceful intentions.

The Biological Weapons Convention (BWC) of 1972 prohibits the possession, development, and stockpiling of biological weapons, but it lacks verification measures (1,2). When that treaty was negotiated, many countries considered biological weapons to have little military utility. However, it is increasingly apparent that others, including some convention signatories, now disagree with that assessment. Opportunities represented by the end of the cold war, along with increasing suspicions and allegations that a few signatories were violating the convention, led the states parties to agree to a politically binding information exchange that began in 1987. When such "confidence-building measures" appeared inadequate, international concern provided impetus for enhancing global security by negotiating a legally binding regime to strengthen the effectiveness of the BWC.

In 1991, a two-year study of the feasibility of measures to verify compliance with the convention was undertaken by verification experts from its parties. The "VEREX" report was presented at a special conference in 1994, which then established an ad hoc group to negotiate a protocol that would strengthen the BWC (3). That group's mandate includes matters of trade and scientific cooperation and measures to promote compliance. Its draft protocol will be presented to the states parties at another special conference before the sixth BWC review conference scheduled for 2001.

That protocol will address a number of areas including compliance measures, confidentiality provisions (such as confidential business and national security information), assistance and protection against biological and toxin weapons, scientific and technological exchange for peaceful purposes and technical cooperation, confidence-building measures, and national implementation measures.

Three major elements of the protocol under negotiation by the ad hoc group are annual declarations of dual-capable facilities, challenge investigations, and nonchallenge visits (4). *Dual-capable facilities* are those that could be used for either biological weapons or peaceful purposes. Both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Federation of American Scientists (FAS) support annual declarations and challenge investigations as elements of an effective protocol, although the two groups disagree on some details of those protocol elements. We also disagree on the value of nonchallenge visits, which include proposed transparency and declaration clarification visits. FAS believes that these visits are essential for an effective protocol; industry, however, does not believe their value overrides their risk to confidential proprietary information and facility reputations. Both groups agree, however, that managed access should apply to all on-site activities (5,6).

Those activities will almost certainly include challenge investigations on evidence of noncompliance with the 1972 Convention. Such investigations will require a vote of the Executive Council of States Parties to proceed. On-site activities may

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Biological Weapons Convention: Once Again, GMP Compliance is Key

The Foreign Relations Authorization Act for Fiscal Years 2000 and 2001 (H.R. 3427, 17 November 1999) lays out particulars for U.S. participation in the Biological Weapons Convention (BWC). It calls the biotech and pharma industries "a national asset" and recognizes that "one bacterium strain can represent a large proportion of a company's investment," and "its potential loss during an arms control monitoring activity" could be worth billions of dollars. The bill proposes a series of industry trial investigations and visits "both during and following negotiations to develop a compliance protocol" to ensure that effective compliance procedures protect national security and concerns of affected industry and research institutions.

The chemical industry has experienced these sorts of concerns through the Chemical Weapons Convention (www.stimson.org/pubs/cwc/const.htm). Inspection activities, facility access, and information provided are subject to negotiation. Of course, logistical and proprietary differences may complicate inspections under the BWC. Its protocol declaration is structured differently, designed to focus on "most relevant facilities" (www.armscontrol.org/ACT/june00/bwcjun.htm). Negotiators have been careful to make sure no one will have to declare proprietary or national security information.

On the "Biological and Toxin Weapons" site (www.boku.ac.at/iam/efb/btwcabst.htm), J.P. Robinson writes that the CWC verification regime "affords useful parallels" for the BWC. He points to "dual-use chemicals" as indicating that "there is already considerable international effort to harmonize national and international regulations relating to pathogens that present danger to public and animal health and to the environment." Both promotional and regulatory measures could facilitate harmonization of national, regional, and international safety rules for pathogens "involving both the collection of data and the inspection of facilities," he writes.

International regulators apply harmonized GMPs to inspection reports from other countries. Robinson suggests that such requirements will make it hard for a GMP-inspected facility to carry out covert manufacture of prohibited products. He concludes that facilities meeting international standards and subject to regular inspection are "unlikely to present a risk." Although it may mean a few new rules or inspections, compliance with GMPs as usual will likely be the way to comply with the BWC as well.

FAS maintains a "Biological and Toxin Weapons Verification Program" site (www.fas.org/bwc). PhRMA's web site includes a "Biological and Chemical Weapons Convention" page (www.phrma.org/srpub/bwc.html). The Stimson Center's "Chemical and Biological Weapons Nonproliferation Project" (www.stimson.org/cwc) lists treaties, conventions, and protocols, with position papers from groups offering diverse opinions. **—Penny L. Cass**

also include transparency visits to declared facilities and clarification visits to address questions that arise from declarations that have not been resolved through a consultation process.

To protect confidentiality, managed access rules were developed for the Chemical Weapons Convention (CWC) with the help of the U.S. chemical industry (5). Nearly identical managed access rules are in the draft (rolling) text of the BWC protocol (6) and may be adopted because of their wide support, although differences between biologicals and chemicals need to be addressed. The rules call first for negotiation between a visiting team and the visited state party regarding the particular inspection activities to be conducted and the extent and nature of access to particular places within the perimeter of a facility. States parties can take such measures as they deem necessary to protect confidentiality, which inspection teams must fully respect. States parties are obliged, however, to make every reasonable effort to provide alternative means to answer inspection team questions or concerns within the mandate of a visit.

FAS and PhRMA agree that industry's fears concerning possible loss of confidentiality during on-site activities could be reduced by implementing legislation in the United States that would maintain the constitutional rights of all inspectees. Thus the protocol also would have to be compatible with those rights. Principally, the U.S. implementing legislation should mandate that facility site managers — not the government — make managed access decisions during all on-site activities, consistent with constitutional and national security requirements. Each facility's management knows what is confidential business information, what can be shared with a visiting team, and what are the best alternate means of satisfying the team's requests.

Five Key Points

FAS and PhRMA propose several key points for inclusion in U.S. implementing legislation. First, the rules for, rights under, limits of, and obligations under managed access should be defined clearly in the protocol and supported in the implementing legislation.

Site managers should have the right to make managed access decisions during on-site activities at nongovernmental facilities. Implementing legislation for any treaty essentially delegates its implementation to individuals and groups, so delegating managed access decisions to site managers would be consistent with precedent. It also would be consistent with search and seizure provisions of the U.S. Constitution (Fourth Amendment).

Facility owners should participate in the preparation and review of U.S. declarations that involve their facilities, and both the U.S. government and the company or companies involved should approve such declarations before their submission. In anticipation of possible disagreements, a resolution mechanism or procedure should be established before declarations are required.

Industry input. The biopharmaceutical industry and other relevant institutions should assist the government in developing criteria for evaluating nominated inspectors, and the government should solicit and consider industry concerns when evaluating candidates. The government therefore should notify owners of all declared facilities, publicly announce the nominations of inspectors, and invite comments before evaluating candidates.

Defining terms. We propose that the definition of *confidential information* in the protocol and in U.S. implementing legislation

should parallel standard industry protections (and exceptions for information already in the public domain). All participants in on-site activities should be subject to confidentiality agreements based on those standards. Suggested language follows:

> Applying the standard legal language for exceptions to on-site activities under the protocol would mean that *proprietary information* shall not be deemed to include information that (a) is in or becomes in the public domain without violation of this agreement by the inspectors; (b) is already in the possession of inspectors, as evidenced by written documents, prior to the disclosure thereof by the inspected facility; or (c) is rightfully received from a third entity having no obligation to the inspected facility and without violation of this agreement by the inspectors.

Industry strongly proposes including those key points in the implementing legislation, and FAS supports industry on these points.

We hope that this joint statement will help support a protocol to the BWC that strengthens the prohibitions against the development, production, and stockpiling of biological or toxin weapons. Implementing legislation that both conforms with the protocol and protects the vital interests of U.S. industry is essential for successful application of the protocol in the United States. Inclusion of the points proposed here in that legislation (and development of such legislation in advance of ratification) would ease industry concerns regarding confidentiality and promote further industry support for the protocol.

References

(1) Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) Weapons and Toxic Weapons and on Their Destruction, 10 April 1972, 26 UST 585, T.I.A.S. No. 8062, 1015 U.N.T.S. 163. Entered into force on 26 March 1975. Available at www.fas-org.

(2) Discussions of FAS and PhRMA positions on the BWC Protocol are available at www.fas.org and www.phrma.org/srpub/bwc.html#phrma.

(3) United Nations, Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxic Weapons and on Their Destruction, BWC Ad Hoc Group 3 (January 1995). The document is available at www.brad.ac.uk/adac/sbtwc/ahg27.htm.

(4) For example, see the recent draft text for the protocol from the United Nations, Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxic Weapons and on Their Destruction, BWC Ad Hoc Group 47 (October 1999). The document is available at www.brad.ac.uk/adac/sbtwc/ahg48.htm.

(5) Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction (Corrected version in accordance with Depositary Notification C.N.246.1994. TREATIES-5 and the corresponding Process-Verbal of Rectification of the Original of the Convention, issued on 8 August 1994), Part X, Paragraphs 38–52.

(6) Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, BWC Ad Hoc Group 47 (Part II) 20 October 1999, 16th session, Geneva, 13 September–8 October 1999, Annex IV, Part G, Paragraphs 29–35. **BP**