



POLICY FORUM: BIOLOGICAL WARFARE

Strengthening the Biological Weapons Convention

Thomas P. Monath and Lance K. Gordon

Heighted tensions surround the threat of biological warfare and terrorism. Negotiated at the height of the Cold War to outlaw such weapons, the Biological and Toxin Weapons Convention (BTWC) has been in effect since 1975. However, the BTWC lacks any international compliance regime to bolster its broad prohibitions against the development, production, stockpiling, and weaponization of offensive biological weapons. Negotiations on this topic are currently taking place. One of the most important controversies is whether to allow on-site visits to biological facilities without previous allegations that a treaty violation has occurred.

Technologies used to develop and manufacture drugs and vaccines could be used to make biological weapons. Such activities are the reason why certain facilities should be subject to declaration and potential visits. The development of many vaccines requires that the biological agents of concern, or modified strains of these agents, be grown in large-scale cultures. States that are party to a strengthened convention would be required to declare facilities engaged in research on biological weapons defense, vaccine manufacture, maximum containment laboratories, and research activities with specified biological agents. These facilities would be subject to planned or random visits.

Growing concerns about biological weapons terrorism have also increased the emphasis on defensive programs; these are also subject to visits under a compliance protocol. Earlier this year, the United States announced that it would immunize active duty forces against anthrax and would develop vaccines against other biological threat agents. Our company and selected other biotechnology companies were identified as potential contractors for research, development, or production of these vaccines and would thus be primary targets of compliance investigations under the BTWC. As representatives of an industry engaged in defensive programs, we consider such declarations and visits to be non-threatening and manageable. More important, we acknowledge that the United States

cannot endeavor to strengthen the BTWC by imposing a compliance protocol while refusing to fully comply with such a protocol within its own boundaries.

However, faced with the possibility of visits under the treaty, some other U.S. pharmaceutical companies have raised legitimate concerns about the risks to confidential business information, fearing that visits or inspections might subject proprietary vaccine cultures to sampling, analysis, and potential theft. Although inspections by the



Biological defense. In a training exercise, Army soldiers wear protective masks against chemical and biological weapons.

U.S. Food and Drug Administration and Western European national drug control authorities are familiar and nonthreatening, the unusual purpose and potentially intrusive nature of weapons visits, together with the possibility that inspectors from some countries might not respect confidentiality and patent laws, are concerns. Other anxieties include (i) vulnerability to false positive conclusions reached by inspectors through unvalidated or inaccurate testing of samples, (ii) environmental sampling of the grounds around a manufacturing facility that might reveal the presence of a naturally occurring microorganism, leading to false accusations, and (iii) the potential stigma accompanying such visits, leading to a possible loss of company reputation and contracts. Finally, it is feared that visits will be costly and divert personnel from other duties.

Although no biopharmaceutical company or research facility in the United States is engaged in any offensive biological weapons activities, this is not the case in certain other countries. In those countries, on-site visits or the threat of visits to

biological facilities would undoubtedly impede progress in the development of biological weapons of mass destruction. Some argue that it is easy to hide such programs, but they underestimate the role of intelligence-gathering activities in locating targets for on-site inspections. At least some undeclared facilities would eventually come to light.

The risks of losing confidential business information, genetic material, or proprietary cultures, including the constant threat of corporate espionage, are the day-to-day concerns of industry. The specialized problems associated with a BTWC compliance regime should be easily managed. On-site activities, including access to records relating to fermentation, in-process testing, or other manufacturing procedures; documentation relating to biohazards and occupational safety; and research involving animals are already subject to scrutiny and simply do not pose a special threat. Protection of cultures or other proprietary materials can be achieved by requiring on-site testing and by inspection protocols that prevent removal of samples of commercial value from the facility. Moreover, sampling and analysis would be strictly limited to specific biological threat agents. Careful consideration given to the methodology used for analysis and confirmation of results, and to verifying that tests are accurate, could essentially eliminate false positive results. The development and validation of such tests is difficult but is not insurmountable.

Environmental sampling would only be required after a disease outbreak, the accidental release of an agent into the environment, or an allegation of treaty violation. These circumstances are exceptional and do not relate to the monitoring of legitimate activities.

The concern that some inspectors would be untrustworthy needs to be squarely addressed by diligent security measures that exclude individuals with conflicting interests. But this is everyday practice. There are far greater hazards in normal commercial intercourse.

It is the time for U.S. industry to take the moral high ground and to focus collective wisdom and creativity to bring about a resolution of the issues surrounding on-site activities and the compliance protocol. The fundamental starting place is the recognition of the importance of strengthening the BTWC and the positive results that would ensue, not on hypothetical and unlikely negative outcomes of a compliance regime. Leaders in the U.S. biopharmaceutical industry need to rally behind the objectives of a strengthened treaty. Only then can the operational details be resolved.

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The authors are officers of OraVax Incorporated, Cambridge, MA 02139, USA. E-mail: tmonath@oravax.com