Executive Summary

Biological weapons have long been recognized as abhorrent, which is why 145 nations have joined a 1972 treaty that bans the development, production, stockpiling, and transfer of germ weapons. Even at the time the Biological and Toxin Weapons Convention (BWC) became international law, it was understood to be more of a normative than an enforceable agreement. True to treaties of the 1970s, the BWC included no provisions to monitor the compliance of member countries with its prohibitions against using diseases as weapons to harm man, livestock, and plants.

The absence of monitoring provisions meant, for example, that no inspectors ever investigated suspicions that the Soviet Union was violating the BWC. Public allegations to that effect dated back to a 1979 outbreak of anthrax caused by an accident at a biological weapons production facility in a town then known as Sverdlovsk. In 1994, the BWC's membership finally chartered negotiations to craft a monitoring protocol. However, in December 2001, after rejecting a draft protocol and introducing a series of proposals intended to serve as alternatives to a legally binding, multilateral accord, the US government called for an end to negotiations. Chapter 1 of this report summarizes the somewhat troubled history of the BWC and efforts to strengthen this treaty.

In the remainder of this report, a group of experts from the US pharmaceutical and biotechnology industries assesses the suitability of the US government's alternative proposals, providing technical counsel that reshapes and improves them. This group jointly has over 280 years of experience in various types of industry facilities, with specialties ranging from drug research and development to process scale-up and manufacture of medicines. Each expert is well versed in various government regulations, compliance requirements, and inspections as they pertain to biotechnology facilities. Each is also a veteran of countless encounters with the internal scientific entities that govern activities in university settings and at industrial facilities. Their recommendations, summarized in Chapter 5 of this report, draw upon this deep well of experience.

The industry experts agreed with the US government's July 2001 decision to reject the draft BWC monitoring protocol, despite the fact that this text included several of the monitoring techniques that the experts argued would be useful for inspectors. Their main rationale was that no matter how good the inspection techniques, the inspectors would not have a fighting chance if they were too few in number, lacking in essential skills, and not deployed on site for a sufficient amount of time to accomplish their jobs. The draft protocol was deficient in all of these respects.

The US government made two types of proposals to supplant a formal BWC monitoring protocol. The first type centered on traditional monitoring that would deploy inspectors to certain locations to ascertain whether a prohibited activity had occurred. In the second category are proposals aimed at having individual nations strengthen laws, practices, and capabilities related to the handling of dangerous

pathogens, the conduct of research, the ability to detect disease outbreaks, and the prosecution of individuals engaged in offensive bioweapons activities.

US PROPOSALS TO MONITOR BWC COMPLIANCE

First, the US government proposed that the authority to investigate suspicious outbreaks of disease or allegations of biological weapons use remain with the United Nations Secretary General. The second US proposal would have member governments try to resolve compliance concerns via a bilateral consultation process wherein one option would be to open sites of concern voluntarily to inspection. US industry experts deemed this pair of proposals at best ineffectual and at worst, possibly damaging to US industry and national security interests since neither appears structured for meaningful monitoring results.

Industry experts could find little merit in leaving the capability to investigate suspicious disease outbreaks in the hands of the very body that failed to do anything to explore the root causes of the Sverdlovsk outbreak or any of the other charges of BWC violations voiced over the last quarter century. In addition, the group observed that this US proposal made no mention of a right to investigate allegations that a facility was covertly developing, testing, manufacturing, or storing biological weapons. If a challenge inspection system is not geared to pursue violators aggressively, then it does not serve US security interests.

The group questioned the value of a voluntary visit knowing that a violator could easily clean up evidence of foul play before issuing an invitation to inspectors. Moreover, the industry experts noted that a government might insist that an industry facility host such an inspection for political reasons. Such circumstances would be doubly objectionable since the "volunteered" industrial site would have to endure an inspection with negligible monitoring value.

As Chapter 2 explains in more detail, the industry experts expressed a conviction that it is incumbent on any investigation or monitoring activity to be able to discern the difference between a facility engaged in legitimate research and manufacturing activities and one involved in illegal biological weapons activities. The group affirmed the conclusions of a May 2001 Stimson Center report, entitled *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol*. Briefly, in that report, a different group of industry experts outlined monitoring strategies and techniques (e.g., site tours, interviews, document reviews) that inspectors could use to detect and sort out inconsistencies with a facility's stated purpose, ultimately differentiating between violators and compliant facilities.

Accordingly, the industry experts agreed to write detailed plans to guide the conduct of trial inspections to test the feasibility of their proposed monitoring strategies and techniques at two principal kinds of industry facilities, manufacturing plants and research and development sites. This group of industry experts expects their trial inspection plans to help lay the foundation for the US government and industry to meet the requirements of Public Law 106-113. This 1999 congressional mandate, which both

the Clinton and Bush administrations have ignored to date, stipulates that the Executive Branch complete a cost-benefit analysis after holding trial inspections at various US government, academic, and industry sites. Similar to clinical trials that fully ascertain the benefits and risks of candidate drugs, the group concurred that securing field research data on BWC monitoring techniques and strategies is essential to the utility of any attempt to construct a monitoring protocol.

US PROPOSALS FOR ACTION BY INDIVIDUAL STATES

In addition, the Bush administration introduced several initiatives asking BWC members to take individual action to:

- strengthen disease surveillance;
- stiffen the security of dangerous pathogens;
- establish oversight of genetic engineering research;
- enhance biosafety;
- develop and adopt code(s) of conduct for professionals working with dangerous pathogens; and,
- pass legislation criminalizing offensive biological weapons activities and adjust or create bilateral extradition agreements to enable prosecution of biocriminals.

All of these proposals, according to the industry experts, suffer from the same handicap, namely the failure to articulate an international standard that governments would be expected to meet. Absent identification of and agreement on such standards, governments will have little to compel them to take action. Many governments will enact measures that fall short of worthwhile standards either unintentionally, because they cannot decipher the existing discrepant regulatory concepts, or intentionally, because they seek to perpetuate illicit activities. The let-each-government-do-as-it-pleases approach would further foster an uneven patchwork of domestic laws and practices that might have little near-term value and could prove difficult to harmonize in the future. All of these outcomes are unsatisfactory.

Disease Surveillance, Criminalization, and Code of Ethics

The industry specialists applauded the suggestion that BWC member governments individually support the World Health Organization's disease surveillance and outbreak response capabilities. Likewise, the group thought the Office of International Epizoonotics and the Food and Agricultural Organization, which work to contain outbreaks of animal and plant diseases, certainly deserved the backing of the international community. The industry specialists agreed that countries should enact laws penalizing individuals for developing, producing, and using biological weapons. However, worrying that the US proposal might result in the creation of safe havens for bioterrorists in countries that brush off this

proposal or pass weak laws, the industry group advised instead adopting an international criminalization treaty.

A scientific ethics code serves mainly to reassure the public that scientists are applying their skills responsibly. Accordingly, the industry experts viewed the US government's proposal to have BWC members establish a professional code of ethics for those working with dangerous pathogens as posing the most minimal of impediments to individuals attempting to acquire an offensive bioweapons capability. Noting that governments have either compelled scientists or appealed to their sense of patriotic duty to get them to work on weapons programs in the past, the group's most positive assessment of this proposal was that it would do no harm. Were ethical codes in place, some industry experts argued that scientists *might* be emboldened to blow the whistle on a covert weapons program. Chapter 3 of this report provides a more in-depth discussion of the group's reaction to this trio of proposals.

Biosafety, Biosecurity, and Research Oversight

As Chapter 4 discusses, the industry experts were particularly concerned that the US proposals for biosafety, biosecurity, and research oversight would result in individual governments taking fragmented, if not superficial, action. They did not consider allowing governments to set their own arbitrary standards to be a constructive step forward. Therefore, the industry experts recommended that states adopt mandatory practices in each of these areas. The industry group cited as models for uniform standards the pertinent regulations issued by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH).

Establishing select lists of pathogens, including toxins that are dangerous to humans, animals, and plants, would facilitate the implementation of biosafety, biosecurity, and research oversight standards. For example, the CDC employs a select list to govern transfer of some human pathogens. Risk-stratified lists of human, animal, and plant pathogens need to be agreed upon to help anchor the standards. Such lists could change over time, but it would be counterproductive if too many agents were inappropriately categorized as high risk.

With regard to biosafety, the industry experts stated that the United States needs to get its own house in better order. Government-funded organizations in the United States must follow the CDC/NIH biosafety guidelines, but for other institutions adherence is optional. CDC/NIH biosafety standards should be made mandatory for all US facilities, and these or substantially equivalent standards should be in place globally. As is the case in the United States, the standards should be relaxed for clinical laboratories, which conduct primary diagnostic procedures on a large volume of samples at biosafety level 2, although some samples warrant biosafety level 3 precautions.

Sound reasons exist for establishing universal biosecurity standards. Biosecurity regulations currently vary in strength—some incorporate oversight and penalties for noncompliance, others do not. Other biosecurity regulations apply only to very limited areas of activity (e.g., shipping). The industry experts identified as an appropriate model for a minimum global standard the US access, transfer, and chain-of-custody regulations for select pathogens and toxins, or their equivalent.

Access and transfer restrictions alone are insufficient in that they do not even begin to account for the dangerous pathogens and toxins that are already present in organizations worldwide. Therefore, the industry group recommended a companion biosecurity measure: a "house cleaning" activity. Around the world, academic and research institutions, industry facilities, culture collections, and other facilities should be required to conduct a thorough inventory of the strains that they possess; declare to the appropriate authorities those delineated on the select agent lists of dangerous human, animal, and plant pathogens; and, in consultation with authorities, dispose of them, as appropriate.

Another aspect of biosecurity that the US proposals do not address is that of physical security. As these enhanced standards are instituted, it may be easier for terrorists or governments aspiring to a biological weapons capability to identify those facilities handling select-list agents. Accordingly, these facilities may themselves become targets for foul play. Therefore, in the not too distant future, the industry group suggested undertaking a clearer articulation of physical security requirements.

The industry experts recognized that the effective implementation of any standards hinges on training, which should be conveyed first in universities and colleges and regularly reinforced in the workplace. Lamentably, the industry experts observed, US institutions of higher learning have placed less and less emphasis on basic training in biosafety and research practices in recent decades. If higher standards are to become a reality, all pertinent entities have to embrace the best practice of continual training, from the time one becomes a student until one retires.

The second foundation of implementing tougher standards begins at the level of the individual organizations that are working with dangerous pathogens or conducting research with genetically modified organisms. At universities, research institutes, industrial and government facilities, the appropriate infrastructure must be put in place to oversee these activities. For example, designated individual(s) at a facility would be responsible for proper training of personnel; review of research proposals involving genetically modified organisms; and evaluation of the sufficiency of risk assessments and containment for proposed projects. National regulations should require the creation of a governing infrastructure along the lines of the one laid out in the NIH Guidelines for Research Involving Recombinant DNA Molecules, where it does not already exist.

Next, the only way to ensure that standards are being uniformly applied nationwide is for countries to establish a national capacity to oversee facilities working with dangerous pathogens and engaged in research involving genetically modified organisms. This regulatory body would:

- receive declarations about pertinent activities and capabilities from academic, research, industry, and government organizations;
- certify biosafety and biosecurity practices at these facilities;
- review, approve, and track all projects involving genetically modified organisms; and,
- enforce research oversight, biosafety, and access, transfer, and clean house regulations.

The industry group strongly urged that noncompliance penalties (e.g., loss of job, loss of government grants, suspension of licenses) be an integral part of agreed international standards. Absent the articulation and enforcement of considerable penalties for noncompliance, some individuals or organizations would make only a minimal effort to abide by the regulations.

The culminating step in the implementation of global biosafety, biosecurity, and research oversight standards would be to create an international body to coordinate, promote, and administer these activities, including the updating of standards, as appropriate.

Singly, research oversight, biosafety, and biosecurity enhancement measures will not go far in thwarting nations or terrorists from engaging in wayward research, experiencing leaks at covert weapons facilities, or gaining access to dangerous pathogens. Collectively, however, global adoption of the CDC/NIH guidelines or their equivalent would raise the bar, hampering the ability of aspiring proliferators to achieve an offensive weapons capability.

The industry group also underscored that biosecurity, biosafety, and research oversight standards also constitute safe, sound practices for those working with select-list pathogens. Finally, should a formal BWC inspection process ever be instituted, the improved standards would aid the efforts of inspectors in differentiating between legitimate research and commercial enterprises and illicit weapons activities.