Toward Enhanced Implementation of the BWC:
Why National Regulatory Commissions May Be a Good Idea

By Robert Schwartz[1]

Abstract

In considering ways to enhance national implementation of the Biological Weapons Convention, it is useful to begin by observing the piecemeal method adopted by many countries. Although both scalable and adaptable, this approach has resulted in the appearance of significant gaps in the implementation of the Convention. The United States provides an excellent example of the benefits and perils of such a strategy. By examining the situation in the United States it becomes apparent that an entity like a national regulatory commission may be well-suited to advance significant national and international interests, despite its shortcomings and as a complement to a verification protocol.

I. Introduction

In recognition of the grave threat posed by biological and toxin weapons, states parties to the Biological Weapons Convention (BWC) have undertaken a solemn commitment to prohibit the development, production, and stockpiling of such weapons.[2] In the wake of the abortive negotiations of the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint (VEREX), the enactment of comprehensive and effective national implementing measures seems both practical and essential. Although such implementing measures are no substitute for a verification instrument, these efforts could help to ensure the realization of the principal aims of the BWC, while also advancing significant national and international interests and assisting in the development of a robust and broadly-supported verification protocol to be developed in the future.

Even though many BWC member-states have labored to fully implement the Convention, these efforts have often fallen short due to their piecemeal approach. For example, with regard to the United States, there are no fewer than thirty-nine (39) national measures which might be relevant to the implementation of the BWC,[3] yet recent reports have exposed a gross lack of oversight of laboratories engaged in biodefense activities, among other failures.[4] Accordingly, despite the good intentions of states parties like the United States, it is apparent that

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[2] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BWC) art. I, Mar. 26, 1975, 26 U.S.T. 583, 1015 U.N.T.S. 163.

[3] United Nations Office at Geneva, Disarmament, National Implementation of the BWC, http://www.unog.ch/80256EDD006B8954/(httpAssets)/BBCCCC514AA386A3C1257355003AA13D/$file/BWC_NID_Report-070912.htm#us (last visited Dec. 3, 2007).

[4] Jia-Rui Chong, *Experts detail risks of bioagent program*, L.A. TIMES, Oct. 5, 2007; Emily Ramshaw, *Texas A&M hearing reveals lack of oversight in country's biodefense labs*, DALLAS MORNING NEWS, October 4, 2007.

implementation of the Convention could be enhanced by the establishment of national entities to oversee and regulate BWC-related activities.

One such possibility would be a national regulatory commission with a broad mandate, adequate resources, considerable expertise in the relevant disciplines, investigatory powers, and adjudicatory authority. A commission of this nature could harmonize the disparate regulations; promote transparency, efficiency, and accountability; and ensure that vital national security needs are addressed. In addition, a national regulatory commission could act as a clearinghouse for relevant information, thereby promoting transparency both nationally and internationally and helping to facilitate compliance with the Convention, including the confidence building measures. However, because any such commission could easily become a farce, national regulatory commissions should be considered but an intermediate and complementary step toward the ultimate goal of comprehensive multilateral monitoring of compliance with the BWC.

II. Obligations of States Parties to the BWC

BWC member-states are obligated to undertake implementing measures to effectuate the aims of the Convention. Pursuant to Article IV of the BWC, each state party to the Convention, in accordance with its constitutional process, shall:

> take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of th[e] Convention, within the territory of such State, under its jurisdiction or under its control anywhere.[5]

Moreover, in April 2004, the United Nations Security Council adopted Resolution 1540, which calls upon all states parties:

> (a) To promote the universal adoption and full implementation, and, where necessary, strengthening of multilateral treaties to which they are parties, whose aim is to prevent the proliferation of nuclear, biological or chemical weapons;
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> (b) To adopt national rules and regulations, where it has not yet been done, to ensure compliance with their commitments under the key multilateral nonproliferation treaties;
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> (c) To renew and fulfil[l] their commitment to multilateral cooperation, in particular within the framework of the International Atomic Energy Agency, the Organization for the Prohibition of Chemical Weapons and the Biological and Toxin Weapons Convention, as important means of pursuing and achieving their common objectives in the area of non-proliferation and of promoting international cooperation for peaceful purposes; [and]
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> (d) To develop appropriate ways to work with and inform industry and the

[5] BWC, *supra* note 2, at art. IV.

public regarding their obligations under such laws[.][6]

Accordingly, it is incumbent upon all states parties to the Convention to establish implementing measures as may be appropriate to realize the mandates in Article IV and Resolution 1540. These implementing measures may take on a variety of forms depending on the particular circumstances and legal system of each BWC member-state.

III. Enhancing National Implementation of the BWC

Following the unsuccessful Ad Hoc Group negotiations regarding a verification protocol, the pursuit of enhanced national implementation of the BWC became one of primary importance. In this way, the fundamental ends of the Convention can be furthered, while also helping to rebuild good will for future multilateral negotiations. Although such enhanced national implementation may more readily present itself as small, incremental measures, one solution that offers the promise of remedying a number of material problems and advancing key national and international interests is the establishment of national regulatory commissions, despite the apparent shortcomings of such an approach.

a. National Regulatory Commissions

The creation of national-level regulatory commissions by BWC member-states would both enhance national implementation and serve important national and international interests. A properly impaneled and empowered commission would be able to ensure compliance with the Convention at the state level; efficiently coordinate the planning and distribution of resources for biodefense activities; increase transparency; provide for comprehensive and coherent planning and response with regard to accidents and security; be flexible and responsive; and create genuine accountability. In addition, such commissions could help to further important international interests, including increased compliance with the BWC, meaningful confidence building measures, and experimentation towards a workable and widely-supported verification instrument. Nonetheless, it should be noted at the outset that such commissions face significant obstacles, including an aversion to bureaucracies and regulation and the potential for national regulatory commissions to become a subterfuge for non-compliant BWC member-states.

i. National Interests

Although some BWC member-states may be reluctant to create a national regulatory commission, there are number of valid reasons why states parties should be inclined to support such commissions.

1. Ensure Compliance with the BWC at the State Level

First, a national regulatory commission would help to ensure uniform compliance with the BWC at the state level. Among other obligations, all BWC member-states are required to prohibit the development, production, and stockpiling of biological and toxin weapons "of types and in quantities that have no justification for prophylactic, protective or other peaceful

[6] S.C. Res. 1540, ¶ 8, U.N. Doc. S/RES/1540 (April 28, 2004).

purposes[.]"[7] Accordingly, states parties are obliged to closely examine any national activities that may transgress the prohibitions of the BWC. In practice, this has proven to be a difficult exercise, both because such activities may be scattered among a number of departments and agencies and because the precise strictures of the BWC are somewhat ambiguous.

For instance, in the United States, the Department of Energy and the Department of Homeland Security are currently attempting to operate a Biosafety Level 3 (BSL-3) facility at Lawrence Livermore National Laboratory (LLNL), one of the United States' primary nuclear weapons research and development facilities. This laboratory would perform biodefense operations involving small-animal challenges of aerosol bioagents and biotoxins, as well as genetically modified microorganisms.[8] According to an environmental planning document for the BSL-3 laboratory, "[a]ll work with infectious microorganisms in the proposed facility must be approved by LLNL management in strict accordance with . . . [the] Biological Weapons Convention . . . [which] permits defensive research for the purpose of developing vaccines and protective equipment."[9] This seemingly innocuous statement begs the questions of what expertise LLNL's management brings to bear on the matter of compliance with the BWC and under what criteria would such determinations be made? Furthermore, because these officials have been given multiple mandates, including pursuing research to detect and counter the bioterrorist threat, it also seems appropriate to question whether such officials possess the objectivity required to make these determinations. Given that the issue of compliance with the BWC is a difficult one even for authorities in the field,[10] it is reasonable to express some trepidation with these decisions being made at the local level, particularly without detailed guidance and assistance from experts in a variety of disciplines.

Moreover, in the United States, even at the highest levels of government and with regard to research testing the very limits of the BWC, it has sometimes been the case that determining compliance with the Convention has been overlooked. For example, a former senior official in the Clinton administration "conceded that in retrospect, someone should have been responsible for reviewing [a number of secret research projects on biological weapons] to ensure that they were not only effective in defending the United States, but consistent with the nation's arms-control pledges."[11] That such a glaring oversight could occur during the midst of the Ad Hoc Group negotiations is particularly troubling and indicative of the magnitude of the problem.

Additionally, in the United States, the National Research Council has observed that "no national or international review body currently has the legal authority or self-governance responsibility to evaluate a proposed research activity prior to its conduct to determine whether

[7] BWC, *supra* note 2, at art. I.

[8] DEPARTMENT OF ENERGY, DRAFT REVISED ENVIRONMENTAL ASSESSMENT FOR THE PROPOSED CONSTRUCTION AND OPERATION OF A BIOSAFETY LEVEL 3 FACILITY AT LAWRENCE LIVERMORE NATIONAL LABORATORY, LIVERMORE, CALIFORNIA 8 (2007).

[9] *Id.* at 19.

[10] *See* Milton Leitenberg, *Distinguishing Offensive from Defensive Biological Weapons Research*, CRITICAL REVIEWS IN MICROBIOLOGY, August 1, 2003, at 223-257; COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NATIONAL RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM: CONFRONTING THE DUAL USE DILEMMA (National Academies Press 2004); NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY, PROPOSED FRAMEWORK FOR THE OVERSIGHT OF DUAL USE LIFE SCIENCES RESEARCH: STRATEGIES FOR MINIMIZING THE POTENTIAL MISUSE OF RESEARCH INFORMATION (2007).

[11] Judith Miller et al., *U.S. Germ Warfare Research Pushes Treaty Limits*, N.Y. TIMES, September 4, 2001.

the risks associated with the proposed research, and its potential for misuse, outweigh its potential benefits."[12] However, the select agent regulations of the Department of Health and Human Services (HHS) specify that "[a]n individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary."[13] Select agents are those biological agents and toxins designated by HHS as having "the potential to pose a severe threat to public health and safety."[14] To apply for approval to conduct a restricted experiment, "an individual or entity must submit a written request and supporting scientific information."[15] This level of oversight, while welcome, is insufficient to cover the broad range of activities that may result in non-compliance with the BWC, and it fails to provide for the cost-benefit analysis suggested by the National Research Council. Nonetheless, the select agent regulations governing restricted experiments demonstrate both that the unique dangers posed by certain areas of research warrant special attention and that such oversight may be workable in practice.

In light of the above, one possible solution would be to create a national regulatory commission with the mandate to establish regulations and/or codes of conduct to ensure compliance with the BWC. Whether such regulations are promulgated by the commission itself or are codes of conduct formulated by an outside body and promoted by the commission is secondary; what is essential is that any biodefense activities take place within a principled framework that establishes boundaries and provides a moral compass in a sometimes murky area of research. Once promulgated, these regulations could facilitate governmental, industrial, and academic compliance with the BWC at the local level. If a difficult issue should arise at that level, the matter could be referred to the national regulatory commission, which could be charged with resolving such disputes. The commission could also review government-wide programs to ensure compliance with the Convention. In addition, a national regulatory commission could be given adjudicatory powers and tasked with resolving thorny issues relating to compliance and penalties for violations of the applicable regulations.

2. Efficiently Coordinate the Planning and Distribution of Resources for Biodefense Activities

Second, a national regulatory commission could efficiently coordinate the planning and distribution of resources for biodefense activities. Such a commission would also be able to coordinate available resources to respond to verifiable threats, thereby facilitating increased compliance with the BWC and directing vital resources toward the most pressing national needs. Following the terrorist attacks of September 11, 2001, and the subsequent anthrax mailings in the United States, concerns for the potentially devastating consequences of a biological weapons attack were heightened. As a result of these fears, the United States has spent more than $40

[12] COMMITTEE ON RESEARCH STANDARDS AND PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, *supra* note 10, at 3.
[13] 42 C.F.R. § 73.13(a) (2005). There are two classes of restricted experiments: (1) experiments "utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally"; and (2) experiments "involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight." *Id.* at § 73.13(b).
[14] 42 C.F.R. § 73.3(a) (2005).
[15] *Id.* at § 73.13(d).

billion on biodefense since 2001, and such spending is now allocated among eleven federal departments and agencies.[16] In the United States, even within a single department engaged in biodefense activities, there has been a distressing lack of planning and coordination of resources. For instance, the Office of Inspector General of the Department of Energy (DOE) concluded that:

> DOE has not developed and executed a coordinated plan for the development, construction, and operation of biosafety level-3 (BSL-3) laboratories. Consequently, there is no assurance that projects are being directed to the laboratory best suited to meet requirements; that resources are being effectively utilized; that security implications are being addressed; and, that capabilities are not being inappropriately duplicated.[17]

While the Department of Energy has no doubt undertaken reforms in response to the above allegations, the quantity of resources involved and their vast distribution indicate that such concerns are well-founded. A rational approach would be to coordinate the planning and distribution of such resources at the national level to ensure that essential needs are addressed and resources are equitably distributed; tasks which are well-suited for an entity like a national regulatory commission, which would have expertise in both the menace posed by bioterrorist attacks and the most promising areas of research to combat such threats. A presidential directive signed by President Bush in 2004, *Biodefense for the 21st Century*, promised to "fully integrate[ ] the sustained efforts of the national and homeland security, medical, public health, intelligence, diplomatic, and law enforcement communities."[18] However, despite this bold proclamation, such complex integration will require a sustained effort, something that is more appropriate for an organic entity like a national regulatory commission rather than a static presidential directive, or the like.

3. Enhance Transparency

Third, a national regulatory commission could enhance the transparency of national programs to counter deliberate outbreaks of diseases. In the United States, the National Science Advisory Board for Biosecurity has observed that "[a] lack of public understanding and appreciation for the reason for conducting and communicating dual use research, sensationalism of dual use research findings, and concerns about public safety and national security all serve to undermine public trust in the life sciences research enterprise."[19] A lack of transparency also

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[16] Lois Ember, *Biodefense Spending: U.S. is not spending enough on prevention, group says*, CHEMICAL & ENGINEERING NEWS, June 18, 2007, at 13.

[17] U.S. DEPARTMENT OF ENERGY OFFICE OF INSPECTOR GENERAL, INSPECTION REPORT: COORDINATION OF BIOLOGICAL SELECT AGENT ACTIVITIES AT DEPARTMENT OF ENERGY FACILITIES 2 (2005).

[18] Biodefense for the 21st Century 2 (2004), *available at* http://www.fas.org/biosecurity/resource/documents/hspd-10.pdf (last visited Dec. 3, 2007).

[19] NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY, *supra* note 10, at 26. *See also* Gigi Kwik Gronvall et al., *High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations*, BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE 82 (Vol. 5, Number 1, 2007) ("Public engagement should be a priority for all laboratories, and federal funds should be made available specifically for that purpose. As part of a proactive public engagement program, the need for individual high-containment laboratories in the context of the overall U.S. biodefense strategy should be clearly articulated to the public by the federal government and the laboratories themselves.").

erodes international confidence in a BWC member-state's compliance with the Convention. As indicated above, in the United States, biodefense activities are scattered among a number of departments and agencies. These agencies have varied policies regarding the transparency of their activities. For instance, meetings of the Institutional Biosafety Committee (IBC) at Lawrence Livermore National Laboratory are closed to the public, while similar meetings at Los Alamos National Laboratory are open to the public.[20] In addition, the IBC at Los Alamos maintains a website that includes the minutes of their meetings, while the minutes of IBC meetings at Lawrence Livermore are only available through the cumbersome and time-consuming Freedom of Information Act process.[21] Although there does not appear to be a rational basis for making such a distinction between these two facilities, currently there is no mechanism available to ensure consistency among the various departments and agencies engaged in biodefense activities. Furthermore, such a commission could act as a clearinghouse for information concerning national programs to counter deliberate outbreaks of disease, in addition to offering technical assistance and advice regarding national implementation, as recommended by the Weapons of Mass Destruction Commission.[22]

4. Provide for Comprehensive and Coherent Planning and Response with Regard to Accidents and Security

Fourth, a national regulatory commission could provide for comprehensive and coherent planning and response with regard to accidents and security. In the United States, it was recently reported that laboratories that possess, use, or transfer select agents and toxins have experienced more than 100 accidents and shipping mishaps since 2003.[23] The number of these incidents has risen steadily in conjunction with an increase in the number of these labs over the past few years.[24] A national regulatory commission could be given the mandate to establish a comprehensive regulatory regime to prevent accidents, provide for consistent reporting thereof, and penalize any offenders, under appropriate circumstances.

Relatedly, a national regulatory commission could analyze security threats, both internal and external, and develop and enforce security regulations and protocols. Facilities involved in biodefense research are threatened by three, distinct terrorist scenarios: (1) facility damage or destruction from terrorist attacks that result in a loss of containment; (2) the theft and subsequent release of pathogenic material by one or more terrorists with no connection to the facility; and (3) the covert theft and subsequent release of pathogenic material by an individual with access to the facility. With regard to the third scenario, available evidence suggests that the individual

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[20] *See* Lawrence Livermore National Laboratory Institutional Biosafety Committee, http://ibc.llnl.gov/ (last visited Dec. 3, 2007); Los Alamos National Laboratory Institutional Biosafety Committee, http://www.lanl.gov/safety/biosafety/bio_committee.shtml (last visited Dec. 3, 2007). The National Institutes of Health (NIH) Guidelines require the creation of an IBC when research is conducted at or sponsored by an entity receiving any NIH support for recombinant DNA research. *See* NATIONAL INSTITUTES OF HEALTH, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES) 10, 23 (2002), *available at* http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_lnk_2002z.pdf (last visited Dec. 3, 2007).

[21] Los Alamos National Laboratory Institutional Biosafety Committee, *supra* note 20.

[22] WEAPONS OF MASS DESTRUCTION COMMISSION, WEAPONS OF TERROR: FREEING THE WORLD OF NUCLEAR, BIOLOGICAL, AND CHEMICAL ARMS 118 (2006).

[23] The Associated Press, *U.S. Labs Mishandling Deadly Germs*, N.Y. TIMES, October 2, 2007.

[24] *Id.*

responsible for the 2001 anthrax mailings was connected to a microbiological laboratory.[25] In September 2007, Lawrence Livermore National Laboratory was fined $450,000 by the Office of Inspector General of the Department of Health and Human Services for violations of the select agent regulations.[26] The fine concerned two shipments—containing over 4,000 vials of anthrax—from LLNL to two laboratories in Florida and Virginia in September 2005.[27] Among other violations, "LLNL failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of anthrax[.]"[28] This incident highlights the real and continuing threat posed by insider terrorist attacks, a threat that is increasing as more facilities and individuals become engaged in biodefense activities.

Furthermore, the Government Accountability Office (GAO) recently reported that "[n]o single federal agency has the mission to track and determine the risk associated with the expansion of BSL-3 and BSL-4 labs in the United States, and no single federal agency knows how many such labs there are in the United States."[29] According to Keith Rhodes, Chief Technologist for the GAO, this alarming state of affairs "has caused particular concern among officials at the Federal Bureau of Investigation . . . because the laboratories themselves could become the source of agents that might be used in terrorist attacks."[30] As a result of this lack of oversight, "no one is responsible for determining the aggregate risks associated with the expansion of these high-containment labs."[31] As has been widely acknowledged, as more laboratories of this kind become operational and more individuals are approved to perform such research, the aggregate risks increase.[32] Accordingly, it is essential that one entity, of whatever nature, be charged with tracking the overall number of such facilities, as well as determining the cumulative risks associated with their proliferation. An ideal entity for such an undertaking would be a national regulatory commission, which would have expertise in the panoply of issues relating to biodefense.

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[25] David Johnston and William J. Broad, *Anthrax in Mail Was Newly Made, Investigators Say*, N.Y. TIMES, June 23, 2002.

[26] Department of Health and Human Services Office of Inspector General, Fraud Prevention & Detection, Enforcement Actions, Administrative Actions, Civil Monetary Penalties, Select Agents and Toxins, http://www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html#6 (last visited Dec. 3, 2007).

[27] Jaxon Van Derbeken, *Lab fined $450,000 for mishandling anthrax*, S.F. CHRONICLE, Oct. 7, 2007.

[28] Department of Health and Human Services Office of Inspector General, *supra* note 29.

[29] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, HIGH-CONTAINMENT BIOSAFETY LABORATORIES: PRELIMINARY OBSERVATIONS ON THE OVERSIGHT OF THE PROLIFERATION OF BSL-3 AND BSL-4 LABORATORIES IN THE UNITED STATES 13 (2007).

[30] Eric Lipton, *U.S. Called Lax at Policing Labs Handling Biohazards*, N.Y. TIMES, October 5, 2007; *see* U.S. GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 32, at 14 (noting that "the FBI has a need to know the number and location of BSL-3 and BSL-4 labs for forensic purposes" and that some intelligence agencies "need to know a subset of the number and location of high-containment labs within the United States because these labs represent a capability that can be misused by terrorists or people with malicious intent").

[31] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 32, at 13.

[32] *See id.* at 14 ("According to experts, there is a baseline risk associated with any high-containment. With expansion, the aggregate risks will increase. However, the associated safety and security risks will be greater for new labs with less experience. In addition, high-containment labs have health risks for individual labs as well as the surrounding community."); Eileen Choffnes, *New Labs, More Terror*, BULLETIN OF THE ATOMIC SCIENTISTS, September/October 2002, at 29-32; Jonathan B. Tucker, *Biological Threat Assessment: Is the Cure Worse Than the Disease?*, ARMS CONTROL TODAY READER: THE 2006 BIOLOGICAL WEAPONS CONVENTION REVIEW CONFERENCE, November 2006, at 29; Lipton, *supra* note 33.

A national regulatory commission could also facilitate national emergency planning, in addition to providing grants and training to applicable organizations and individuals, such as those involved in law enforcement, emergency response, health care, and related fields. While many BWC member-states currently engage in centralized emergency planning for bioterrorist attacks, these efforts would be furthered by establishing a national regulatory commission to act as a locus for bioterrorism planning and response.

5. Establish a Flexible and Responsive Entity

Fifth, a national regulatory commission offers BWC member-states the opportunity to establish a flexible entity that is capable of responding to changing circumstances and technological developments. Advances in life sciences, while certainly laudable, may also allow for the creation of novel biological agents and toxins that are capable of evading detection and prophylaxes.[33] Any regulatory regime must be able to readily adapt to such changes and the varying nature of the biological threat, whether it be from nations, terrorist organizations, or malicious individuals. A properly authorized and well-functioning national regulatory commission could offer such flexibility because it would be responsive to national needs and priorities.

6. Create Genuine Accountability

Finally, and perhaps most fundamentally, a national regulatory commission could create genuine accountability at the state level. The centralization of oversight and regulatory responsibilities would of necessity create an entity, with individuals therein, that could be held accountable for any failures. Such accountability could promote efficiency and incentivize individual compliance with BWC-related obligations and applicable regulations.

ii. International Interests

Until negotiations concerning a verification instrument can be resumed, the most promising and plausible area for increasing the effectiveness of the BWC lies in enhancing national implementation. To that end, national regulatory commissions would also help advance significant international interests by increasing compliance with the BWC, facilitating meaningful confidence building measures, and allowing for experimentation toward a feasible and broadly-supported verification instrument.

1. Increase Compliance with the BWC

First, national regulatory commissions could increase compliance with the BWC by enacting national standards and regulations mandating compliance with the BWC. The oftentimes piecemeal approach that has seemingly been a hallmark of this area could be replaced by a uniform and transparent implementation regime. Such commissions could also be given the authority to conduct investigations and inspections to ensure compliance with the BWC. Pursuant to Article VI of the Convention,

[33] NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY, *supra* note 10, at 1-2.

> (1) Any State Party to th[e] Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.
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> (2) Each State Party to th[e] Convention undertakes to co-operate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.[34]

A national regulatory commission would be the ideal liaison between an accused BWC member-state and the Security Council. Moreover, a properly composed and well-functioning commission would undoubtedly be in possession of information capable of confirming or dispelling any accusations.

2. Facilitate Existing and Potential Confidence Building Measures

Second, national regulatory commissions could help facilitate existing and potential confidence building measures (CBMs). While voluntary CBMs were adopted by review conferences in 1986 and 1991, "many states are struggling to comply at even the most rudimentary level."[35] The creation of national regulatory commissions would necessitate the centralized compilation of a broad spectrum of relevant information. Such commissions could easily be tasked with ensuring compliance with the voluntary CBMs. In addition, national regulatory commissions would be well-positioned to comply with any additional CBMs, voluntary or mandatory, that might be adopted in the future.

3. Allow for Experimentation to Inform Future Negotiations Concerning a Verification Instrument

Finally, national regulatory commissions offer the opportunity for experimentation that could inform any future negotiations concerning a verification instrument. Since in many respects national regulatory commissions would resemble the protocol envisioned by the Ad Hoc Group, such commissions could help to elucidate the proper mandate, composition, authority, reporting requirements, and inspection and investigation regime that would be vital to the establishment of an effective verification instrument that is capable of garnering broad support among states parties. Moreover, because numerous BWC member-states would ideally establish national regulatory commissions, the experimentation process would be fostered by varied and simultaneous commissions.

For example, the United States has taken the position that "the traditional trappings of arms control, such as declarations and investigations, do not work with respect to biological

[34] BWC, *supra* note 2, at art. IV.
[35] Trevor Findlay, *Verification and the BWC: Last Gasp or Signs of Life?*, ARMS CONTROL TODAY READER: THE 2006 BIOLOGICAL WEAPONS CONVENTION REVIEW CONFERENCE, November 2006, at 19.

weapons."[36] In rejecting the draft verification protocol, the United States highlighted, among other concerns, "the potential risks for industry proprietary commercial information."[37] However, according to experts from the United States' pharmaceutical and biotechnology industry,

> if multidisciplinary inspection teams are allowed sufficient time on site and empowered to use pre-inspection research and analysis, site tours, document reviews, interviews, and sampling, they can discern legitimate from cheating facilities. Moreover, the industry experts stated that the operators of commercial facilities, well versed in hosting all manner of regulatory inspections, would be able to protect their proprietary business data during such inspections at the same time that they helped the inspectors achieve their aims.[38]

Whether the concerns of the United States are well-founded could be resolved by national regulatory commissions, without the risk of revealing proprietary commercial information to other countries. Although the investigation and inspection regime would of necessity be intra-national, this process could both help to prepare hosting facilities for the rigors of international verification and reveal practices necessary to ensure that such verification is practical and robust.

iii. Shortcomings of National Regulatory Commissions

Despite their potential benefits, there are a number of obvious shortcomings associated with national regulatory commissions. First, many BWC member-states are hostile to the notion of increasing bureaucracy and regulation. However, because such commissions could promote efficiency and accountability and be crafted in such a way as to not stifle innovation or hamper legitimate biodefense activities, these concerns are not well-founded. Second, many countries may not have the need for or resources available to establish a full-fledged national regulatory commission. Fortunately, such commissions are sufficiently scalable to address the particular situation in each BWC member-state. Finally, and most importantly, national regulatory commissions may be susceptible to the sort of corruption and concealment that threatens to undermine the effectiveness of the BWC; however, these concerns merely point to the need for a verification protocol, to which national regulatory commissions could be an effective complement.

b. Considerations Regarding National Regulatory Commissions

While each national regulatory commission would of necessity vary depending on the particular circumstances and legal system in each of the BWC member-states, there are a number

[36] U.S. Biological Weapons Convention Talking Points 2 (Sept. 2, 2002) (on file with author).
[37] John Borrie, *The Limits of Modest Progress: The Rise, Fall, and Return of Efforts to Strengthen the Biological Weapons Convention*, ARMS CONTROL TODAY READER: THE 2006 BIOLOGICAL WEAPONS CONVENTION REVIEW CONFERENCE, November 2006, at 8.
[38] HENRY L. STIMSON CENTER, COMPLIANCE THROUGH SCIENCE: US PHARMACEUTICAL INDUSTRY EXPERTS ON A STRENGTHENED BIOWEAPONS NONPROLIFERATION REGIME 25 (2002).

of general considerations that should inform any such pursuits. First, a national regulatory commission should be given a broad mandate, which may include the following:

- Promulgate and enforce regulations to ensure compliance with the BWC;
- Coordinate the planning and distribution of resources to meet national priorities, avoid waste, and minimize any associated risks;
- Ensure uniform and appropriate oversight;
- Enhance transparency;
- Provide for comprehensive and coherent planning and response with regard to accidents and security;
- Establish a mechanism for outside verification of compliance with the BWC; and
- Prepare reports on biodefense research needs, priorities, accomplishments, and expenditures; compliance with the BWC; and suggestions for legislative proposals and reforms.

Second, a national regulatory commission should be composed of a broad cross-section of stakeholders, including representatives from government, academia, industry, and the public. Moreover, in order to ensure the independence of such a commission, the ability to appoint members should be distributed to the greatest extent possible. For instance, in the United States, the thirteen members of the Veterans' Disability Benefits Commission are appointed by the President and the majority and minority leaders of Congress, and the Commission is independent of government agencies, such as the Department of Veterans Affairs and the Department of Defense.[39] This model should be emulated by any such commissions.

Third, a national regulatory commission should be given the authority to fulfill its mandate. Among other things, this would require that such a commission have the power to promulgate regulations, hold hearings, take testimony, receive and directly secure evidence, conduct inspections and investigations, and appoint committees or advisory boards. Finally, a national regulatory commission should receive dedicated funding and have an independent staff to avoid conflicts of interest.

IV. Conclusion

National regulatory commissions, while not a panacea for the multitude of issues relating to compliance with the BWC, nonetheless offer an excellent starting point for a discussion about enhancing national implementation of the Convention. Such commissions offer the opportunity to establish and enforce a uniform regulatory regime to ensure compliance with the BWC; promote efficiency, transparency and accountability; address pressing national security needs; and act as a clearinghouse for information both nationally and internationally. It is hoped that

[39] 117 Stat. 1392, 1676-79 (2003).

the discussion above, which highlights difficult issues relating to BWC compliance and biodefense oversight in the United States, will serve as a touchstone for further efforts to enhance national implementation of the BWC.