

An Arms Control Today Reader



The 2006 Biological Weapons Convention Review Conference

Articles and Interviews on Tackling the Threats Posed by Biological Weapons

November 2006

Arms Control TODAY

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Arms Control Today (ACT), published by the Arms Control Association (ACA), provides policymakers, the press, and the interested public with authoritative information, analysis, and commentary on arms control proposals, negotiations and agreements, and related national security issues. ACA is a national nonpartisan membership organization dedicated to promoting public understanding of and support for arms control policies. In addition to *ACT*, ACA provides information through its web site, regular press briefings, and commentary and analysis by its staff for journalists and scholars in the United States and abroad.

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Time for Collective Action to Tackle the Threat From Biological Weapons

On November 20, representatives of many of the 155 states-parties to the Biological Weapons Convention (BWC) will gather in Geneva for three weeks of deliberations on how to strengthen the biological weapons ban. At a time when multilateral arms control is in deep crisis, the Sixth Review Conference of the BWC will face the tremendous challenge of agreeing on concrete actions to reduce the threat of disease as a weapon of war and terror.

In this reader, leading experts summarize new and old dangers associated with biological weapons and recommend ways of addressing them. Included are articles previously published in *Arms Control Today*, as well as an exclusive interview with Ambassador Masood Khan, the designated president of the review conference, who shares his vision of a successful meeting.

Since the last full and substantive review of the BWC in 1996, the global prohibition of biological weapons has come under pressure from several directions.

The September 11, 2001, terrorist attacks and the anthrax letter attacks that followed have spawned new fears of bioterrorism. Governments have yet to fully adapt the BWC, an agreement among states, to this new challenge.

To be sure, BWC member states have made some progress in implementing the treaty's rules and prohibitions at the national level, as advocated by the United States. But there is a darker side to the reaction to bioterrorism. Governments, particularly the Bush administration, have also responded with a vast increase in biodefense spending. Although some of these activities may lead to better medical countermeasures against a possible attack, experiments that appear to cross the line of what is permitted by Article I of the BWC "could undermine the ban on offensive development enshrined in the treaty and end up worsening the very dangers that the U.S. government seeks to reduce," as Jonathan Tucker pointed out in an October 2004 *ACT* contribution.

One way to address this problem is greater openness about sensitive activities. As Nicolas Isla and Iris Hunger argued earlier this year, "[A] good starting point for building confidence in compliance is to increase transparency." In Geneva, states-parties have an excellent opportunity to make the annual information exchanges between states-parties more comprehensive and useful.

At the same time, the knowledge required to develop more deadly biological weapons has spread more widely than ever before. Mark Wheelis warns us that "biology is in the midst of what can only be described as a revolution" and that "this technology will have great power both for peaceful and hostile uses."

The contributors to this reader agree that the response to the potential misuse of the life sciences for hostile purposes must be multilayered and suggest several possible actions that states-parties might take in Geneva. Jonathan Tucker, for example, calls for more effective and internationally harmonized biosafety and biosecurity measures. Christopher Chyba suggests novel mechanisms for the oversight of dual-use research in the life sciences. John Hart, Frida Kuhlau, and Roger Roffey advocate more stringent codes of conduct for biodefense scientists.

Yet, even these important efforts may not be sufficient to avert the danger of a new biological arms race. In the long run, the BWC requires collective action at the level of governments, industry, and individual scientists. A legally binding international agreement to establish an Organization for the Prohibition of Biological Weapons, comparable to but smaller than the International Atomic Energy Organization or the Organization for the Prohibition of Chemical Weapons, remains an essential goal. Only such an institution would have the mandate to monitor state-level compliance with the BWC continuously and organize joint responses to possible breaches of the convention. Creating such a multilateral framework would also strengthen the sense of ownership of all states-parties and reverse the current trend to portray biological weapons proliferation as a problem limited to a few "states of concern."

It should be possible to overcome some of the differences that led to the failure of the last review conference in 2001 because, as Trevor Findlay remarks,

“there has been some quiet movement that is changing the context of the bio-verification debate.” Today, verification is a broad concept that encompasses many of the useful activities that member states and other international organizations already undertake at the national level to improve compliance.

Nicholas Sims cautions that expectations for the sixth review conference are modest and that its primary task will be to “reach agreement on where that treaty regime stands in 2006 and how best to steer its constructive and balanced evolution cautiously through to the seventh review conference in 2011, when conditions may be more favorable to advance.”

If he is correct, the most important short-term task is to continue the dialogue among states-parties that has developed over the last three years of annual meetings, to make the intersessional process more relevant to current issues, and to enable states-parties to take concrete action prior to the next review conference in 2011.

Even if it is not possible to restart discussions on a multilateral verification framework at this time, states-parties should agree at least to discuss measures that might contribute to a future monitoring mechanism. Improving exchanges of information among member states about treaty-relevant activities, taking advantage of the United Nations’ capacity to investigate instances where biological weapons may

have been used, and setting up a small but efficient secretariat to support various activities under the BWC would be significant moves in this direction.

The threat from biological weapons is real. The BWC must be able to react to new scientific and technical developments, such as the “nonlethal” biochemical weapons under development in the United States and Russia. As John Borrie warns, “These kinds of problems that threaten the norm created against hostile use of the life sciences are not going away, and the BWC must tackle them at some point or lose credibility and relevance.”

After many years of setbacks and compromises, diplomats and experts dealing with the BWC have become skillful in the art of lowering expectations. It is a hopeful sign that Ambassador Khan has promised that he “will not use the lowest common denominator as the yardstick for success, but the median point that represents common ground.”

The Arms Control Association hopes that the ideas and proposals contained in this publication will help states achieve a successful outcome to the review conference.

Oliver Meier
International Representative
Arms Control Association

Failure Is Not an Option:

An Interview With Ambassador Masood Khan, President-Designate of the Sixth BWC Review Conference

Biological Weapons Convention (BWC) member states will gather Nov. 20 to Dec. 8 for a review conference five years after a similar meeting ended divisively. Prospects for success this year are uncertain even as a modest work program has helped restore confidence in the BWC process. *Arms Control Today* spoke on September 23 with the designated conference president Ambassador Masood Khan of Pakistan about his expectations for the 2006 review conference.

ACT: *Ambassador Khan, as President-designate, what are your expectations for the forthcoming Sixth Review Conference of the Biological Weapons Convention (BWC)? In particular, in your view, what would constitute success for the review conference?*

Khan: I will come to [what constitutes] success later but let me tell you that the sixth review conference should succeed. That's an imperative. It should have concrete, tangible results that add value to the BWC and strengthen it as a barrier against biological weapons. Its outcome should be based on consensus but with added value. We will not use the lowest common denominator as the yardstick for success, but the median point that represents common ground.

ACT: *How do you think the global context, in particular U.S. tensions with Iran, will influence discussions?*

Khan: First, on the overall, global context with regard to disarmament diplomacy. Three major events—the nuclear Nonproliferation Treaty (NPT) Review Conference in May 2005,¹ the UN Summit in September 2005,² and the Small Arms and Light Weapons Review Conference³ in June—did not seem to have achieved the results that a majority of states were hoping to achieve. At the BWC review conference, however, we should have a strong possibility of bringing the international community to one shared platform. This event could represent a peak in disarmament diplomacy.

About the other external dynamics: We will try to manage them within the setting of the BWC, and we will try to keep them specific to biological weapons issues.

ACT: *Which topics do you expect to be the most difficult ones at the review conference, and on which issues do you expect to see convergence?*

Khan: There is a growing convergence that there should be a solid outcome, to build on the successful engagement of the states-parties in the recent past, particularly during the expert and the annual meetings from 2003 to 2005. At the moment, we are not talking about divergences but common ground.

ACT: *The last review conference in 2001 ended in controversy as the U.S. blocked consensus on a draft verification protocol and thus member states haven't agreed on a substantive final document since 1996. What do you think will be the consequences if member-states again fail to agree on a substantive final document?*

Khan: Well, I think there was a compromise of sorts in 2002 and that is why we had the annual meetings.⁴ But in our preparations I have banished the word "failure," because the use of this word could be self-indoctrinating and, consequently, self-debilitating. I have advised negotiators of states-parties to do the same, that is to banish the word failure. We are trying to put success on the table and define what it could mean and what it could be.

ACT: *You already mentioned the intersessional process. What in your view are the lessons of this novel exercise that has taken place the last three years, and how can the review conference reflect on those lessons?*

Khan: [The meetings] touched on very important dimensions including national implementation, security and oversight of pathogens, capabilities for responding to and investigating alleged use of biological weapons, mechanisms for disease surveillance and response, and codes of conduct for scientists. Now, let me enumerate some of the lessons that were learned, and this is my personal view. As these discussions were not expected to lead to binding commitments, they tended to be more collegial, cooperative, and constructive. In such a setting, states-parties and all other actors learn more from each other. These meetings have also raised awareness about the threat of biological weapons. The process was less polemical. The meetings also kept the focus on the BWC and tried to make it responsive to contemporary challenges, for instance scientific and technological developments. In my view, such discussions serve as building blocks that states-parties can use for possible agreements when they are ready to do so, and they also work as catalysts for agreements.

ACT: *Now in your consultations, did you get a sense that member-states want there to be a continuation of this intercessional process? In particular, there have been conflicting signals from Washington whether this process should be continued. Do you think the United States would support a new intercessional process?*

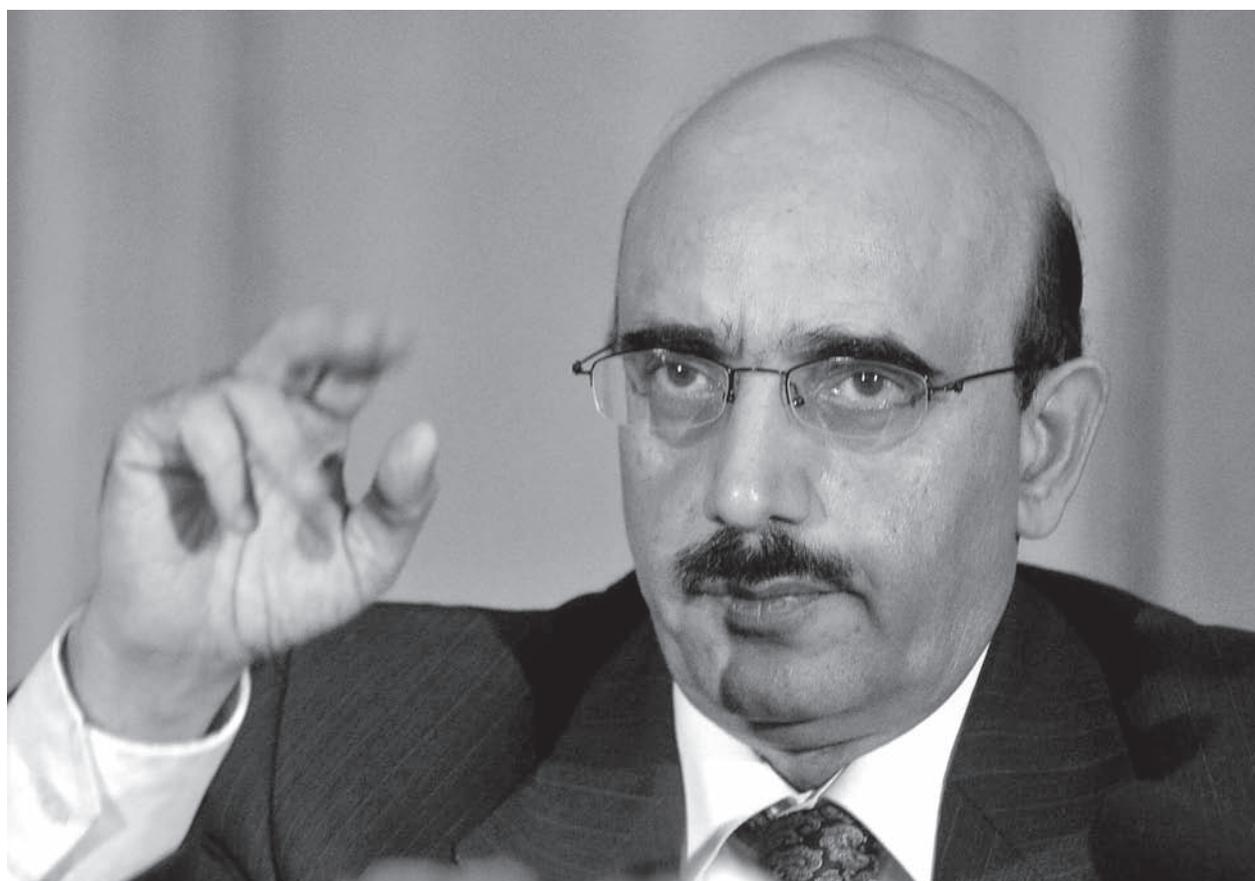
Khan: It is for the United States to elaborate

its position. While speaking to the states-parties and delegations in informal settings, I haven't received any conflicting signals. There is a growing sense among states-parties that the sixth review conference should recommend or decide on an intersessional calendar from 2007 to 2010. But first they have to give their concurrence in principle and then they have to [decide on the specific issues to be included in a work program]. There are some states who have said that the calendar should not be the only outcome, and that there should be a focus on other issues as well.

ACT: *What other issues do you mean? Are you talking about a substantive review of the convention itself?*

Khan: Yes absolutely. But let me share my personal thoughts about the likely outcome of the review conference. When I have been talking to the different groups or states-parties, I have been emphasizing that we should have a concise document that will not only be useful to states-parties as a record of their understandings and commitments in the fight against biological weapons but it should be such a document that can communicate effectively to the media, to the scientific community, industry, and the general public, because they are all stakeholders.

Second, in terms of the outcome it's important for the states-parties to recapture and reaffirm very briefly core elements of the convention and understandings reached by states-parties in the



Farooq Naeem/AFP/Getty Images

Pakistani Ambassador Masood Khan (and president-designate of the sixth Biological Weapons Convention review conference) addresses the press during a November 2004 press conference in Islamabad.

past. One theme that I have been emphasizing is the phenomenal advances in the life sciences, as it will be both prudent and desirable to state

You mentioned biosecurity. This has high priority. In fact, it was discussed extensively during the previous intercessional process. And I think

"We will not use the lowest common denominator as the yardstick for success, but the median point that represents the common ground."

— Ambassador Masood Khan, on the sixth BWC Review Conference.

that the convention applies to all relevant scientific and technological developments.

And from my point of view, it would also be useful for states-parties to recall the understanding that the convention implicitly prohibits the use of biological weapons. And a final point in this context that I want to make is that we should in the final document or the declaration reflect in some way our deliberations on a number of specific issues that were passed on to the states-parties by the fifth review conference as well as any fresh proposals that states parties may put forward.

Such proposals would of course be subject to consensus.

ACT: *I would like to ask you two brief questions on the intersessional process. Do you think that it would be desirable for states-parties to develop uniform guidelines for implementation so as to avoid creating a patchwork of inconsistent national regulations? And more generally, what is your sense of what topics might be on the agenda of a new intersessional process and the work program for such a process?*

Khan: Let me tell you that the comfort level for having a calendar is high, so it's not a cause of concern but it is inextricably linked to the question of what would constitute the calendar or what would constitute the work of the states-parties. These two things are interrelated. My sense is that in this area the states-parties are consulting with each other. I know that the European Union is meeting and within the Western Group there is a smaller group meeting who call themselves JACKSNNZ.⁵ The Non-Aligned Movement⁶ is meeting and there is a group of Latin American countries, who are preparing these proposals.⁷ Some of these proposals have already been circulated.

You asked me what the most urgent topics from my personal point of view were. I would list four. They are universal adherence, faithful and effective compliance, the fight against the threat of bioterrorism, and the capacity to deal with the developments in the biosciences that have enhanced the lethality and range of biological weapons. Now these subjects from my own personal perspective are the most urgent and should receive the attention of the states-parties.

that biosecurity is part of overall compliance. You need to streamline your national institutions, not just the legislative and administrative part, but all of the mechanisms that are there. It will receive the attention of states-parties, but I'm not so sure with how much specificity.

ACT: *Another issue is biodefense and the huge increase in biodefense spending. Do you hope to address this issue at the review conference in anyway?*

Khan: Biosecurity in a wider sense includes not only physical security but non-transfer of tangible or intangible bioweapon technology. All precautions should be taken to ensure that research into biodefense programs has a defense orientation; it is amenable to scientific oversight; and it conforms to the BWC.

ACT: *How would you like to see the issue of compliance addressed this year?*

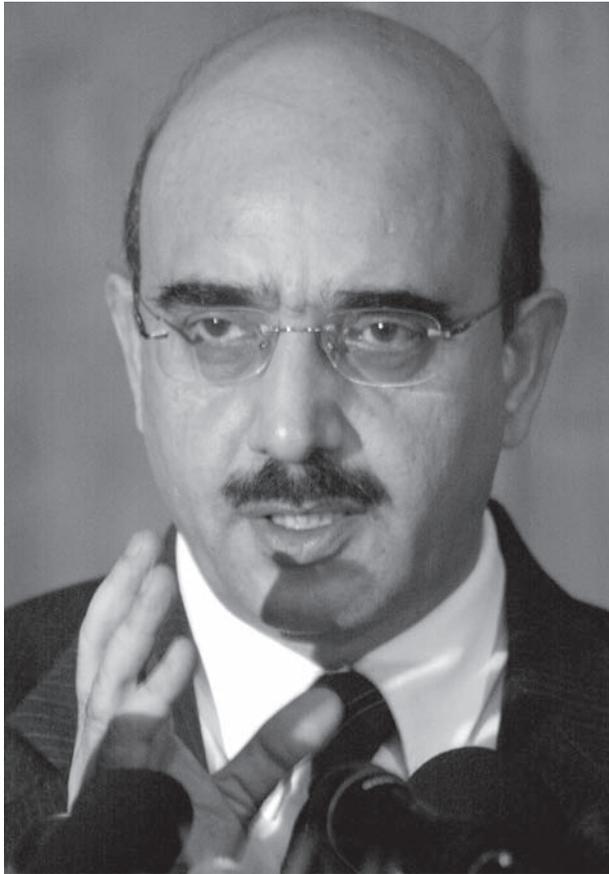
Khan: I won't go into specifics but let me give you my sense of what the states-parties have been focusing on. More or less everybody is comfortable with an article by article review [of the BWC] that should cover all aspects. States-parties want a comprehensive review.

And then, as you mentioned, there should be a review of action on the five topics, mandated by the fifth review conference, and which were considered during 2003 and 2005 and I have listed them.

The third responsibility—and there has been intense debate on this subject—is the preview of and possible decisions on an intersessional calendar or meetings and activities on agreed topics.

Then there is confidence-building measures, universalization of the convention, and interest of the states-parties in new scientific and technological developments relevant to the convention. I already mentioned bioterrorism, compliance, and verification.

And one important point is coordination with other organizations and activities. In the past four of five years other organizations have been very active, such as the World Health Organization [WHO], the Security Council which has passed Resolution 1540,⁸ Interpol, the Food and Agriculture Organization, the World Organization for Animal Health, the



Ambassador Masood Khan of Pakistan will serve as president-designate of the Sixth Review Conference of the Biological Weapons Convention.

International Committee of the Red Cross. You need to develop a new approach toward coordinating their activities. The WHO in particular has come up with International Health Regulations (IHR) and they also have a sophisticated disease surveillance center here in Geneva. All these organizations need to talk to each other, need to share information with each other, and need to strategize together. Finally, states-parties have been talking about implementation support arrangements for the convention, because if you have a robust intercessional process in the next cycle, then you would need some sort of support.

ACT: *Do you have any other remarks?*

Khan: I would like to emphasize the importance of building good interpersonal chemistry among negotiators and states-parties. Another requirement is that there should be good conference management. It should not be inefficient. Then I'm saying: build synergy at the international level between different organizations dealing with deliberate or natural release of disease, and I have just listed them. And finally I would like say that there should be enhanced coherence and cohesiveness at a national level, to show the success of the implementation of the BWC.

ACT: *Thank you very much.*

ENDNOTES

1. After four weeks, the 2005 nuclear Nonproliferation Treaty Review Conference ended May 27 without consensus on next steps for stopping the spread of or eliminating nuclear weapons. (See *ACT*, July/August 2005.)
2. At the UN Summit in New York Sept. 14-16, world leaders endorsed a document setting out a broad agenda for the international organization and its member states in the coming years. However, the document contained no action plan for mitigating threats posed by chemical, biological, and nuclear arms.
3. A two-week UN conference in New York aimed at cracking down on the worldwide illicit trade of small arms ended July 7 without a final agreement on measures to reduce the spread of the weapons. Delegates also failed to create a road map for future action.
4. At the second part of the fifth review conference in November 2002 states-parties agree to meet three times before the next review conference to discuss ways to improve national measures and existing international mechanisms to combat biological weapons. Meetings between experts and states-parties representatives took place in 2003 on improved national legislation and better national oversight over dangerous pathogens; in 2004 on enhancing international capabilities to deal with alleged cases of biological weapons use and strengthening and broadening national and international efforts for disease surveillance; in 2005 on codes of conduct for scientists.
5. JACKSNNZ are an informal grouping of non-EU, non-nuclear participants of Western Group states. Participants are Japan, Australia, Canada, (South) Korea, Switzerland, Norway, and New Zealand.
6. The Non-Aligned Movement is an international organization of 115 members representing the interests and priorities of developing countries. The movement has often demanded a time-bound framework for nuclear disarmament.
7. At the meeting of the Preparatory Committee for the Review Conference Argentina, Brazil, Colombia, Costa Rica, Chile, Ecuador, Guatemala, Mexico, Peru, and Uruguay tabled a joint working paper.
8. Passed April 28, 2004, UN Security Council Resolution 1540 requested all governments to put in place "appropriate, effective laws" to deny terrorists access to biological, chemical, and nuclear weapons, their delivery systems, and related materials. The 15-member Security Council approved the resolution under Chapter VII of the UN Charter opening the door to punitive actions to enforce the resolution. The United States was the chief architect of the measure.

The Limits of Modest Progress: The Rise, Fall, and Return of Efforts to Strengthen the Biological Weapons Convention

Next month, Biological Weapons Convention (BWC) member states will gather for a review conference five years after a previous meeting dissolved amid acrimony. So far, the signs are that countries participating in November's BWC review meeting will avoid a repeat of late 2001's scarring experience. Since 2002, a modest work program has helped to rebuild a measure of confidence in the BWC process. On the whole, states-parties have been able to move beyond political rhetoric and toward improving practical implementation of BWC provisions. The conference may take these efforts further still, but given the changes transforming the life sciences, these efforts may be too little and perhaps too late.

The BWC and the Draft Protocol

The BWC emerged from the Nixon administration's recognition that a biological arms race was not in the United States' strategic interest and that it should abolish its germ weapons program. The BWC was signed in 1972 with the United Kingdom, United States, and Soviet Union as depository states. Three years later, it entered into force.

However, a major shortcoming of the BWC was that, despite its comprehensive ban on biological weapons, it lacked mechanisms for ensuring confidence in compliance. Indeed, BWC member-states as diverse as the Soviet Union and South Africa carried on clandestine germ-warfare activities. Meanwhile, although successive five-year review meetings acknowledged the convention's weaknesses, not until the 1990s did an agreement emerge to develop a regime to enhance confidence in compliance. A special BWC conference in 1994 set up an Ad Hoc Group to develop a legally binding instrument to strengthen the convention.

The Ad Hoc Group Negotiations

From the early stages of the Ad Hoc Group negotiations, the United States and Russia were ambivalent about the prospect of a verification instrument. Efforts at trilateral inspections of facilities potentially relevant to biological warfare programs among the United Kingdom, the United States, and Russia in the early 1990s had encountered mixed success. Meanwhile, Iraqi deception and obfuscation seemed to be successfully impeding the UN Special Commission

(UNSCOM) investigation of Saddam Hussein's biological warfare activities.¹

This ambivalence about the value of a protocol hampered the creation of a robust instrument. Over time it became apparent to other Ad Hoc Group delegations that the United States was not prepared to provide the leadership it had displayed, for instance, in the Chemical Weapons Convention negotiations. Such leadership was necessary for creating a robust compliance regime in the face of continual resistance from countries with minimalist positions on verification, such as China and Cuba, India, Iran, and Pakistan, the hard-line members of the Nonaligned Movement (NAM).² Russia, meanwhile, remained largely silent, apart from trying to establish basic definitions and "objective criteria" in the evolving protocol draft. If accepted, these would have undermined the convention by circumscribing the scope of its existing prohibitions.³

As the draft protocol text was fleshed out—at one stage, the rolling text was more than 300 pages long and contained thousands of brackets around passages of text not yet agreed—U.S. officials increasingly expressed their concerns about its compliance elements. These concerns became more strident as the chairman of the negotiations, Ambassador Tibor Tóth of Hungary, tried to push the Ad Hoc Group's work toward completion before the fifth BWC review meeting in late 2001. Tóth released a composite text in late March 2001, choosing the compromise

most likely to secure general agreement.

In public, the strongest U.S. reservations hinged on the draft protocol not being sufficiently robust and on the potential risks for industry proprietary commercial information. It was also clear, however, that U.S. concerns related to protecting national security-related biodefense activities from prying eyes.

Washington's negotiating positions on aspects of the draft agreement such as the content of required declarations, routine visits to check these declarations, and investigations of alleged noncompliance with the BWC contributed to the dilution of the draft protocol's verification provisions. Moreover, uncompromising U.S. rhetoric in the Ad Hoc Group format, often in response to provocation from NAM minimalists, exacerbated wider polarization in the negotiations. For instance, although the United States was a conscientious defender of informal export control regimes such as the Australia Group, which developing countries perceive as discriminatory, it was also publicly sceptical of modest proposals for assistance and cooperation measures. Hard-line NAM countries eagerly exploited this; they were no keener on a protocol than the United States appeared to be.

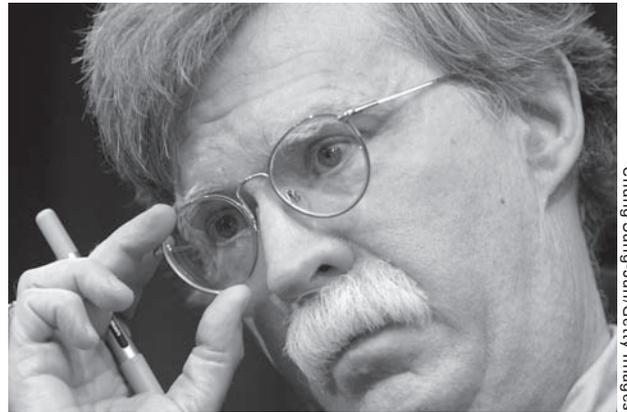
In July 2001, matters came to a head. The leader of the U.S. delegation, Donald Mahley, announced to the Ad Hoc Group negotiations that the United States rejected the draft protocol.⁴ This rejection was not altogether unexpected as it followed months of diplomatic rumor about the interagency review underway in Washington as President George W. Bush's policy team took up their posts. Nevertheless, the announcement triggered a blame game in the protocol negotiations along regional-group lines that swiftly led to its collapse.

2001 BWC Review Conference

Despite the bitterness generated by the failure of the protocol negotiations, it seemed that delegations at the review conference would cobble together an agreed outcome by the final day of December 7, including Ad Hoc Group follow-up plans. It still remained difficult to reflect the United States' insistence on tough language in the final declaration on alleged BWC noncompliance by certain countries, but it looked like even this could be resolved through careful drafting.

That is, until John Bolton, then Bush's undersecretary of state for arms control and international security, introduced a fresh demand. The United States, he said, could agree to annual meetings, starting in November 2002, "to consider and assess progress by states parties in implementing the new measures or mechanisms for effectively strengthening the BWC."⁵ In exchange, however, the conference would have to agree to terminate the Ad Hoc Group's mandate. The message was clear: further work on a compliance regime was unacceptable to the United States and must stop.

Five years on, it is perhaps difficult to see the significance of Bolton's eleventh-hour demand or why other members of the BWC, including those in the Western Group, reacted to it so strongly. After all,



Chung Sung-Jun/Getty Images

During the 2001 Biological Weapons Convention (BWC) Review Conference, then-Undersecretary of State for Arms Control and International Security John Bolton issued a controversial demand that the conference agree to terminate the Ad Hoc Group, which was established in 1994 to create a legally binding instrument to strengthen the convention.

the draft protocol was widely regarded as less than optimal, even by its strongest supporters. Moreover, it probably would have been impossible to "re-boot" Ad Hoc Group negotiations and subsequently negotiate a better package. Was the United States not just doing everyone a favor by ending the charade of further Ad Hoc Group work?

It disturbed many that the United States had been instrumental in undermining elements of the draft protocol it then rejected for being too weak. It seemed to confirm the impression that the United States was not negotiating in good faith. Moreover, Western Group solidarity had held during the final Ad Hoc Group session's blame game, despite the difficulty the new U.S. position posed for other Western Group members. Even Washington's closest friends and allies felt betrayed that the new condition was announced without any consultation on the final day of the meeting. In addition, Bolton's high-handed tone annoyed many of his European Union colleagues, which resulted in a subsequent emergency Western Group meeting melting down. With it, any last hope of rapprochement with the other regional groups evaporated.

Although the United States was often unhelpful in the Ad Hoc Group negotiations and formally rejected the draft protocol, it would be wrong to claim that it was solely or even largely to blame for the failure of efforts to strengthen the BWC through legally binding measures. In principle, protocol negotiations could have continued without the United States, which was, after all, exercising its sovereign national prerogative, not formally imposing it on others. That efforts did not continue reflected the reality that many countries had misgivings about a compliance regime that failed to capture the United States and its large biotechnology industry. The evident pleasure with which some NAM delegations sought to make the United States a scapegoat was hypocritical in view of their own efforts to prevent robust compliance measures during the Ad Hoc Group negotiations.

Nevertheless, the November 2001 review conference could have been a chance to leave behind this poisonous atmosphere if the United States had reclaimed a position of leadership by sharing its

own positive vision for moving forward. Although this would not have tempered hard-line NAM criticism or guaranteed a review-meeting consensus, it would have mollified the majority of BWC moderates. It could also have served to isolate the minimalists. Instead, the United States delegation conveyed that any further BWC-related work would be under sufferance and that the Bush administration had no time for the views of others, even of close allies and other supporters.

Slight Return

In the absence of any other realistic options, the review meeting was suspended for a year, which left matters in limbo. In September 2002, the United States once again incurred widespread displeasure by proposing that the scheduled two-week resumption (November 11-22) be reduced to one half-day at which the decision would be made simply to convene another review meeting in 2006. Prospects appeared bleak for any kind of work to follow the resumed review meeting.

Instead, following intense shuttle diplomacy by Tóth, members achieved a modest consensus by the time the resumed review meeting wound up on November 15. The deal included holding annual one-week meetings in Geneva from 2003 until 2005. These would be supported by the work of additional two-week-long expert meetings to discuss a number of specific aspects of BWC implementation, including biological security, national penal legislation, international surveillance of disease, responses to suspicious outbreaks of disease or alleged use of biological weapons, and codes of conduct for scientists.⁶ Any results or conclusions of these meetings were to be agreed upon by consensus and reported to this fall's review conference. In effect, this ruled out formal consideration of resuming the protocol negotiations.

On the Comeback Trail

The good news is that this pragmatic approach has worked better than expected. So far, a cautiously positive mood has developed in the lead-up to November's review meeting. At the preparatory meeting in April, for instance, states-parties were able to agree with relative ease on a provisional agenda and meeting rules.⁷ Agreement was reached despite tensions between Iran and Western countries, the United States in particular, about Tehran's nuclear activities, manifested by Iran's somewhat mischievous insistence on wanting the upcoming review conference to focus again on the 2001 rejection of the draft protocol.

BWC president Ambassador Masood Khan of Pakistan overcame these and other difficulties with skillful nudging. Khan kept informal consultations under his control and ensured that members negotiated in the meeting chamber rather than behind closed doors in regional groups. This was important because it avoided the circling of regional-group wagons at the first sign of trouble and a divisive dynamic taking hold that would have set back

prospects for the review meeting in November. Significantly, there were many points of commonality in various group statements, including those of the European Union, NAM, CANZ (Canada, Australia, and New Zealand), and an emerging group of moderate Latin American countries.

Still, the rebuilding of trust has been on specific terms. For the majority of countries active in the BWC review process, the quandary remains whether to insist on verification steps that risk alienating the United States and some NAM countries or to pursue the pragmatic approach that has kept the process ticking since 2002. At a time when fears about biological warfare have resurfaced, the BWC has not been able to work on new collective, binding agreements or play a role beyond encouraging national adherence to the convention. It also has had little to say as concern has shifted from the 1990s' focus on clandestine, state-run biowarfare programs to the contemporary emphasis on countering bioterrorism, a change in perception spearheaded by the United States.

Big Issues

November's review meeting provisional agenda encompasses all of the BWC treaty provisions by means of an article-by-article review. In addition, there are many derivative issues ranging from enhancing confidence-building measures to allowing more civil society participation in any BWC follow-up work. Meanwhile, the life sciences themselves continue to transform. For example, new domains such as synthetic biology pose practical challenges to the effectiveness of traditional nonproliferation responses, and states need to consider what these advances mean for the BWC. Yet, states will not be able to address all of these issues in depth in just three weeks. Rather, an important indication of the BWC review process's health will be its ability to make meaningful progress on some bellwether issues. These include:

1. *What to do in cases of alleged biological weapons use.* At the 2001 review meeting, the United States accused Iraq, North Korea, Iran, Syria, and Sudan, as well as the al Qaeda terrorist network, of violating BWC prohibitions.⁸ Yet, the United States did not present evidence to support its accusations. Since then, the matter has not been addressed. In the absence of a broader verification protocol, there remains the UN secretary-general's more limited investigation mechanism on weapons use.⁹ A question mark, however, hangs over whether in practice this mechanism would be acceptable to some states, including China, Cuba, Iran, and the United States. Therefore, a priority for the BWC regime should be to ensure that a robust and credible means exists to investigate alleged violations of the convention, but this is unlikely in the current political atmosphere.

2. *The BWC in context: How does the convention fit with other multilateral activities to prevent biological weapons?* The international community has launched a plethora of new initiatives since 2001, including UN Security Council Resolution 1540, the Proliferation Security Initiative, and activities involving the World Health Organization, Interpol, and other international organizations.¹⁰ A recent report by the UN secretary-general underlined the need for coordination between these efforts.¹¹

States-parties have been able to move beyond political rhetoric and toward improving practical implementation of BWC provisions. **The conference may take these efforts further still, but given the changes transforming the life sciences, these efforts may be too little too late.**

3. *What should the extent and shape of follow-up activities after the sixth review conference be?* The United States has made it clear it will not agree to work on a verification mechanism or a BWC “organization” much more ambitious than the small unit currently attached to the UN Department for Disarmament Affairs. This aside, there appears to be considerable scope for practical next steps, provided these are focused and the case is persuasive, in particular to the United States.

Governments and other experts have suggested many ideas for follow-up to the review meeting. More proposals will undoubtedly emerge in coming months as policymakers focus their attention on preparing national positions for the review meeting and blocs such as the European Union and regional groups gather to coordinate views.

The most acceptable proposals are likely to be those focused on further improving national implementation of the BWC.¹² A Canadian proposal for an “accountability package” presented at the April preparatory meeting contains a number of concrete proposals, including specific steps on national implementation, enhanced confidence-building measures, strengthened national implementation support, and annual meetings “to consider the state of implementation of the convention and new developments relevant to its purpose.”¹³ To this end, the package also outlines a proposal that has already found wide support in the BWC: to put the small secretariat unit on a more secure footing and to develop its capabilities.

Wider events also have a role to play. Continuing deadlock in the Conference on Disarmament, an inability by states to reach agreement on an outcome document at the July UN small arms review conference, and the expected difficulties at the Third Review Conference of the Convention on Certain Conventional Weapons in November will make many moderate countries keen to achieve a final document at the cost of ambitious pro-

posals. Moreover, there is a general expectation among BWC delegations that although the United States has in general played a constructive role in the post-2002 follow-up process, it will continue to have firm positions that constrain ambitious plans.

Pakistan, which will chair the BWC review meeting, is hoping for success. April’s preparatory meeting showed that Khan understands the nuances of working with the so-called hard-liners, including Iran and Cuba, which took over as NAM coordinator in September, and he may have sufficient influence with his colleagues to help secure the necessary compromises.

Wild-card issues could have a great influence over the prospects of a successful review outcome. The “war on terror” has shifted orientation toward issues of bioterrorism as a number of new multilateral agreements on aspects of terrorism attest.¹⁴ This has suited many BWC members. Dealing with terrorism is a more palatable focus in the current political environment than state noncompliance. However, a Middle East security situation that deteriorates further in the lead-up to the review meeting or a biological weapons attack could turn current expectations about the BWC process on their head.

Choosing a Way Forward

BWC delegations have not always shown they are aware of the distinction between the BWC political process and the norm against biological weapons, which surpasses contemporary preoccupations. Acrimony and shabby dealing have sometimes characterized the review process, and this has done little to strengthen the convention’s prohibitions. Consequently, November’s review meeting will be an important test for the BWC’s stewardship.

This November, pragmatism will almost certainly win out over ambitious proposals for verification steps. It is obvious to most BWC delegations that any hope of a return to negotiations on a verification protocol remains illusory for the moment. A crisis similar to 2001, however, is unlikely unless problems arise such as those that threatened the 2006 preparatory meeting. Khan seems conscious of this and has consulted intensively with a wide range of BWC delegations to try to avoid any nasty surprises, although these could still emerge.

The U.S. attitude will be pivotal. Moderates in the BWC context seem to realize that members will have to tailor proposals for follow-up work on strengthening the convention or its implementation to what Washington is prepared to live with, as Canada has tried to do in its “accountability package” proposal. This means emphasis on the specific and incremental. Less likely is substantial progress to clarify and enhance a robust investigation mechanism for cases of alleged noncompli-

ance, although such a mechanism would seem rather important in view of the historical prominence of noncompliance concerns, such as those voiced by the United States in 2001.

A BWC review conference that produces a final document including specific and meaningful follow-up steps to strengthen its implementation would help to put to rest many rifts of the last decade. Whether it will orient the convention's membership toward effectively responding to current and future challenges is another matter entirely. These challenges include responding to the implications of new advances in the life sciences and clarifying whether so-called nonlethal biochemical incapacitant weapons are banned, such as those used by Russian Special Forces in the 2002 Moscow theatre siege.¹⁵ These kinds of problems that threaten the norm created against hostile use of the life sciences are not going away, and the BWC must tackle them at some point or lose credibility and relevance.

For U.S. policymakers, there is also a broader issue to consider. In the long run, the United States cannot have its cake and eat it too. For the last five years, the BWC process has operated in a kind of oxygen tent, effectively quarantined from decisively responding to important issues that may impinge on the convention's effectiveness. This has largely been at the behest of the United States, which has often been severely critical about the efficiency of the BWC process. But Washington has taken a tough line against alleged violators of the convention's prohibitions. In 2003, for example, it invaded Iraq partly on the justification Saddam Hussein had a hidden biological weapons program. Meanwhile, its own biodefense activities, including building highly classified facilities to research biological weapons, are raising legitimate international concern that the United States is violating the BWC.¹⁶

Since 2002, most states active in the BWC process have cooperated fully with Washington's expectations. By continuing to resist the development of measures that would enhance transparency about its activities and overall confidence in compliance with the BWC over the longer run, however, the United States could fatally undermine general acceptance that biological weapons are barbaric and must remain banned. In other words, U.S. policymakers need to recognize that their current policies could have unintended and negative consequences for national security, reversing the foresight of a previous administration that biological weapons are not in the greater interest of the United States or of the world.

With skill and a little flexibility, Washington's biodefense concerns can be squared with multilateral cooperation in effective ways. A welcome first step would be to entrust the BWC process with follow-up work and view the sixth review conference more in terms of its potential for shared benefit than as an irksome drag. This would signal that the BWC has returned from the political wilderness, and it would resemble the leadership the United States has often shown the world in enhancing collective security in the past. **ACT**

ENDNOTES

1. Despite trenchant criticism of UNSCOM's efforts and those of its successor, the UN Monitoring, Verification and Inspection Commission, U.S. efforts after the invasion of Iraq in 2003 to find biological weapons or infrastructure were no more successful.
2. The NAM is an international organization of 115 members representing the interests and priorities of developing countries. China and Mexico are not formal members of the NAM but often associate themselves with NAM positions in the BWC context.
3. See BWC Articles I and III. For the text of the BWC and most official documents of the review process, see <http://www.unog.ch/bwc>.
4. Statement by the United States to the Ad Hoc Group of Biological Weapons Convention States Parties, July 25, 2001.
5. Jenni Rissanen, "Left in Limbo: Review Conference Suspended on Edge of Collapse," *Disarmament Diplomacy*, No. 62 (January/February 2002).
6. For details of this mandate, see BWC/CONEV17 (2002).
7. BWC/CONEV/PC/1 (May 2006).
8. Statement of United States to the Fifth Review Conference of the BWC, November 19, 2001.
9. Articles VI and VII of the BWC outline procedures for referral to the UN Security Council to investigate breaches of the BWC, including alleged use of biological weapons. In turn, various General Assembly resolutions and UN Security Council Resolution 620 created a way for these allegations to be forwarded from the Security Council to the UN secretary-general for investigation. See BWC/MSP/MX/INE.3 (2004).
10. Resolution 1540 enhances the UN Security Council's institutional role in coordinating nonproliferation efforts against weapons of mass destruction (S/RES/1540 (2004)). The U.S.-led Proliferation Security Initiative (PSI) stresses practical cooperation by PSI voluntary partners in physical interdiction efforts against weapons of mass destruction. See Piers D. Millett, "The Biological and Toxin Weapons Convention in Context: From Monolith to Keystone," *Disarmament Forum*, No. 3 (2006).
11. "Uniting Against Terrorism: Recommendations for a Global Counter-Terrorism Strategy—Report of the United Nations Secretary-General," A/60/825 (April 2006).
12. Nicolas Sims, "Towards the BWC Review Conference: Diplomacy Still in the Doldrums," *Disarmament Diplomacy*, No. 82 (Spring 2006), pp. 8-16.
13. BWC/CONEVI/PC/INE1 (April 2006).
14. These include the International Convention for the Suppression of Acts of Nuclear Terrorism, agreed in New York on April 13, 2005.
15. See David P. Fidler, "The Meaning of Moscow: 'Non-Lethal' Weapons and International Law in the Early 21st Century," *International Review of the Red Cross* Vol. 87, No. 859 (September 2005), pp. 525-552.
16. "The Secretive Fight Against Bioterror," *The Washington Post*, July 30, 2006, p. A1.

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Back to Basics: Steering Constructive Evolution of the BWC

When the Sixth Review Conference of States-Parties to the Biological Weapons Convention (BWC) meets later this year, it will mark the first full review of this 155-member treaty since 1991. The previous two gatherings of this once-every-five-years event took a backseat to somewhat separate and ultimately unsuccessful efforts to strengthen the convention with a legally binding instrument. This year's meeting would be well served if it resumed the process sidetracked for the past 15 years of steering the constructive evolution of the treaty regime, drawing on the latent strength of the BWC as it stands, and resisting the temptation to amend, supplement, or diminish it.

Resuming this path will not be easy. States-parties have agreed to numerous "extended understandings," definitions, and politically binding commitments. These commitments recorded in the form of Final Declarations at the review conferences of 1980, 1986, and 1991 were reaffirmed and in some cases strengthened during the fourth review conference of 1996. Even reaffirming all the individual points of agreement achieved in past years will be difficult.

A Preparatory Committee (PrepCom) meeting later this month in Geneva could be crucial to shaping the success of the review conference. Traditionally, the BWC PrepCom has limited itself to strictly organizational tasks: approving the agenda, budget, documentation and committee structure for each review conference; allocating vice presidencies; and nominating chairs and vice-chairs for its committees.

This month's PrepCom, however, should do more than merely approve routine organizational decisions. Ambassador Paul Meyer of Canada recently called for the PrepCom to "be structured in such a way as to foster substantive discussions" and to look for ways to create "review conference deliverables."¹ The April 26-28 meetings will not allow much time for negotiation, but the PrepCom could usefully spend this time in part by commissioning technical work from its secretariat—a small staff complement provided by the UN Department for Disarmament Affairs—so that the conference itself could consider draft budgets and programs.

The Agenda

To arrive at a consensus agenda, however, the states-parties will first have to find a way to patch over the wounds that still remain from the failed 1995-2001 Ad Hoc Group effort to craft a strengthening protocol (see sidebar) and the deeper differences that lay behind that breakdown. Those differences include deep U.S. reluctance to support binding multilateral instruments, the feasibility of effective verification in the biological weapons field, and the relative value of national versus international measures in this arena. Indeed, the continuing divisions have reportedly already been reflected in the inability so far of the three treaty depositaries (Russia, the United Kingdom, and the United States) to decide whether the review conference needs to take up all of the three-week period (Nov. 20-Dec. 8) that it has been allocated.

The Europeans can be expected to play a key role in resolving such differences and in keeping the issue of the strengthening protocol on the long-term review conference agenda without hampering the ability of this year's gathering to carry out effective work. In particular, the Europeans made clear in recent statements that the European Union "remains committed to developing measures to verify compliance" with the BWC. Yet, they also seem to recognize that, given the intransigence of the United States (and others) on the subject of verification, this could only be a distant prospect. They have said that at the review conference, "efforts should focus on specific, feasible and practical enhancements to strengthen the Convention and its implementation."²

If the EU efforts to bridge the gaps are successful, it should be possible for the PrepCom to tee up several useful proposals for the review conference to

Status of the BWC

Signatory States yet to Ratify:

1. Burundi
2. Central African Republic
3. Côte d'Ivoire
4. Egypt
5. Gabon
6. Guyana
7. Haiti
8. Liberia
9. Madagascar
10. Malawi
11. Myanmar
12. Nepal
13. Somalia
14. Syria
15. United Arab Emirates
16. Tanzania

Non Signatory States:

1. Andorra
2. Angola
3. Cameroon
4. Chad
5. Comoros
6. Djibouti
7. Eritrea
8. Guinea
9. Israel
10. Kazakhstan
11. Kiribati
12. Marshall Islands
13. Mauritania
14. Micronesia (Federated States of)
15. Mozambique
16. Namibia
17. Nauru
18. Samoa
19. Trinidad and Tobago
20. Tuvalu
21. Zambia

consider and ultimately agree on. Indeed, several practical proposals, particularly from Canada and the EU, have already drawn widespread interest.

Action Plans for Universalization and National Implementation

Efforts to encourage countries to sign and ratify the treaty have thus far been diffuse and spasmodic. Sixteen states have yet to ratify the treaty despite signing it more than three decades ago; more than 20 states have not even signed the treaty. State-party action plans for universalization and national implementation could make this effort more systematic and durable.

Action plans could persuade states-parties to take more seriously their treaty obligations to take legislative or other "necessary measures to pro-

hibit and prevent" banned activities. Prohibition on its own is not enough; the "prevention criterion" quoted from Article IV of the convention is a stringent one and rightly so. There has been an increasing emphasis too on the need for national legislation to include penalties that can be imposed directly on individuals and on the need to close jurisdictional loopholes.

The first step, however, is to take the measures required by Article IV of the convention. In March 1980, the first review conference called on all states-parties that had not yet taken such measures to do so "immediately." Twenty-six years later, no one knows exactly how many have done so, but the most comprehensive survey, published in 2003, found many gaps.³ National implementation, like universalization, is incomplete, hence the need for action coordinated on behalf of the states-parties as a whole.

The Chemical Weapons Convention (CWC) experience offers some useful tips. CWC states-parties inaugurated action plans both for universalization and national implementation in 2003 with some success. The CWC, although only in force since 1997, already has a membership of 178. By contrast, the BWC has been in force since 1975 but only claims 155 states-parties. Yet, the BWC is no less vital a treaty.

The CWC experience of 2003-2005 also shows that many governments welcome help in drafting legislation on implementing such international conventions. Many are willing to acknowledge that past legislation has sometimes been less than comprehensive in meeting its coverage of CWC obligations, a point on which BWC states-parties should be usefully forewarned in launching their own action plan for BWC national implementation. They should keep the "prevention criterion" of Article IV at the forefront of their minds and demand the highest standards both in the drafting and the application of national implementation measures. Fortunately, BWC states-parties can benefit from useful initiatives in national implementation technical assistance and capacity building, including draft model legislation, by the Verification Research, Training and Information Centre (VERTIC) and the International Committee of the Red Cross.

Additional Transparency and Confidence-Building Measures

Confidence-building measures (CBMs) were formally introduced into the BWC regime in 1986-1987. They were enhanced and expanded in 1991, and since 1992 every state-party has been under a politically binding commitment to make an annual declaration on or before April 15, supplying information in eight categories. User-friendly options of "nothing to declare" and "no change" make the task minimal for many, yet participation remains patchy. Some states-parties report scrupulously and even put their declarations online for all the world to see; others ignore the entire program. Most states-parties have reported occasionally, but very few report every year and in every category.

The United Nations has neither the authority nor the resources to add value in processing the CBM declarations. Indeed, the only true systematic work has been done by a private group: the Study Group on Biological Arms Control at the University of Hamburg, which has conducted exhaustive surveys of the CBM declarations from 1987 to 2003 to ensure that this aspect of the BWC receives attention.

At both the 1996 and 2001 review conferences, proposals were made to improve this process, but the measures did not advance. This year's conference should introduce a long overdue rationalization so that the program actually builds confi-

dence in the BWC and in states' compliance with the obligations flowing from it.

Transparency measures are particularly needed to govern countries' actions to protect against a biological weapons attack. Biodefense is not forbidden, but any biological agents and toxins held must be of types and quantities that match the treaty's criteria in Article I—prophylactic, protective or other peaceful purposes—and so too must any development or production activities. There are legal issues that await authoritative resolution over where the BWC places the limits of permissible biodefense, especially when programs

BWC Verification: A Decade-Long Detour?

During the early 1990s, revelations about the biological weapons programs of Iraq and the Soviet Union raised concerns about the ability of the Biological Weapons Convention (BWC) to verify compliance by states-parties. The treaty bans the development, acquisition, or stockpiling of bacteriological and toxin weaponry, but has weak measures to verify compliance. States-parties can either seek consultations or pursue a complaint with the UN Security Council, permitting the permanent members of the Security Council to veto a BWC investigation. These weaknesses became even more apparent in the early 1990s as negotiators wrapped up work on the Chemical Weapons Convention, which includes far more comprehensive verification and compliance measures.

These concerns led in 1991 to the formation of the Ad Hoc Group of Governmental Experts (VEREX) during the treaty's review conference that year. VEREX was charged with studying the scientific and technical feasibility of verification measures. After evaluating 21 possible on-site and off-site measures, the group produced a final report in 1993 that suggested a compliance regime that required a combination of declarations and on-site inspections. (See *ACT*, June 1994.)

A special conference in September 1994 approved the formation of another Ad Hoc Group (AHG) that would be open to all states-parties. For the next six years, the AHG worked on crafting a legally binding protocol to the BWC under the direction of its chairman, Hungarian diplomat Tibor Tóth. Negotiations on an integrated text focused on resolving differences over definitions and various inspection procedures. In March 2001, with the review conference just months away, Tóth released a "chairman's text," incorporated compromises based on his private discussions with various delegations, and proposed solutions to other outstanding issues. At a meeting in May 2001, many states expressed reservations about the text but did not reject it outright. (See *ACT*, May 2001.)

However, at the final meeting of the AHG prior to the 2001 review conference in July, the United States declared that it would not support the draft protocol or continuation of the AHG. Ambassador Donald Mahley, head of the U.S. delegation, told the group that the United States was concerned that the on-site inspec-

tion measures would jeopardize commercial proprietary information while having "almost no chance of discovering anything useful to the BWC" in "less-than-innocent" facilities in other countries. He said the United States was also concerned that the protocol would not provide adequate protections for U.S. biodefense programs, while the negotiations themselves were providing some states with the leverage to undermine national export control agreements, such as the Australia Group. (See *ACT*, September 2001.)

Although no other state joined the U.S. position and many states agreed that the group's mandate remained valid, the meeting was unable to produce a final report for the review conference.

In December 2001, the review conference itself got off to a rocky start when, on the opening day of the meeting, the United States generated controversy by taking the unprecedented step of naming states it believed to be harboring active biological weapons programs. John Bolton, then undersecretary of state for arms control and international security, accused Iraq and North Korea of harboring biological weapons programs. Bolton, the head of the U.S. delegation, also said that the United States was concerned about possible programs in Iran, Libya, Syria, and Sudan. (See *ACT*, December 2001.)

Bolton threw the entire conference into turmoil on Dec. 7, the last day of the meeting, when he announced that the United States would seek the formal end of the AHG's mandate. Although Bolton claimed that the United States had made its views on the group's work clear during its last meeting, many diplomats were still caught off-guard by the sudden announcement. The sudden U.S. move forced Tóth to suspend the review conference for one year. (See *ACT*, January/February 2002.)

During that next year, states-parties discussed various proposals for moving forward, but given the strong U.S. resistance, the review conference avoided a discussion of verification or compliance issues entirely. Instead, states-parties approved Tóth's plan to hold a series of annual meetings before the next review conference. During those meetings, BWC states-parties would discuss several national implementation and nonproliferation measures, but the agenda did not address verification issues or the fate of the AHG. —MICHAEL NGUYEN

extend to the design of weapons and equipment for purposes of threat assessment, that is, employing weapons and agents to develop antidotes and other defenses.⁴ In principle, it should be possible to con-

limits, so no BWC-wide impetus could build up.

It would be best to supersede the 2003-2005 pattern of agenda-limited separate meetings of experts and states-parties with single combined two-week-

This year's Biological Weapons Convention would be well served if it resumed the process sidetracked for the past 15 years of steering the constructive evolution of the treaty regime, **drawing on the latent strength of the BWC as it stands, and resisting the temptation to amend, supplement, or diminish it.**

duct biodefense without transgressing the limits.

Nonetheless, some aspects of such work continue to generate apprehensions of malign intent. The CBM program was supposed to include biodefense information so that countries could be reassured that other states' protective programs are just that and are not tipping over into the development of an offensive capability or preparing for breakout from the BWC's restrictions. Yet, an understandable reluctance to reveal areas of vulnerability has sometimes prevailed over the good intentions of those who made CBMs an integral part of the BWC in force. It is a problem of long standing and there are no easy solutions, but a thorough review of the BWC cannot afford to ignore it.

A partial solution, proposed in *Arms Control Today* by Jonathan Tucker in 2004, may bear re-examination. Tucker called for integrating Canada, the European Union, and the United States into a collaborative biodefense network in order to "give the international community greater confidence that Washington is not pursuing a unilateral path in this highly sensitive area and that its biodefense [research and development] program is fully compliant with the BWC."⁵

Annual Meetings

One good thing to come out of the "work program" of 2003-2005 was two sets of annual meetings in between the review conferences. Governments acquired the habit of spending two weeks each year in BWC experts meetings and one week each year in BWC states-parties gatherings.

Annual meetings of states-parties through 2007-2010 would be a natural development to help the BWC bridge the long interval between the sixth and seventh review conferences. The EU has already started appropriate action in this direction, having begun to draft a proposed second "work program" for 2007-2010 to be considered by the review conference.

Hopefully, narrow topics will be replaced by broader themes for this second "work program." The 2003-2005 series was limited to five topics in all, with minimal integration of outcomes across years. So, for example, there was no opportunity in 2005 to take stock of developments in national implementation since 2003 or of subsequent progress on the 2004 topics. Additionally, much of the BWC was officially off-

long and BWC-wide annual meetings that include states-parties and experts. If that is not possible, the aim should be to cover the entire range of BWC issues systematically, with no aspect of the treaty regime ruled off-limits. Moreover, the agenda should be reorganized to put the time available to better use each year, with analysis and synthesis documents leading to more substantive final-document outcomes than were obtained in 2003-2005 despite the best efforts of the successive chairs.⁶

Continuity might be enhanced through working groups on particular themes brought together at the annual meetings. Alternatively or additionally, the meetings of experts, if retained, might be used in part to exchange views systematically on scientific and technological developments relevant to the BWC. These are all possibilities which states-parties should consider, seeking agreement on the best of them, between now and November.

Establishing a Scientific Advisory Body

Some mechanism is needed to provide expert advice to states-parties, collectively, on developments in science and technology relevant to the BWC. Review conferences have attended increasingly to developments in genetics and other life sciences. Yet, the pace of change is such that conducting these collective assessments of BWC-relevant developments only every five years is not satisfactory.

Scientific advisers meeting at least once a year, as or within the meeting of experts, to pool their assessments and formulate advice for the annual meeting would contribute much to the health of the BWC by keeping states-parties up to date. They might also suggest prudent constraints on research. For example, Tucker has suggested "developing an international mechanism to regulate hazardous 'dual-use' research"⁷ through review and oversight by the scientific community, a difficult but ultimately necessary enterprise.

Providing Implementation Support

Canada has usefully proposed that some resources be dedicated on an ongoing basis to implement tasks assigned by the review conference or between reviews by the annual meeting of states-parties. This vehicle could be financially supported by BWC states-parties and be built on the small staff complement provided to the review conference by the

UN Department for Disarmament Affairs.

Such a process would significantly enhance the chances of success of any action plans or the further-elaborated programs of CBMs and transparency measures. It would also be an appropriate channel for financial support to the BWC, such as what the EU has provided under its joint action funding “to enhance the universality of the convention through outreach and to help states-parties improve their national implementation through the provision of assistance.”⁸

Final Declaration

Will the conference produce a final declaration? When the last review conference concluded without even having tried to agree on one, having been persuaded not to resume work on the nearly completed draft left over from its first session in December 2001, there was some talk of the BWC being better served by the simple decision of November 2002. According to conference president Ambassador Tibor Tóth, the new process was going to produce “concrete actions with results.” Brave words, but not justified by events.

A final declaration is essential. In the history of the BWC, it is the means by which states-parties record their points of agreement, exhort one another to further efforts, and accept for themselves collectively politically binding commitments. It is also the vehicle for extended understandings, definitions, and procedures to be accumulated. Without a final declaration as the goal of the sixth review conference, momentum and progress will be much more difficult to achieve. The PrepCom is likely, following precedent, to include in the agenda for the conference an item, “preparation and adoption of the final document(s),” which does not guarantee a final declaration.

It will, however, make that outcome more likely if it recommends integrating the lessons learned from the 2003-2005 work program into an article-by-article review of the convention and structures the agenda accordingly. Moreover, the PrepCom should aim to achieve a firm understanding among delegations that the conference will be organized around the task of agreeing on producing a full, substantive, final declaration as its central activity.

Conclusion

Going back to basics means emphasizing the worth of the BWC as a disarmament treaty in its own right, to be reviewed on its own terms. It is not primarily a counterproliferation device because that would distort the perspective into an essentially discriminatory mentality in which only some states are of concern. It is also not primarily a counterterrorism device because that would distort the perspective into an essentially discriminatory mentality in which only nonstate actors are of concern. Either perspective tends to downplay reciprocity and to let most governments off the hook too easily, as if they are tangential to the threat rather than central to the treaty relationship. It is their obligations that matter and their compliance with those obligations which

must be, first and foremost, subject to review.

The BWC is an absolute renunciation—note the “never in any circumstances” language of Article I—applying to the governments of all states-parties as much as to the individuals on their territory, within their jurisdiction, and under—or sometimes not sufficiently under—their control anywhere. The world is not to be divided between “responsible” and “irresponsible” possessors of biological weapons. There are to be no possessors at all.

It is not just a moral or humanitarian norm against which national actions and legislative and administrative provisions are to be measured. It is not just a hollow framework within which control measures are to be inserted. It is much more than merely a norm or a framework; it is a legally binding set of carefully negotiated obligations, the full implications of which are still being drawn out, constituting a global treaty that needs cherishing and nurturing. Its distinct treaty regime is in the process of evolution, capable of reinforcement within the terms of the treaty text as it stands. The task for this month’s PrepCom is to lay the groundwork for November so that the sixth review conference can reach agreement on where that treaty regime stands in 2006 and how best to steer its constructive and balanced evolution cautiously through to the seventh review conference in 2011, when conditions may be more favorable to advance. **ACT**

ENDNOTES

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Verification and the BWC: Last Gasp or Signs of Life?

At first blush, the outlook for cooperative, multilateral verification of compliance with the 1972 Biological Weapons Convention (BWC) looks grim. In 2001-2002, ten years of work devoted to preparing for and then negotiating a draft protocol to establish a standing verification organization for the treaty collapsed.¹ In subsequent meetings of experts and annual meetings of states-parties devoted to discussing, not negotiating, a variety of BWC-related topics, verification rarely featured. Meanwhile, national policies toward BWC verification appear to have remained static.

The United States instigated the abrupt halt to the protocol negotiations at the treaty's Fifth Review Conference. U.S. officials apparently remain steadfast in their view that effective verification of the BWC is impossible and that attempting it will be both delusional and dangerous to U.S. national security and commerce. Only a few Western states have been willing to hold aloft the banner of full-fledged verification.

It is reasonable to ask whether, in these circumstances, as the BWC's Sixth Review Conference approaches in November and December of this year, there is any hope for moving forward on verification measures. The short answer is that there will be no agreement to return to the protocol negotiations, no new initiative to create a standing verification body for the treaty, and no wholesale climbdown by the United States on biological verification. The v-word itself likely will continue to be avoided in any final document, as it has been for years in deference to U.S. sensibilities.

Still, some gains can be made. A modest form of progress is possible on what might be termed quasi-verification measures, those which fall short of a full verification regime but could help to improve monitoring of the BWC. Indeed, even as the BWC regime appears to have stagnated in recent years, there has been some quiet movement that is changing the context of the bio-verification debate. Even if these efforts do not produce results at the conference, they may herald developments beyond it.

A Broader View of Verification

First, the concept of verification in the arms control and disarmament field has been considerably broadened since the end of the Cold War, not just due to that great sea-change but to the events of September 11, 2001; the perceived rise of global terrorism; and the exposure of Pakistani scientist Abdul Qadeer Khan's nuclear smuggling network. In turn has come the increased willingness of the UN Security Council, at least compared to its traditional reticence, to involve

itself in ensuring compliance with international strictures on the proliferation of so-called weapons of mass destruction (WMD),² in some cases. Most notable to date has been its two-fold attempt to achieve the verified disarmament of Iraq, but the Security Council has also acted on North Korea's ballistic missile threat and seems to be moving inexorably toward action in the case of Iran.

Perceptions of verification have also changed as a result of the Bush administration's attempt to portray multilateral arms control and its accompanying verification edifices as outdated remnants of the Cold War that are inappropriate in the current era. Although undoubtedly self-serving, enabling the United States to justify its opposition to any verification measures for the 2002 Strategic Offensive Reductions Treaty and the proposed fissile material cutoff treaty, this has had the beneficial effect of forcing the arms control community to re-examine its long-held assumptions about the nature of verification. In any community that is 50 years old, it is only natural that certain shibboleths will form, sacred cows will be anointed, and unorthodox views accordingly shunned.

Today the international community's collective view of verification has, by and large, been broadened to include virtually any activity that contributes to the full implementation of a treaty. The argument goes that because all measures designed to contribute to full implementation require monitoring to ensure compliance, they become part of the total verification package. The realization has come quite late, for instance, that noncompliance consists not simply in a state violating the central article of an arms control or disarmament agreement, by acquiring a banned weapon, but also in not fulfilling all of the treaty's legal obligations, both nationally and internationally.

In an age of global terrorist threats, it has become crucial, for instance, that all states have national implementation measures to prevent their citizens or those

of other countries from using their territory for nefarious purposes. It is vital that transshipment of goods be regulated and port security enhanced. Monitoring how states comply with these obligations becomes a form of verification. Indeed, this may be as important as verifying whether most governments are seeking weapons of mass destruction, especially because the majority are, in reality, what might be termed “serial compliers.”

As a result, reporting and transparency measures, once regarded in some quarters as simply providing a baseline for on-site inspections, have assumed much greater importance in the verification universe. This is exemplified by UN Security Council Resolution 1540 of April 2004 and its April 2006 follow-up, Resolution 1673, which demand that all states not just adopt national implementation measures to stop nonstate actors acquiring weapons of mass destruction but compels them to report their activities to the council. Cooperative threat reduction programs, export control regimes, and measures such as the Proliferation Security Initiative are all increasingly perceived as being part of the broad verification-compliance enterprise because they all involve a form of monitoring that generates verification-relevant information.

Not only has the verification envelope been pushed, but it has collided with a previously immovable object, compliance and enforcement. States have for too long neglected the compliance aspects of treaties, both in drafting and implementing them. What happens after a state engages in serious, deliberate noncompliance? This question was rarely posed in designing verification systems. Thanks to the United States, the compliance issue has been rejoined, both in the sense of being increasingly debated and in the sense of a reassertion of its indissoluble link to verification. This is not simply a Bush administration invention but a return to arms control's original philosophy.

None of this is to say that the Bush administration's ideological attack on multilateral verification has been an unalloyed good. On the contrary, in many respects it has been destructive of confidence and trust among the very states on which the United States depends to pursue its global aims. As former Department of State official Avis T. Bohlen has said of John Bolton, the former undersecretary of state for arms control and international security, who oversaw the U.S. hatchet job on the BWC protocol, “He was absolutely clear that he didn't want any more arms control agreements. He didn't want any negotiating bodies. He just cut it off. It was one more area where we lost support and respect in the world.”³ Yet, what started as a U.S.-led redefinition of the boundaries of verification for its own purposes has, for better or worse, now permeated the multilateral dialogue on arms control and disarmament.

All of these developments have arguably had their greatest impact on the biological weapons category of weapons of mass destruction given the absence of a traditional verification regime for such weapons and continuing U.S. opposition to one being created. There has been a profusion of ideas that amount to monitoring of BWC implementation at least, if not verification of compliance. Improved biosecurity to avoid proliferation of dangerous pathogens, for instance, requires not just new standards but monitoring to ensure implementation. Enhanced confidence-building measures (CBMs) improve transparency, a hallmark of verification regimes.

Better global disease surveillance is surely monitoring and hence a form of verification.

Verifiability Revisited

A second trend that may ultimately break up the biological weapons verification logjam is more specific to that class of weapons. Since the demise of the protocol, developments have occurred that call into question the assertion by some that the BWC is essentially unverifiable. Notable is the work of Amy Smithson in Washington, D.C., at the Henry L. Stimson Center and the Center for Strategic and International Studies. As she notes, “Policymakers, industry officials, and the general public are commonly told that the BWC is ‘unverifiable’ due to the complex, dual-use nature of biological materials, equipment, and technologies and the claim that inspections would automatically reveal sensitive defense or business information. These assertions hang in the air unchallenged.”⁴

Drawing on a wealth of expertise in industry, academia, and among inspection veterans, Smithson's three painstakingly researched reports collectively amount to a rebuttal of the “inherent unverifiability” thesis.⁵ Smithson, like the Bush administration, concludes that the draft protocol as it stood in 2001 was unworkable, but her studies indicate that it is possible to craft a mechanism to monitor industry facilities without necessarily compromising national security or commercial confidentiality. The same presumably may apply to biodefense facilities, research facilities permitted under the treaty to develop antidotes and other means of countering biological weapons threats. Smithson's final report recommends that full field trials be held to test the proposed mechanism. This would partly fulfill the obligations of a U.S. law, ignored by the Clinton and Bush administrations, that mandates a thorough experimental and analytical assessment of the capabilities of on-site inspections for monitoring BWC compliance.⁶

In addition to this pioneering research, there has been, for the first time since attempts in the early 1990s to investigate the former Soviet biological weapons program, extensive field experience of multilateral biological weapons verification in the search for such activity in Iraq. The UN Special Commission (UNSCOM) did some of this path-breaking work before 2001, which the United Kingdom subsequently used in designing proposals for the verification protocol; more experience was subsequently garnered by UNSCOM's successor, the UN Monitoring, Verification and Inspection Commission (UNMOVIC). This work was supplemented by the Australian/U.S./British Iraq Survey Group, which conducted its own search for biological weapons in Iraq after the coalition invasion in March 2003.

Changes in U.S. Policies Toward Multilateralism

A third, more recent trend with a potential impact on biological weapons verification may be characterized as the smoothing of the rougher edges of the Bush administration's view of the utility of multilateralism. Tactically, U.S. policy has already mellowed somewhat under Secretary of State Condoleezza Rice in a variety of areas, notably with respect to Iran, North Korea, and the International Criminal Court. Even if the administration's substantive views have not changed very much, the absence of the more combative Bolton from biological weapons policy and some subsiding of the rancor that resulted from the demise

of the protocol has moderated the political context of the debate over biological weapons verification.

It is now difficult to imagine the complete absence of an internal debate in the lead-up to the review conference and beyond. The yawning gap between the administration's realistic appraisal of the biological weapons threat and its completely negative assessment of the role that verification might play in dealing with the threat is surely unsustainable. In the post-Bush administration future, alternative perspectives on verifiability may well seep into the policymaking process, especially if taken further by additional research, scientific trials, and a thorough study of the lessons of the various Iraq biological weapons verification exercises.

Limits of Progress

To be sure, these developments do not portend a sudden change in official U.S. or other states' attitudes toward verification of the BWC, especially since Bush administration objections have been as much ideological as substantive.

For example, a recent fact sheet on the State Department website baldly states that "international mechanisms and procedures will not contribute to the verifiability of the BWC."⁷ Other countries, which due to U.S. commandeering of the verification issue never had to reveal their true positions, undoubtedly continue also to hold anti-verification views, albeit for different reasons.

Russia, which has never revealed everything it knows about the Soviet biological weapons program—the most egregious violation of the BWC to date—views less than fondly the prospect of a standing verification regime that might do some retrospective sniffing around. Although China has more or less happily accepted the intrusive verification provisions of the Chemical Weapons Convention (CWC), it undoubtedly continues to wish to avoid further international constraints on its sovereign prerogatives and biotechnology prospects.

Cuba, India, Iran, and Pakistan, always wary of the protocol, presumably remain that way, even though they are part of the nonaligned group that officially contends that "the only sustainable method of strengthening the convention is through multilateral negotiations aimed at concluding a non-discriminatory legally binding agreement, dealing with all the Articles of the Convention in a balanced and comprehensive manner."⁸ This code language advocates a link between verification and the provision of assistance in biotechnology to the developing world, an issue that helped sink the protocol. On the other hand, a group of Latin American countries, in their own declaration, have expressed a willingness to develop with other delegations an "incremental process" toward providing the BWC with an "adequate verification mechanism."⁹

The remaining, largely Western flag-bearers for BWC verification have mostly retreated into quiescence. Despite threatening otherwise, it seems they never seriously contemplated continuing with the protocol negotiations without the United States, as they did when Washington withdrew from negotiations to implement the Kyoto Protocol on climate change. Occasionally, Canada or Switzerland makes a ritualistic plea for a return to the protocol negotiations or speaks

in favor of a comprehensive, multilateral verification mechanism of some sort, but their hearts seem not to be in it. A joint statement by Australia, Canada, and New Zealand in April 2006 failed even to mention verification.¹⁰ Japan and Germany, which because of their large biotechnology industries consistently expressed qualms about some aspects of biological weapons verification, have gone particularly quiet.

The German view was reflected in the European Union Common Position this March that said rather lamely that the EU "remains committed to developing measures to verify compliance" with the BWC.¹¹

Only Sweden and the United Kingdom, after a period of Foreign Office soul-searching, admit to remaining true believers. British Undersecretary of State for the Foreign and Commonwealth Office David Triesman said in early 2006 that the British government continues to favor creating an "inspections mechanism" for the BWC.¹² In the annual states-parties meetings, London submitted a concrete proposal that called for updating and strengthening the UN secretary-general's mechanism for probing alleged use of chemical and biological weapons.¹³

It went nowhere, in part because the meetings were constrained from making recommendations, much less instigating action. It also reflected the fact that in the decades-long tussle between BWC reformists and BWC minimalists,¹⁴ momentum has swung back in favor of the latter.

Implications for the Review Conference

It remains difficult at this stage to predict how these various trends will play out at this year's review conference. In general, expectations are being kept deliberately low. After the drama over verification at the conference five years ago, there is an awareness that this topic, at least as traditionally conceived, is unlikely to be advanced by any delegation, much less attract the attention it deserves.

Nonetheless, the broader conception of verification that has recently emerged means that there are several quasi-verification options that are likely to receive attention at the meeting. This is in part because they have been debated at one of the annual meetings of states-parties since the last review and because there is general recognition of their value.

National Implementation Measures

The most obvious area is national implementation measures, including legislation. This field was considered at the first of the annual meetings, in 2003. A new dynamic to the issue was imparted by UN Security Council Resolution 1540, which directs all states, whether BWC states-parties or not, to adopt measures to prevent nonstate actors from acquiring biological weapons. There seemed to be unanimity at a seminar on the BWC held in Tokyo in February 2006 that national implementation measures must be advanced by the review conference.¹⁵ It is difficult to see the conference failing to acknowledge, if not endorse, what is now obligatory for all states.

Yet, it is also not likely that the review conference will go beyond what the Security Council already demands in terms of reporting, which the council requires annually and which it scrutinizes via its 1540 Committee. This is partly because states will argue that the council is already "seized" of the matter and partly because many states are struggling to comply even at the most rudimentary level.

The conference could, however, establish some form

of regularized support, including advice, assistance, and capacity building, for states that are struggling to comply with respect to biological weapons, in the same way that the Organization for the Prohibition of Chemical Weapons supports its members in their national imple-

the conduct of investigations. The mechanism has been used 12 times in six states, the last in 1992, sometimes on the initiative of the secretary-general himself. Since then, the arrangements have atrophied: the lists are incomplete and the procedures outmoded, not least due to

There will be no agreement to return to the protocol negotiations, no new initiative to create a standing verification body for the treaty, **and certainly no wholesale climb-down by the United States on biological verification.**

mentation measures for the CWC. Canada has proposed such a step as a specific conference outcome. Given that voluntary financing will be the key to such an initiative, its prospects have been improved by the EU's decision to expand its funding of nonproliferation initiatives to include biological weapons issues.¹⁶ Such a role could be one of a number envisaged for a BWC institution or secretariat, various versions of which have been proposed by several states.

Of the major WMD arms control treaties, the BWC is the only one that has no such secretariat. The verification protocol would have established an Organization for the Prohibition of Biological Weapons, and since its demise, the United States has opposed any initiative that smacked of "creeping institutionalization."

Confidence-Building Measures

A second area likely to be considered by the conference is the strengthening of the voluntary CBMs that have been progressively adopted by review conferences in 1986 and 1991. These take the form of annual declarations by states to each other of their BWC-relevant activities. Few states comply annually and rigorously. Proposals have been made since the CBMs first went into effect to expand the range of information sought, make them mandatory, and provide for more sophisticated compilation, analysis, and dissemination.¹⁷ It is not clear which of these ideas will be entertained at the conference, but a number of states will be highlighting them. In particular, the EU is attempting to seize the moral high ground by having each of its members annually file a complete CBM return covering all nine declarations.¹⁸

Secretary-General's Investigatory Capabilities

A third item that could be considered by the review conference, the most directly related to traditional verification, is a review and updating of the UN secretary-general's investigatory mechanism. This 15-year-old arrangement originates from ad hoc probes requested by the UN General Assembly. In the early 1980s, the secretary-general was tasked with investigating the alleged use of chemical and toxin weapons in Indochina and Afghanistan. In 1982 the assembly institutionalized the procedure, giving the secretary-general standing authority and (modest) capacity for investigating future allegations of chemical, biological, and toxin weapons use in violation of the 1925 Geneva Protocol. The Security Council endorsed the arrangement in 1986. The mechanism comprises a list of experts that could be made available by states for investigative missions, a list of certified laboratories available for testing samples, and a set of recommended procedures produced by an expert group for

the extensive experience of UNSCOM and UNMOVIC and scientific and technological developments in chemical and biological monitoring and verification.

Fostered initially by the United Kingdom's initiative, the issue is gaining momentum. Many states are now on record as wanting the mechanism revived. They include all of the EU and many other European states, in addition to Australia, Canada, Japan, and New Zealand. The UN Secretariat is ready to do its bit to review the mechanism, including by following up its 2002 request to UN member states for new nominations of experts and laboratories. The EU in March 2006 committed its members to update their expert and laboratory offerings.¹⁹ A series of reports by independent commissions as well as UN-instigated reports has also recommended updating the mechanism.²⁰

Most importantly, there are signs that the United States might be brought around to not standing in the way of this relatively modest reform. This would be in keeping with its at times newly pragmatic, albeit minimalist, acquiescence in multilateral initiatives. It would not only partly atone for overbearing U.S. behavior in quashing the BWC protocol at the last review conference but would be entirely consonant with President George W. Bush's 2001 list of alternatives to the protocol, one of which was "procedures for addressing compliance concerns." Further, the mechanism would still only deal with allegations of use and not research, testing, production, stockpiling, and transfer.

One potential difficulty might be that the mechanism was originally intended to address the verification lacuna in the 1925 Geneva Protocol, rather than the BWC. The protocol has a different set of states-parties and covers chemical and biological weapons use. An attempt at the 2004 intersessional meeting to have the BWC states-parties request the secretary-general to update the mechanism failed to gain consensus, presumably because of the fear that a revived mechanism could lead to BWC verification. Because the mechanism was established by the UN General Assembly outside the BWC context, one can easily imagine procedural objections alone being used to scuttle a renewed attempt to send such a request to the secretary-general.

By contrast, one verification initiative that would definitely sour the review conference would be a proposal to reconvene the Ad Hoc Group, which until 2002 had been negotiating the verification protocol and which has never been formally wound up. Re-enacting the battles of the last review conference would be counterproductive and not in the best interests of biological disarmament. During the April preparatory meeting for the conference, states-parties agreed on an agenda that removed some

explicit references to the work of the Ad Hoc Group and verification. Although there may now be broad acquiescence to the U.S. desire to terminate the group and its mandate, spoilers such as Iran could use the issue to try to derail the conference.

Conclusion

Compared with discussions about strengthening the elaborate nuclear safeguards system or managing the intrusive, routine on-site inspections mandated by the CWC, the international conversation about BWC verification, often conducted *sotto voce* and without even using the dreaded v-word, must seem pathetically wan. Yet, in an area so fraught with controversy and past failure, even the realization of some of the modest possibilities discussed above would be a triumph.

Much of what happens at the review conference on the verification front, however defined, will in any case depend on broader currents that will be swirling around the event. As Nicholas Sims reminds us, tensions between Iran and the United States alone, although largely unrelated to the biological weapons issue, could help sink the conference.²¹ Ideological sparring between the West and the nonaligned states about the privileging of certain BWC commitments over others—proxy for the Western fixation on compliance versus developing-country demands for free biotechnology—could also derail matters. This is quite apart from arguments over institutionalization and procedural wrangles over how the intervening years before the seventh review conference should be usefully employed.

What is needed on the BWC verification issue is for a white-knight state to step forward to lead the charge of the reformists. With so much dependent on the attitude of the United States and most states engaged with the world's only superpower on issues far more important to their national interests than biological weapons verification, however, none is likely to appear. The best that can be expected is modest movement forward with U.S. acquiescence, if not enthusiasm. Hardly worthy of Bush administration non-proliferation official Carolyn Leddy's laudable admonition to us to "succeed in our efforts to eliminate the proliferation of weapons of mass destruction."²² Yet, as she also says, "[a]nything else is not an option." **ACT**

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Building Transparency Through Confidence Building Measures

Transparency is an integral component of arms control. It can dispel concerns of noncompliance by reassuring actors that others are not misusing technologies or goods for hostile purposes. It can also deter actors from engaging in banned activities for fear that their activities will be exposed. In biological arms control, transparency is of pronounced importance because dual-use material, equipment, and knowledge are extensively embedded in contemporary biotechnology.

The potential for the abuse of these technologies increases each year as they become more advanced and diffuse. As the Department of State recently reported, “[T]he fact that biotechnology equipment and materials can be used interchangeably for peaceful or nefarious purposes, and the ease and speed by which illegal activities can be concealed make verification of compliance with the [Biological Weapons Convention (BWC)] an especially difficult challenge.”¹

Although identifying illicit biological activities is difficult, a good starting point for building confidence in compliance is to increase transparency. Biological activities in a country must be open to other states-parties, particularly those activities that have a higher potential for misuse such as those conducted as part of a national biodefense program. This is an issue that has been promoted most recently by UN Secretary-General Kofi Annan.²

Currently, the only instrument under the BWC intended to enhance transparency is the confidence-building measure regime. This takes the form of an information exchange system covering themes relevant to biological arms control. Unfortunately, these confidence-building measures (CBMs) have done little to increase transparency since their inception 19 years ago. Few states have consistently participated, and many of those that have participated sporadically have also provided inadequate information.

Given the unsuccessful end of the Ad Hoc Group negotiations in 2001, which would have led, among other things, to a mandatory declaration system as part of the BWC, it is critically important to bolster the current mechanism. When states-parties gather for the BWC’s sixth review conference at the end of this year, they need to take steps to enhance these measures and thus provide genuine support for the biological weapons ban itself.

CBMs: Past Performance

The purpose of the CBM regime is “to prevent or reduce the occurrence of ambiguities, doubts and suspicions.”³ These declarations are intended to serve the same purpose as those successfully implemented into other international treaties such as the Chemical Weapons Convention. As part of the BWC, CBMs were first agreed on at the second review conference in 1986⁴ and were further expanded at the third review conference in 1991. This expansion provided the current form: seven declarations to be submitted annually before April 15 (see figure 1). Annual CBM submission is a political obligation, and failing to do so brings a country into technical non-compliance with the BWC.

A truly transparent environment can emerge only when there is universal participation by all actors. More than 40 percent of the member states, however, have never submitted a declaration, and the majority that have submitted did so on an irregular basis. Submissions between 1987 to 2005 were provided by only eight countries: Canada, Finland, Germany, the Netherlands, Norway, Russia, Spain, and the United States. The highest degree of participation occurred in 1996 when 53 countries submitted. This was followed by a downward trend to a low of 33 participating countries in 2003. To name just a few surprising examples: India participated only in 1997; Iran provided CBMs only in 1998, 1999 and 2002; Sweden failed to submit CBMs in 2002 and 2003; and the United Kingdom did not submit in 2001.

The mechanism is further weakened by the low quality of data, which is often incomplete, inaccurate, and at times misleading. Even those countries that have long been active proponents of the BWC are not putting much effort in submitting high-quality CBMs. For example, Italy declared a number of vaccine production sites but failed to name the diseases against

which the vaccines were made, a requirement of the CBM. Spain's CBMs failed to mention the budget allocated to biodefense facilities.⁵ And submissions on past bio weapons programs have often been lacking in critical detail, negligent of information requested, inconsistent at times with information presented in open sources, and often submitted only once with no effort at an update in subsequent years.

Improvements Needed

Clearly, improvements need to be discussed at the sixth review conference or later during a focused meeting on the future of CBMs. The declarations need to be altered to make their topics more relevant and to provide better data for analysis. Other steps should include ensuring CBMs are submitted on time; improving the accessibility, verifiability, and the ease of use of submitted data; and ensuring that the CBMs remain relevant in a changing technological and political environment.

Some states-parties have argued that before revising the CBMs, more efforts should be made to increase participation in the current CBM system. Clearly, however, a vicious cycle is currently in place in which limited participation diminishes confidence in the CBM mechanism and impairs the quality of submissions. Therefore, participation in the CBM process and the quality of submissions are only likely to improve in unison.

Form Reform

The relevance of individual CBM topics has always been a matter of discussion. The addition of new topics was last discussed at the fifth review conference⁶ in 2001, although broader political problems prevented any modifications from being adopted. Nevertheless, several new topics were proposed, including requesting information on plant inoculants and biocontrol-agent production sites, more information on research with animal pathogens, details on animal and plant disease outbreaks of concern, and lists of animal vaccine production sites.

Furthermore, there are a number of activities, such as aerosol generation and aerosol particle behavior studies, that are extremely relevant to biological arms control and not accommodated by the current CBM topics. More comprehensive reporting on biotechnologies with a high potential for misuse is needed, regardless of whether they are undertaken as part of a national biodefense program. Other additions could include the incorporation of questions pertaining to codes of conduct for scientists and the future implementation of any export/import monitoring.

To focus the declarations on the most relevant issues, the elimination of particular topics also needs to be considered. During interviews conducted in December 2005, one Western European and Other Group (WEOG) country suggested that declarations of past offensive or defensive biological research and development programs are superfluous given that all of the activities declared should have been discontinued by now and will not help build current transparency.

Another WEOG government suggested ending the declaration of civilian vaccine production facilities because there are a number of other equally relevant processes that could indicate biological weapons capacity, including

Figure 1 Confidence Building Measures

To build confidence, states-parties to the Biological Weapons Convention have agreed to submit annually seven declarations providing information on themes relevant to biological arms control. The information is provided in seven declarations, termed Forms A through G.

- A. i) Exchange of data on research centers and laboratories
 - ii) Exchange of information on national biological defense research and development programs
- B. Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins
- C. Encouragement of publication of results and promotion of use of knowledge
- D. Active promotion of contacts
- E. Declaration of legislation, regulations and other measures
- F. Declaration of past activities in offensive and/or defensive biological research and development programs
- G. Declaration of vaccine production facilities

animal vaccine facilities and military vaccination programs. Most other states-parties, however, indicated that they would not favor the elimination of any topics because they are all relevant in building a comprehensive image of biological weapons potential in a country. Deletion of a particular topic should only be considered if this does not lead to a loss in comprehensiveness of the declared data. One possibility for deletion would be the declaration of annual case numbers of reportable diseases. Disease outbreak data is collected by the World Health Organization and need not also be requested in the CBMs.

For each form, the ability of the requested data to provide a comprehensive view of the topic in question should be assessed. This would highlight where superfluous information could be removed and where gaps in information need to be filled. In Form F, for example, details on organisms and facilities involved in the past biological weapons programs are not explicitly requested. Form structure and wording should be easily interpretable and serve as a guide for compiling the CBMs. Any confusion or ambiguities must be eliminated to facilitate submissions. For example, in one form the total number of staff workers at a biodefense facility is requested. The form subsequently asks for the number of contractor staff. It is not clear whether the total number of staff should be inclusive of contractor staff or not. States have interpreted these two questions differently in the past.

In terms of format, states-parties have suggested that it would be beneficial to simplify the forms in order for them to be more easily compiled. Such an attempt was already made with the addition of Form 0, which allows states to simply tick a box indicating for each of the other forms whether there is either "nothing to report" or

“nothing new to report.” Further use of tick boxes could allow greater detail to be provided without adding undue burdens and would facilitate any consolidation of data for analytical purposes. Although the replacement of narratives with tick boxes risks “sterilizing” the CBMs and removing any incentive to put thought into the answer or volunteer information, forms should be reviewed with an effort to make them more logical and easier to compile, facilitating comparison and analysis.

It is critically important to bolster the current mechanism of confidence building measures and thus **provide genuine support for the biological weapons ban itself.**

CBM Process Reform: International Level

At the moment, the United Nations is mandated only to collect the CBM declarations, copy them, bind them, and return them to member states. No further processing, analyzing, or translation occurs. A number of reforms to this process could improve the usability, verifiability, and accessibility of the CBMs, thereby enhancing participation. The first reform is to bring CBM submission and distribution into the digital age. Currently, all CBM data is still handled in paper form, including distribution, with more than 1,000 pages per year. Digitizing this process from start to finish would reduce costs and facilitate compilation, submission, and distribution. It may be an assumption that all government ministries and staff have access to computers. Most nations, however, would likely find digitizing the CBMs a welcome change. Ultimately, not every country needs to submit and receive digitally, but countries should be given the option to do so. The United Nations might shoulder the modest cost of scanning submissions that are made in paper form.

A next step from digitizing CBM submissions would be to create a central database where CBMs could be posted on the internet, thus maximizing their accessibility and making them available to a much wider audience. This would also allow studies by independent research organizations. Three countries have already posted this information, including the United States in 2004.⁷ Yet, although much of the information contained in the CBMs is already publicly available through open sources, many states seem reluctant to publish their CBMs so widely. Several states-parties have expressed concern that this step would make the CBMs available to nonmember states and potentially terrorists. Furthermore, the knowledge that the CBMs could be scrutinized by many readers might have negative repercussions and discourage countries from participating. One possible compromise would be to provide a password-protected secure website with access limited to member states.

Translating CBMs would also make them more accessible to states-parties, allowing them to make use of all CBMs regardless of their origin. The main concern is naturally the cost. To make this a politically justifiable act, the CBMs would have to be translated into all six

official UN languages, thus carrying a heavy price tag. States should at least be encouraged, where possible, to submit their CBMs in multiple UN languages. China submitted CBMs in Chinese and English at the beginning of the CBM process but has since stopped.

The most demanding CBM reform and therefore the one with the least consensus among states-parties is analysis. As a principle, there is no agreement among member states on a possible mandate of the United Nations for analyzing the CBMs. Several states-parties favored a neutral role for the United Nations and preferred that it refrain from engaging in any analysis that might reflect badly on any particular state. Furthermore, countries should be undertaking their own analysis and are most likely interested in different aspects of the CBMs, making a UN examination costly while providing little benefit. On the other hand, a significant number of states-parties favored a preliminary analysis by the United Nations. This could make the CBMs more accessible, identify misleading information, and demonstrate the usefulness of building transparency in countries that rarely participate and often do not even look at the CBMs.

Greater transparency in the system would be achieved if an analysis took place. Naturally, different degrees of analysis are possible. The simplest could take the form of an annual participation list, in contrast to the current five-year interval. These could be further developed to include information on submission dates and participation over years as well as details on which topics the CBMs provided answers. A medium-level analysis could involve a summary of the submitted data such as the number of facilities with maximum containment (BSL4) laboratories per country or types of vaccines produced. A high-level analysis could take the form of a comparison of submitted information with other sources. The most exhaustive form of analysis could be on-site visits for verifying submitted data. Any analysis would, naturally, be cost dependent and subject to debate on the BWC floor. Nevertheless, implementing yearly participation lists to be included in the compendium should be less difficult to achieve and would bolster interest in the CBMs. Furthermore, such a list, highlighting countries whose submissions have been consistent and timely, would provide an incentive to participate as it identifies “good performers.” This is particularly relevant for countries that have been accused of having had biological weapons programs in the past and want to demonstrate compliance with the biological weapons prohibition.

In providing the United Nations with a mandate to evaluate the CBMs, such as suggested above, a small task force consisting of three to four staff members would be sufficient initially. It could collect, process, assemble, and disseminate the CBMs as well as ensure timely submissions by sending annual reminders. It could also be given the authority to inquire about technical omissions such as missing pages. With a mandate to promote technical compliance to the BWC, this task force could also identify non-norm behavior and issue lists of “good performers.”

In an effort to clarify any ambiguities or inconsistencies in a submitted CBM, a low-level discussion forum should be established. Several states-parties, however, have warned that any formal or informal discussion on the accuracy of the CBMs would invariably result in finger-pointing and accusations. A solution could be to hold these talks over the internet, on a UN discussion board, so to speak.



UN Photo

UN Secretary-General Kofi Annan advocates countries increasing the transparency of their biological activities, particularly activities that have a higher potential for misuse, such as those conducted as part of a national biodefense program.

CBM Process Reform: National Level

Clearly, there are disincentives and obstacles to participation in the CBM process; otherwise, more states would take part. There are three classes of states that do not participate: those who do not know how or have trouble compiling data, those who do not care, and those who do not want to report. Persuading the first two types of states to participate is a matter of removing obstacles and raising awareness.

First, states need to provide assistance to countries struggling with data collection. For countries with financial or organizational hardships, compiling data can be a substantial barrier; even some EU states indicated that they had difficulties with data collection. This help could take the form of a guide, such as that recently put out by Canada; international workshops; or an e-mail hotline. International partnerships could also be created to provide data collection tutoring in the struggling country or to host a team from the struggling country to observe data collection techniques in another country. This help could be based on historic alliances or regional groupings. Such technical cooperation should be a part of any country's action plan to improve the implementation of the BWC by the states-parties. The EU's recently adopted joint action is a good example where this type of assistance could be offered.

Second, some states have obviously lost faith in the CBM mechanism and do not feel the need to participate. Another possibility is that the country has never had a biological weapons program and feels its participation is unimportant. To ensure that such states participate, the issue needs to be reframed in terms of the importance of transparency in biological arms control and the need for universal participation. Although a reform of the CBMs will make them easier to compile and be of use for analytical purposes, it is also important that the states feel ownership over issues of biological weapons non-proliferation. The importance of all countries' participation must be consistently and frequently emphasized in order to enhance confidence in the regime itself.

Third, the small number of countries that do not want

to report because they have something to hide will not be persuaded to participate by the suggested reforms. With greater participation and higher quality submissions, however, these countries will stand out more clearly, allowing the international community to focus on other nonproliferation efforts.

Conclusion

In the late 1990s, most states regarded the CBM mechanism as a dying instrument because they expected a verification protocol to be concluded and implemented, complete with mandatory declarations. Given that the protocol was not agreed on, however, CBMs remain the only multilaterally agreed mechanism to increase transparency in the area of biological arms control.

As the only source of relevant information exchange, it is vital that the CBMs work as efficiently as possible. Their importance needs to be reaffirmed at this year's review conference, and the necessary reforms have to be agreed on and implemented. Only then can CBMs play a more efficient role as part of a larger system for preventing the proliferation, development, and use of biological weapons. **ACT**

ENDNOTES

1. Bureau for Verification, Compliance and Implementation, Department of State, "Verification and Compliance With International Prohibitions Relating to Biological Weapons," November 1, 2005.
2. "In Larger Freedom: Towards Development, Security and Human Rights for All: Report of the Secretary-General," A/59/2005, March 21, 2005.
3. "Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction: Final Document, Part II, Final Declaration," BWC/CONF.II/13/II, 1986, p. 6.
4. Ibid.
5. Data is drawn from two studies conducted by the authors. See Iris Hunger, *Confidence Building Needs Transparency: A Summary of Data Submitted Under the Bioweapons Convention's Confidence Building Measures 1987-2003* (Austin and Hamburg: The Sunshine Project, 2005). Nicolas Isla, "Transparency in Past Offensive Biological Programmes. An Analysis of Confidence Building Measures Form F. 1992-2003," *Occasional Paper No. 1*, Hamburg Centre for Biological Arms Control, June 2006.
6. "Fifth Review Conference 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, Report of the Committee of the Whole," BWC/CONF.V/COW/1 and Annex 1.
7. In addition, Australia has made available CBMs from 2002, 2004, and 2005. The United Kingdom provided CBMs from 2003 and 2004.

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Biological Threat Assessment: Is the Cure Worse Than the Disease?

In the three years since the September 11 terrorist attacks and the subsequent mailings of anthrax bacterial spores, federal spending to protect the U.S. civilian population against biological terrorism has soared more than 18-fold. For the 2005 fiscal year, the Bush administration has requested about \$7.6 billion for civilian biodefense, up from \$414 million at the time of the 2001 attacks.¹ Several federal agencies are involved in biodefense research and development (R&D),² and the huge increase in funding from the National Institutes of Health for work on “select agents,” or pathogens and toxins of bioterrorism concern, has attracted thousands of academic scientists.³

Of growing concern to U.S. biodefense officials is the possibility that rapid advances in genetic engineering and the study of pathogenesis (the molecular mechanisms by which microbes cause disease) could enable hostile states or terrorists to create “improved” biowarfare agents with greater lethality, environmental stability, difficulty of detection, and resistance to existing drugs and vaccines.⁴ (See *ACT*, July/August 2004.) It is known, for example, that the Soviet biological weapons program did extensive exploratory work on genetically engineered pathogens.⁵ The Bush administration’s response to this concern has been to place a greater emphasis on “science-based threat assessment,” which involves the laboratory development and study of offensive biological weapons agents in order to guide the development of countermeasures. This approach is highly problematic, however, because it could undermine the ban on offensive development enshrined in the Biological Weapons Convention (BWC) and end up worsening the very dangers that the U.S. government seeks to reduce.

Biological Threat Assessment— Weighing the Risks

The Bush administration contends that science-based threat assessment is needed to shorten the time between the discovery of new bioterrorist threats, such as pathogens engineered to be resistant to multiple antibiotics, and the development of medical countermeasures, such as vaccines and therapeutic drugs. This

rationale is flawed, however, for three reasons.

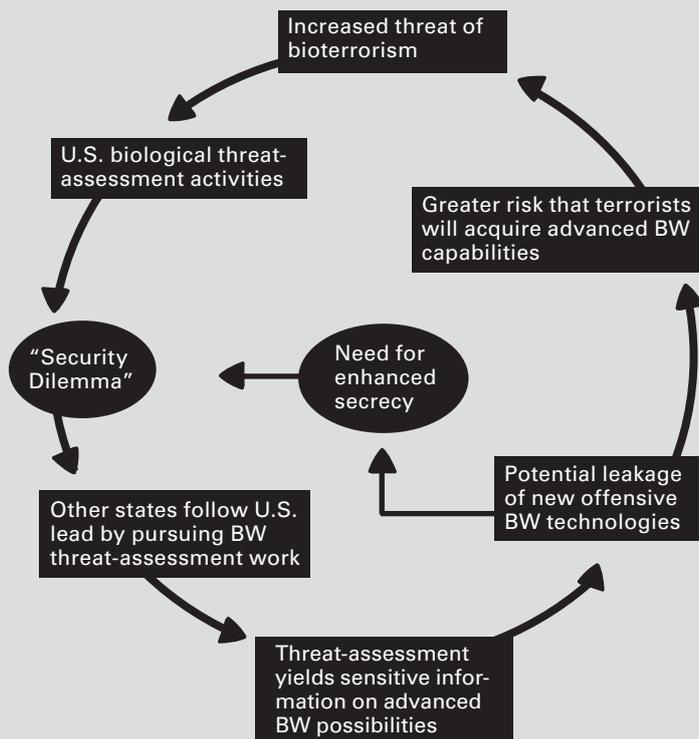
First, the administration’s biodefense research agenda credits terrorists with having cutting-edge technological capabilities that they do not currently possess nor are likely to acquire anytime soon. Information in the public domain suggests that although some al Qaeda terrorists are pursuing biological weapons, these efforts are technically rudimentary and limited to standard agents such as the anthrax bacterium and ricin, a widely available plant toxin. Assistance from a country with an advanced biological weapons program may be theoretically possible, but no state has ever transferred weaponized agents to terrorists, and the risks of retaliation and loss of control make this scenario unlikely. Although more sophisticated bioterrorist threats may emerge someday from the application of modern biotechnology, they are unlikely to materialize for several years.

Second, prospective threat-assessment studies involving the creation of hypothetical pathogens are of limited value because of the difficulty of correctly predicting technological innovations by states or terrorist organizations. Distortions such as “mirror-imaging”—the belief that an adversary would approach a technical problem in the same way as the person doing the analysis—make such efforts a deeply flawed basis for the development of effective countermeasures.

Third, by blurring the already hazy line between offensive and defensive biological R&D, science-based threat assessment raises suspicions about U.S. compli-

Vicious Circle

Threat Assessment, the Security Dilemma, and Technology Leakage



In response to the increased threat of bioterrorism, the United States and other countries are conducting prospective threat-assessment activities. Yet this research generates highly sensitive information that could potentially leak out to proliferant states and terrorists. In order to prevent such leakage, the United States has imposed tightened secrecy and security measures that, while inevitably less than 100 percent effective, heighten suspicions on the part of outside observers about the intentions behind the research. Such suspicions exacerbate the “security dilemma” associated with the inherently ambiguous nature of biodefense research, and fuel the proliferation of threat-assessment activities by other countries. Although subnational groups such as al Qaeda are not themselves subject to the security dilemma, the leakage of sensitive technologies and know-how from state-level programs may render the terrorists’ capabilities more deadly.

ance with the BWC and fosters a “biological security dilemma” that could lead to a new biological arms race. At the same time, the novel pathogens and related know-how generated by threat-assessment work could be stolen or diverted for malicious purposes, exacerbating the threat of bioterrorism.

Current Threat Assessment Activities

Although biological threat-assessment studies have been under way for several years, they have received a major boost under the Bush administration. On April 21, after a 10-month policy review of national biodefense programs, President George W. Bush signed Homeland Security Presidential Directive 10 (HSPD-10). In addition to allocating roles and responsibilities among various federal agencies, this directive requires the Department of Homeland Security (DHS) to conduct a national risk assessment of new biological threats every two years and a “net assessment” of biodefense effectiveness and vulnerabilities every four years. Under HSPD-10, significant resources will be devoted to projecting future threats, not just addressing current ones. According to an unclassified summary of the directive, the U.S. government is “continuing to develop more forward-looking analyses, to include Red Teaming efforts, to understand new scientific trends that may be exploited by our adversaries to develop biological weapons and to help position intelligence collectors ahead of the problem.”⁶

The expression “Red Teaming” dates back to the Cold War, when “red” symbolized the Soviet Union and its Warsaw Pact allies; the term now refers to any simulation involving the actions of a hostile country or subnational group. In the biodefense context, Red Teaming covers a variety of activities including scenario writing

and paper studies, computer modeling of hypothetical biological attacks, and the development and testing of novel pathogens and weaponization techniques in the laboratory in order to guide the preparation of defenses.

To expand U.S. government capabilities in the field of biological threat assessment, DHS recently established a new multi-agency organization called the National Biodefense Analysis and Countermeasures Center (NBACC), headquartered at Fort Detrick, Maryland.⁷ NBACC comprises four specialized centers, including a Biothreat Characterization Center whose mission is to “conduct science-based comprehensive risk assessments to anticipate, prevent, and respond to and recover from an attack.”⁸ The biothreat characterization program at NBACC will explore how bioterrorists might use genetic engineering and other advanced technologies to make viruses or bacteria more deadly or contagious.⁹ During a White House online discussion forum on April 28, 2004, DHS Assistant Secretary for Science and Technology Penrose “Parney” Albright stated, “We are very concerned about genetically modified pathogens that might be, for example, vaccine-resistant or an attempt to elude our detection abilities. We have efforts underway within [DHS, the Department of Health and Human Services (HHS)], and the Department of Defense [to] think through carefully the kinds of genetic modifications and genetic engineering that might be done so we can get ahead of the emerging threat.”¹⁰

In another published interview, Colonel Gerald W. Parker, director of the Science-Based Threat Analysis and Response Program Office at DHS, explained that the laboratory component of threat characterization “will be focused on addressing high-priority information gaps in either understanding the threat or our

vulnerabilities.” When asked if NBACC would conduct exploratory research on genetically engineered pathogens, Parker replied, “We will not be intentionally enhancing pathogenicity of organisms to do ‘what-if’ type studies.... [But] if there is information either in the classified or open literature, and it is validated information, that indicates that somebody may have [enhanced pathogenicity], and that we believe indicates that we might have a vulnerability in our defensive posture, we may have to, in fact, evaluate the technical feasibility and the vulnerability of our countermeasures.”¹¹

The Biological Security Dilemma

Even if, as Parker asserts, threat-assessment studies at NBACC involving the creation of genetically modified pathogens will be carried out only in response to “validated” intelligence that a state or terrorist organization has already done so, other countries may perceive such efforts as a cover for illicit, offensively oriented activities. The reason

is that the distinction between defensive and offensive biological R&D is largely a matter of intent, giving rise to a “security dilemma” in which efforts by some states to enhance their biological security inadvertently undermine the security of others.¹² Because intent is so hard to judge reliably, states tend to err on the side of caution by reacting to the capabilities, rather than the stated intentions, of potential adversaries. As a result, threat-assessment activities that a country pursues for defensive purposes may be perceived as offensive, particularly if those studies involve the genetic modification of pathogens to enhance their harmful properties.

Although the Bush administration has expressed concern about alleged biological weapons development activities in North Korea, Syria, Iran, and Cuba, it appears to have a blind spot with regard to how its own biological threat-assessment efforts are perceived abroad. Rival nations, fearing that the U.S. exploration of emerging biological weapons threats could gener-

Biological Threat Assessment—Then and Now

The origins of current U.S. biodefense policies date back nearly 35 years. In November 1969, President Richard M. Nixon decided to renounce unilaterally the U.S. offensive biological warfare program, which had been established during World War II. To implement this decision, national security adviser Henry A. Kissinger issued National Security Decision Memorandum 35 (NSDM-35), which henceforth banned the offensive development of biowarfare agents and weapons and required the destruction of all existing stockpiles.¹ At the same time, the Kissinger memorandum authorized continued biodefense activities such as the development of therapeutic drugs and vaccines. Although the memo included a provision permitting “research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required,” it did not specify what types of research were justified to facilitate the development of defenses.²

The U.S. decision to renounce its offensive biowarfare program stimulated the multilateral negotiation of the Biological Weapons Convention (BWC), which was opened for signature in 1972. Like NSDM-35, the text of the BWC is vague in its definition of permitted activities, particularly with respect to the assessment of offensive threats. Article I prohibits the development, production, and stockpiling of microbial or toxin agents “of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.” This purpose-based definition is designed to be inclusive and prevent the treaty from being overtaken by technological change, yet it begs the question of what “types and quantities” of lethal pathogens may legitimately be retained for the purpose of threat assessment and the development and testing of countermeasures.

The BWC entered into force on March 26, 1975, during the administration of President Gerald R. Ford, with the United States as one of the original parties. On December 23, 1975, then-national security adviser Brent Scowcroft issued a memorandum providing policy guidelines for U.S. implementation of the BWC. According to the Scowcroft memorandum, biodefense activities permitted under the

convention were limited to “[a]ctivities concerned with the protection of human beings, animals, plants, and matériel from the effects of exposure to microbial or other biological agents or toxins, including vulnerability studies and research, development and testing of equipment and devices such as protective masks and clothing, air and water filtration systems, detection, warning and identification devices, and decontamination systems.”³ Significantly, the Scowcroft memorandum authorized “vulnerability studies” but not the creation of novel pathogens or weaponization techniques for purposes of threat assessment.

During the first two decades after the United States ratified the BWC, the U.S. Biological Defense Research Program was conducted in a reasonably open manner. Threat-assessment studies and development projects were unclassified and described in detailed annual reports to Congress. During the late 1990s, however, heightened concern over chemical and biological terrorism apparently caused some elements of the U.S. biodefense community to alter this policy. The Pentagon and the intelligence community began to conduct secret threat-assessment studies that clearly exceeded the limits for defensive research specified in the Scowcroft memorandum, but Congress was not informed of the change. Indeed, during the Clinton administration, some classified biodefense work took place even without the full knowledge of the National Security Council staff.

In August 2001, the administration of President George W. Bush rejected a draft multilateral protocol that had been under negotiation for six years to strengthen the BWC with a system of mandatory declarations and inspections. One reason for this decision was the administration’s concern that intrusive on site visits to U.S. biodefense facilities might compromise classified threat-assessment research. On September 4, 2001, exactly one week before the terrorist attacks in New York and Washington, a front-page story in *The New York Times* revealed the existence of three secret threat-assessment projects being conducted by the U.S. intelligence community and the Department of Defense:

ate scientific breakthroughs that would put them at a strategic disadvantage, may decide to pursue or expand similar activities. Even if these programs are initially defensive in orientation, they could acquire a momentum of their own that eventually pushes them over the line into the offensive realm.

The biological security dilemma has been inadvertently deepened by policies that the United States adopted after the September 11 attacks to tighten physical security and access controls at laboratories that possess, store, or transfer select agents.¹³ Although these new regulations aim to prevent the theft or diversion of dangerous pathogens and toxins for malicious purposes, they have had the undesirable side effect of reducing the transparency of biodefense R&D at a time when greater openness is needed to reassure outsiders of the benign intent behind such activities.¹⁴ Moreover, since the mid-1990s, the U.S. government has conducted an unknown number of classified threat-assessment studies, three of which were re-

ported by *The New York Times* in September 2001 (see sidebar). The stated rationale for classification is to prevent terrorists from learning about and exploiting U.S. vulnerabilities to biological attack, but secrecy has the pernicious effect of increasing suspicions about U.S. intentions and worsening the security dilemma.

The most serious risk associated with science-based threat assessment is that the novel pathogens and information it generates could leak out to rogue states and terrorists. To prevent such proliferation, the United States will have to impose even more stringent security measures. Yet history suggests that the greatest risk of leakage does not come from terrorists breaking into a secure laboratory from the outside, but rather from trusted insiders within the biodefense community who decide, for various motives, to divert sensitive materials or information for sale or malicious use.

The expanded pool of researchers currently engaged in biological threat-assessment studies could well include a few spies, terrorist sympathizers, or

- *Project Jefferson*, a plan by the Defense Intelligence Agency to reproduce a genetically modified strain of the anthrax bacterium developed by Russian scientists in the early 1990s, in order to determine whether or not the agent was resistant to the licensed U.S. anthrax vaccine.

- *Project Clear Vision*, a project by Battelle Memorial Institute, under contract to the CIA, to reconstruct and test a Soviet-designed biological bomblet so as to assess its dissemination characteristics.

- *Project Bacchus*, an effort by the Defense Threat Reduction Agency, a unit of the Defense Department, to construct a mock biowarfare production facility to assess the feasibility of mass-producing anthrax bacterial stimulant with off-the-shelf equipment.⁴

The Bush administration claimed that all three studies were consistent with the BWC because the underlying intent was defensive, but a number of international legal scholars disagreed. They argued that the recreation of the Soviet bomblet under Project Clear Vision violated the Article I prohibition on the development, production, stockpiling, acquisition, or retention of “weapons, equipment or means of delivery designed to use [biological] agents or toxins for hostile purposes or in armed conflict.” The critics reasoned that, whereas the definition of biological agents and toxins in the first part of Article I is purpose-based and entails a judgment of intent, the ban on munitions and delivery systems in the second part is unconditional so as to prevent BWC violators from acquiring all of the components of a biological weapon under the cover of defensive research and development, making any judgment of compliance impossible.⁵

Beyond the legal issue of treaty compliance, the fact that the United States was conducting classified threat-

assessment studies raised broader political concerns. Particularly troubling to many countries was the fact that the United States had not reported the secret projects in its annual confidence-building measure (CBM) declarations, which were introduced by the BWC Review Conferences in 1986 and 1991 to strengthen the treaty. Because the United States had long portrayed its CBM submissions as the standard for other countries to follow, the omission of classified projects from the U.S. declarations damaged Washington’s credibility with respect to the benign nature of its biodefense program. If Iran had conducted the same projects in secret, for instance, the U.S. government would almost certainly have accused Tehran of violating the BWC. Moreover, in justifying the omissions, the Bush administration seemed to imply that the CBMs—and, by extension, the BWC itself—only covered Defense Department activities and not those conducted by the CIA and other agencies. If this interpretation is allowed to stand, it would tear a gaping loophole in the treaty regime.⁶

ENDNOTES

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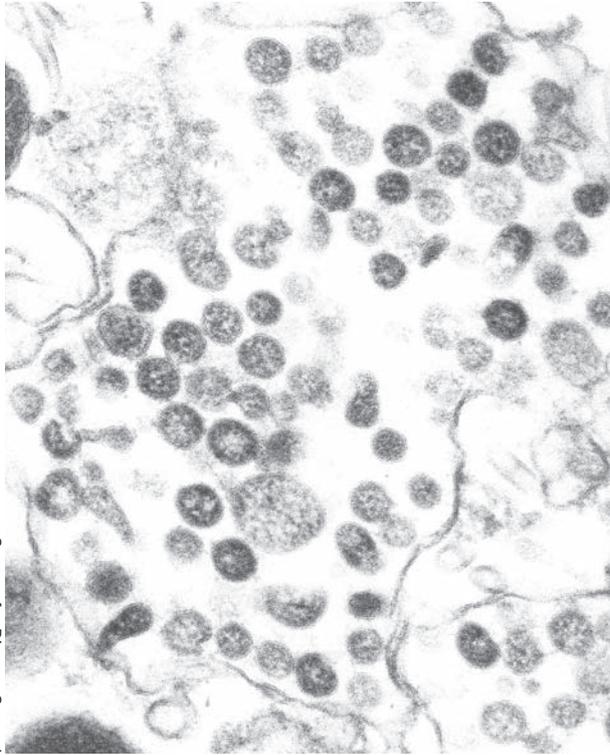
2. Henry A. Kissinger, “National Security Decision Memorandum No. 35,” November 25, 1969, pp. 2-3 (United States Policy on Chemical Warfare Program and Bacteriological/Biological Research Program).

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4. Judith Miller, Stephen Engelberg, and William J. Broad, “U.S. Germ Warfare Research Pushes Treaty Limits,” *The New York Times*, September 4, 2001, p. A1.

5. David Ruppe, “Proposed U.S. Biological Research Could Challenge Treaty Restrictions, Experts Charge,” *Global Security Newswire*, June 30, 2004.

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Centers for Disease Control

The identification of the SARS virus (above) and the rapid development of a diagnostic test and candidate vaccine provide an alternative model to the Bush administration's controversial threat-assessment program. One aspect of that effort involves predicting biological agents that U.S. enemies might develop.

sociopaths. Moreover, because a pathogen culture can be smuggled out of a laboratory in a small, easily concealable plastic vial, the odds of getting caught are fairly low. Security background checks on scientists working with select agents can reduce the threat of diversion but not eliminate it, as suggested by the cases of CIA or FBI insiders who became spies, such as Aldridge Ames and Robert Hanssen. Indeed, although the perpetrator of the mailings of anthrax bacterial spores in the fall of 2001 remains unknown, the technical expertise needed to prepare the highly refined material points to someone with experience inside the biodefense research complex.

Thus, rather than enhancing U.S. national security, science-based threat-assessment projects involving the development of novel pathogens are likely to create a vicious circle that ends up worsening the problems of biological warfare and bioterrorism. Prospective threat assessment entails two simultaneous risks: (1) developing dangerous new technologies that will leak out to proliferators and terrorists and create a self-fulfilling prophecy, and (2) undermining the norms in the BWC and provoking a biological arms race at the state level, even if the countries involved merely seek to anticipate and counter offensive developments by potential adversaries.

Breaking Out Of the Vicious Circle

In order to break out of the vicious circle created by the biological security dilemma, the United States should reduce its current emphasis on science-based threat assessment and pursue a number of strategies

to build confidence in the strictly peaceful nature of its biodefense program.

Enhanced Transparency. The U.S. government should promote greater international transparency in bio-defense R&D by including in its annual confidence-building measure (CBM) declarations under the BWC a comprehensive list of all of its biodefense activities, including classified projects, while omitting sensitive technical details that could assist proliferators or terrorists. (The fact that the United States had not declared the three secret threat-assessment studies uncovered by *The New York Times* suggested to some that it wished to avoid international scrutiny of legally dubious biodefense work.) In those rare cases where the risk of proliferation warrants classification, U.S. officials should explain why the experiments were done and provide a clear rationale for the limits on transparency. As a rule, however, openness should be considered the default condition, and any U.S. government agency seeking to classify specific biodefense projects or activities should be required to justify the need for secrecy.

International Collaboration. A second approach to building confidence would be for the United States to conduct biological threat-assessment studies jointly with other countries. NATO allies such as Canada, France, Germany, and the United Kingdom (as well as non-NATO countries such as Sweden) have advanced biodefense programs. Although the U.S. government conducts some joint R&D with allies, these efforts are currently pursued on an ad hoc basis. Integrating Canada, the European Union, and the United States into a formal system of collaborative biodefense R&D that includes effective oversight would give the international community greater confidence that Washington is not pursuing a unilateral path in this highly sensitive area and that its biodefense R&D program is fully compliant with the BWC.

Russia is also a potential U.S. partner in the biodefense field because of the large number of former bioweapons scientists and facilities remaining from the Soviet bio-warfare program and the existence of several areas in which the two countries have complementary expertise and pathogen strain collections. To date, however, U.S.-Russian biodefense collaboration has been undermined by Moscow's refusal to share a genetically modified strain of the anthrax bacterium and the fact that biodefense facilities under the control of the Russian Ministry of Defense remain off-limits to Western scientists.¹⁵ These issues will have to be resolved before joint U.S.-Russian R&D can become a source of greater international confidence in the BWC compliance of both countries.

Domestic Oversight. A third approach to breaking out of the vicious circle is to improve the domestic oversight of biological threat assessment. In October 2003, the National Research Council of the U.S. National Academy of Sciences released the report of an expert panel chaired by Dr. Gerald R. Fink on preventing the malicious application of "dual-use" research in the life sciences.¹⁶ This report identified seven types of experiments that could result in information with a potential for misuse, including the genetic modification of pathogens to explore the mechanisms by which microbes cause disease. The Fink committee recommended

the creation of a voluntary system for reviewing the security implications of federally funded biological research at the proposal stage. Such oversight would be performed at the local level by Institutional Biosafety Committees and at the national level by a new oversight board made up of scientists and security experts.

On March 4, 2004, the Bush administration responded to the Fink committee report by announcing the planned establishment of a National Science Advisory Board for Biosecurity (NSABB) under the auspices of the National Institute of Health. This new entity will establish guidelines for the security review of sensitive biological research projects in academia and, on a voluntary basis, in private industry.¹⁷ Although the administration announced this initiative with much fanfare, the creation of the NSABB has proceeded at a snail's pace, and its first meeting has not yet been scheduled. Moreover, the advisory board will have no binding regulatory authority, and its mandate explicitly excludes the review of classified biodefense research initiated by the U.S. government and conducted at federal facilities with federal money. According to the NSABB web site, "Government-sponsored research that is classified at its inception...will be outside of the purview of the NSABB. This research is subject to other institutional and federal oversight, and is not the target of this biosecurity initiative."¹⁸

In fact, "other" federal oversight of classified biodefense R&D is extremely limited. Each U.S. government agency involved in such research is responsible for policing its own compliance with the BWC. The Defense Department, for example, has a Compliance Review Group that subjects the department's biodefense programs to internal legal review for consistency with the treaty.¹⁹ Yet this committee is not accountable to the National Security Council or to other federal agencies such as the Department of State, which has the lead on the negotiation and legal interpretation of arms control treaties.

As a matter of principle, U.S. departments and agencies should not be responsible for reviewing the BWC compliance of their own biodefense programs because of the clear potential for conflict of interest. For example, lawyers employed by agencies with an institutional and budgetary stake in biological threat assessment may come under pressure to find loopholes so that legally questionable projects can go forward. For this reason, an interagency review process is needed to create internal checks and balances and build international confidence in the U.S. biodefense program.

Given the tenacity with which federal agencies defend their autonomy and turf, presidential leadership will be required to ensure adequate oversight and accountability for biological threat-assessment studies. Improved oversight mechanisms should be introduced by the executive and the legislative branches. For example, the Homeland Security Advisory Council in the White House might establish an interagency oversight board for biodefense consisting of representatives of the Defense and State Departments, CIA, DHS, HHS, and the intelligence community. This board would review the treaty compliance of all federal threat-assessment programs, including special-access ("black") projects

whose existence is not acknowledged publicly. Congress should also pass legislation requiring all federal agencies involved in biodefense work to submit detailed reports on any classified threat-assessment activities to the House and Senate Select Committees on Intelligence, whose members and staff hold high-level clearances. These committees might also conduct closed hearings to review "black" biodefense projects on an annual basis.

Internal government oversight is not a panacea, however, because it can be corrupted by interagency collusion or a lack of good faith on the part of senior administration officials, particularly in an atmosphere of extreme secrecy. Prior to the Abu Ghraib prison-abuse scandal in Iraq, for example, the Department of Justice's Office of Legal Counsel prepared a memorandum arguing that the president's authority as commander in chief enabled him to disregard domestic laws and international treaties banning torture during interrogations of enemy combatants, thereby nullifying the existing checks and balances.²⁰

Unilateral Restraint. Perhaps the most effective way for the United States to build international confidence in the peaceful nature of its biodefense program would be for the president to make a public statement renouncing the prospective development of genetically modified microorganisms with increased pathogenicity for threat-assessment purposes and urging all other countries to follow suit. As noted above, because the utility of prospective studies of genetically modified pathogens is severely limited by mirror-imaging and other sources of error, abandoning such studies would entail little risk to U.S. national security. On rare occasions, it may be necessary to test the efficacy of standard drugs or vaccines against genetically engineered pathogens that have already been developed by other countries. In these cases, the study should require a special authorization from the president following a careful interagency review to ensure that the proposed work complies with the letter as well as the spirit of the BWC.

To enforce the proposed unilateral ban on the prospective development of new pathogens with increased pathogenicity, the president should encourage scientists within the biodefense community to "blow the whistle" if they become aware of unauthorized studies that violate this policy, regardless of whether the work is being conducted in an academic setting or in a top-secret government laboratory. Confidential reporting channels and legal protections should also be established to shield scientists who expose illicit activities. To bolster the norm of professional responsibility further, scientists working in federal biodefense programs should be required to sign a code of conduct, similar to the Hippocratic oath, that precludes them from deliberately developing agents with enhanced pathogenicity or other harmful properties and requires them to report any deviations from this norm.

At the same time that the United States renounces the prospective development of pathogens for threat-assessment purposes, it should pursue less

provocative ways of getting a jump on defending against new bioterrorist threats, such as bacteria that have been genetically modified to make them resistant to multiple antibiotics. One approach would be for researchers to focus on developing broad-spectrum therapeutic and preventive measures that are not agent-specific. A second strategy would be for the U.S. government to invest in building an R&D and industrial infrastructure that can assess novel biological threat agents as soon as they are detected and then develop, test, and manufacture safe and effective countermeasures. With these systems in place, it should become possible to move "from bug to drug" in a matter of weeks or months, rather than years.²¹ (The recent identification of the SARS virus and the rapid development of a diagnostic test and a candidate vaccine is a case in point.) Because the two alternative strategies would be unequivocally defensive, they would build confidence that the U.S. biodefense program is fully consistent with the BWC.

These practical steps are needed to prevent the Bush administration's growing emphasis on science-based threat assessment from increasing biological weapons proliferation risks, exacerbating the security dilemma, weakening the BWC, and drawing the United States into a dangerous biological arms race. It is time to break the vicious circle before it starts. **ACT**

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Crucial Guidance: A Code of Conduct for Biodefense Scientists

When representatives of up to 155 states-parties meet in Geneva from November 20 to December 8 to consider ways to strengthen the 1972 Biological Weapons Convention (BWC), they are likely to express support for the promotion and creation of “codes of conduct.” These ethical principles are intended to increase scientists’ awareness and accountability and reduce the risk that biological research and development could be misused for biological weapons. Yet, producing concrete guidelines for scientists involved in such a broad research area has proved difficult. For example, a June 2005 BWC meeting of experts charged with addressing the adoption of codes of conduct for scientists did not produce any concrete actions.¹

In fact, it is not realistic to believe that a single broad code can be enacted. States-parties negotiators would be better off focusing on creating a narrower set of guidelines and appropriate oversight mechanisms that would govern a far smaller group of scientists in national biodefense research and development programs, including programs for bioterrorism preparedness and protection. These guidelines could be incorporated into and complement an already existing set of politically binding confidence-building measures, an annual set of national declarations that seeks to build transparency in fields related to the BWC.

Biodefense and the BWC

Although outlawing offensive biological weapons activities, the BWC permits biodefense research and development to develop antidotes and other means of countering biological weapons threats. Yet, the boundary between defensive and offensive biological weapons programs can be hazy. Because it is impossible to know which threats will actually materialize, scientists might carry out research and development activities that arguably could contribute to offensive biological weapons programs.

Moreover, because determining the intentions of other states or nonstate actors is inherently problematic, many intelligence evaluations focus on worst-case scenarios of others’ capabilities. This, in turn, can result in a practically unlimited number of threats and an open-ended demand for resources to evaluate and meet them, especially with regard to possible threats posed by nonstate actors. For example, scientists might develop and test pathogenic strains with modified characteristics, such

as resistance to multiple antibiotics or vaccines; or they might replicate, develop, or test new biological munitions or different methods for delivering them. Such activities or the suspicion that they are taking place inevitably cause states to worry that others are carrying out inappropriate research.

These concerns have grown in recent years as a number of states have expanded their biodefense work. U.S. funding for bioweapons prevention and defense increased dramatically after the September 11 terrorist attacks, from \$1.6 billion to more than \$8 billion requested for fiscal year 2007, which begins October 1. All told, 11 federal departments and agencies have spent more than \$36 billion since 2001.² While spending at the Department of Defense has increased slightly,³ spending on civil biodefense programs has soared from \$414 million in fiscal year 2001 to a requested \$7.6 billion in fiscal year 2005.⁴

Advocacy groups have also raised concerns in recent years about pending congressional legislation to establish a new Biomedical Advanced Research and Development Agency (BARDA) that would serve as a single point of authority within the Department of Health and Human Services for implementing biodefense programs. These groups have criticized provisions in some versions of the legislation to exempt the agency from some Freedom of Information Act provisions requiring public disclosure of the programs. As of July, Congress was still crafting final language on a bill to establish BARDA.⁵

This massive investment in all aspects of biodefense and protection against bioterrorism is unique for the United States. Moreover, the nature and scope of this work in the United States is unclear, leaving some to imagine the worst possibilities. Although the United States has demonstrated

significant transparency in its reports to Congress and the BWC, critics have suggested that it has crossed the border between defensive and offensive research.⁶

In Europe, funding has increased as well, although on a much smaller scale as Europeans have not viewed bioterrorism to be as great or as imminent a threat. Moreover, a significant share of funds in Europe has been directed toward improving general public health efforts to fight infectious disease outbreaks and to prepare against possible pandemics rather than toward preventing a bioterrorist attack.

Codes of Conduct and Confidence Building Measures

The BWC calls for countries to provide information annually on their national biological weapons defense research and development programs, including data on past programs stretching back to 1946. The United States provides information about its program annually, but it is only one of a few states that do this. When countries do provide information, it is usually for domestic policy reasons, such as to inform national parliaments, and not for public scrutiny. These reports are not readily available and only distributed to states-parties.⁷

As many consider these biodefense declarations insufficient, states-parties have sought other means of making national programs more transparent. Indeed, such discussions were at the center of seven years of negotiations to strengthen the BWC that broke down in 2001. At that time, the United States, citing national security and commercial interests, announced that it could not support a draft protocol to the treaty that would have included a set of mandatory declarations of activities and facilities and the possibility of on-site visits.⁸

In response to criticism over its decision, U.S. officials as an alternative proposed continuing discussions on a

limited set of relevant subjects. This so-called new process was subsequently endorsed by the other BWC states-parties in 2002, and it included a discussion of codes of conduct that would more explicitly state generally agreed-on acceptable behavior. The adoption of such codes is an indicator of responsible behavior and helps to ensure appropriate handling of questionable activities. Further, the process of producing codes involves extensive consultations that raises awareness among scientists and fosters internal consultations. A code can also be a valuable tool for educating students and employees.⁹

Most scientists already work under codes of conduct that govern laboratory standards and safe working practices, but they are often unaware of treaties such as the BWC and Chemical Weapons Convention and how such accords affect their work. The existence of ethical or behavioral guidelines can foster an ethical norm among scientists and strengthen oversight. Yet, codes of conduct for scientists who cover biological warfare-related areas are lacking. Such codes should reinforce the “norm” that biological warfare is unacceptable and provide guidance as to how scientists can help prevent it. The United States has proposed that, in the context of the BWC, such a code require generally that scientists use their knowledge and skills for the advancement of human welfare and not for any activities that could be used “for hostile purposes or in armed conflict.”¹⁰

A more precise code, however, should also be formalized to help biodefense scientists identify what constitutes offensive research and development and create a mechanism for reporting potential BWC violations should they occur.¹¹ Instituting such a code would require a firm commitment from scientists, program management, and government but is vital. Although the line between offensive and defensive research will likely change as science advances, many national biode-

Proposed Codes of Conduct

Several codes of conduct have been proposed to guide scientists whose research might potentially violate the Biological Weapons Convention (BWC). One proposal put forward by nongovernmental organizations in 2002¹ would clarify that the BWC prohibits the development, production, stockpiling, acquisition, or retention of all microbial or other biological agents or toxins of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes. In other words, the convention contains no exemption for law enforcement, riot control, or similar purpose. Likewise, it would make clear that the BWC bans the design, construction, or possession for any purpose of delivery mechanisms designed to use biological agents or toxins for hostile purpose or in armed conflict. There is no exemption for peaceful purposes.

In addition, scientists would be advised that constructing novel biological agents, including single-gene changes, for threat assessment is incompatible with the spirit and intent of the BWC and should be disavowed. Similarly, the proposal would steer scientists away from weaponizing active biological agents for defensive purposes. It would also suggest that aerosolization or other dissemination of active biological

agents be performed only in fully contained bench-scale environments and only for purposes of detection, prophylaxis, or medical treatment.

An alternative proposed code of conduct² calls on any person or institution engaged in any aspect of the life sciences to work to ensure that their discoveries and knowledge do no harm. In particular, its authors suggest scientists refuse to engage in any research intended to facilitate or that has a high probability of being used to facilitate bioterrorism or biowarfare. Additionally, they would guide researchers not to contribute knowingly or recklessly to the development, production, or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types or in quantities that cannot be justified on the basis that they are necessary for prophylactic, protective, therapeutic, or other peaceful purposes.

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Debating Definitions

When it comes to codes of conduct and the Biological Weapons Convention (BWC), there can be as much debate about semantics as substance. BWC states-parties have considered the merit of using the term “codes of practice” as opposed to “codes of conduct” because the latter term can be interpreted as applying to individuals only. One suggestion for classification of professional codes is that “ethical codes” aim to be aspirational, “codes of conduct” to be educational and/or advisory, and finally “codes of practice” to be enforceable.¹

State-parties have also expressed uncertainty as to what constitutes a “program.” Does it mean the collective whole of the various military or civilian research and development activities, including individual projects carried out

by defense contractors, or only programs carried out by the defense ministry? The BWC confidence-building measures only call for declarations about a “national biological defense research and development program.”

Some activities formerly characterized as biodefense work now fall under bioterrorism. The distinction is important because work carried out as part of a program to meet perceived bioterrorism threats is probably not directed at other states and may thus be perceived as less threatening. Yet, states may seek to hide some biodefense work that is part of an offensive program by characterizing it as part of efforts to meet bioterrorism threats.

ENDNOTE

1. See www.projects.ex.ac.uk/codesofconduct/Examples/index.htm.

fense programs lack even a basic review of research and development activities. Scientists are also not well informed of the BWC's restrictions.

Several international and nongovernmental organizations have called for the creation of a global code of conduct or declaration on biological weapons that could involve scientists in current biodefense programs worldwide.¹² In the biodefense area, it would be essential to couple such codes of conduct with independent mechanisms that could provide the necessary oversight to assure the public that a biodefense program is purely defensive.¹³ In particular, each institute should establish an independent panel of senior scientists to vet any proposed biodefense work and ensure that it conforms to the established codes of conduct. These panels would then report to an independent national committee.

Canada and Australia already have such mechanisms. Australia has an oversight committee for biodefense work and a code of conduct for scientists in the program. Canada's national oversight committee annually reviews biological and chemical defense research, development, and training activities undertaken by the Department of National Defense to ensure that these activities are defensive in nature and conducted in a professional manner with no threat to public safety or the environment. The committee members' appointments are approved by the deputy minister of national defense and the chief of the defense staff on the recommendation of the committee chairperson. Nominations for membership in the Biological and Chemical Defense Review Committee are solicited by the chairperson from the Canadian Society of Microbiologists, the Chemical Institute of Canada, and the Society of Toxicology of Canada. To provide transparency, the committee publicizes its annual reports on its website.¹⁴ A copy is also provided to the Organization for the Prohibition of Chemical Weapons.

Another complementary mechanism that should be required is an independent international authority available to scientists who have qualms about their research or would like to report activities they believe to be unethical or irregular. This “ombudsman” should be affiliated with the United Nations and be under the supervision of independent scientific organizations and/or academies. States should also consider establishing a scientific advisory committee in the framework of the BWC.

Finally, the BWC states-parties should table national papers that describe internal legal review processes for biodefense work, including its role in the interagency consultation and review processes; relevant whistle-blower regulations; and the manner in which such procedures are compatible with rules governing classified work.

Getting Results at the Review Conference

Although the window is closing, states-parties still have time to submit proposals for the upcoming BWC review conference. These proposals could consider a variety of issues—some procedural, others substantive—connected with the content, promulgation, and adoption of codes of conduct and any results from the 2005 experts meetings on these subjects. The conference may, *inter alia*, adopt a code of conduct, adopt guidelines outlining what a code of conduct should contain, agree on a set of measures or a follow-on process to consider further how best to implement such a code, or simply decide to promote codes of conduct that address specific issues.

To make progress, the scope of these efforts should be relatively narrow. It is not realistic to believe that the conference can develop a broad code of conduct covering biological sciences. In addition, a number of other internationally accepted codes of practice already exist in the field. It would be more feasible and effective for the conference to focus on areas where there could be both a benefit and an additional support for the BWC. For instance, the conference could seek to prevent the potential misuse of science related to potential offensive research or development in state-run biodefense programs or activities.

A far-reaching measure would be for states-parties to agree on a set of follow-on measures or on a process regarding a code of conduct for scientists that results in a legally binding commitment. A more modest but more achievable goal would be for the conference to call on states-parties to report on national codes of conduct and supply the texts of such codes as a confidence-building measure.

After adopting such a measure, states would report on any code of conduct for scientists in the biodefense area, whether there is an independent oversight committee for the national biodefense program, and on other relevant codes of conduct for scientists. States-parties

also need to consider if current confidence-building declarations on national biological research and development programs are adequate or if it needs to be clarified that these declarations also include research and development on bioterrorism defenses. And states-parties could

Although the line between offensive and defensive research will likely change as science advances, **many biodefense programs lack even a basic review of research and development activities.**

describe in their national papers the legal review mechanisms to determine whether their biodefense work conforms to the BWC and if any whistle-blower legislation exists that allows for reporting of activities of concern.

In this way, codes of conduct can be closely tied to the fundamental object and purpose of the convention, increasing the likelihood that states-parties will support such efforts. This step would be particularly helpful if such confidence-building measures were mandatory and included a means of clarifying declarations, voluntary exchanges of information, and voluntary on-site visits to build confidence. States-parties might also consider agreeing on an intersessional mechanism to allow states to offer implementation assistance.

Conclusion

Scientists need codes of conduct for guidance and to help them clarify their thinking on difficult ethical questions. Countries have to prove to their parliaments and general public that a biodefense program is purely defensive and that the involved scientists are working in line with openly agreed codes of conduct. Independent national oversight committees are therefore needed to review ongoing biodefense research and development activities. In addition, the international community should design some kind of independent international authority to counsel scientists concerned about how their research or results might be used.

At this fall's BWC review conference, countries should aid this effort by proposing specific guidelines for codes of conduct covering biodefense research and development programs. States-parties should also seek ways to strengthen the confidence-building declarations under the BWC, such as by adding oversight committees and facilitating reporting on activities of concern. In addition, states-parties should review the current declaration on biodefense programs and make it mandatory. Such measures can help ensure that the search for cures to potential biological weapons attacks does not endanger the BWC in the process. **ACT**

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Preventing the Misuse of Pathogens: The Need for Global Biosecurity Standards

The anthrax-tainted letters sent through the U.S. mail in the fall of 2001, infecting 22 people and killing five, hinted at the mayhem that could result from the large-scale release of a “weaponized” disease agent. Since then, efforts to counter bioterrorism have focused on the medical and public health response to an attack rather than on prevention. Although improved disease surveillance and therapeutic countermeasures are needed, it is also critical to impede biological attacks by making it more difficult for terrorists to obtain deadly pathogens and toxins (poisonous chemicals produced by living organisms).¹

Shortly after the anthrax mailings, the U.S. government tightened domestic regulations on access to hazardous biological materials that have legitimate uses in research and industry but could be misused by terrorists. The United States deserves credit for putting its domestic house in order, but no comparable security measures currently exist at thousands of research centers, clinical laboratories, and culture collections overseas that possess or work with dangerous pathogens and toxins. This lack of international harmonization has created security gaps that could be exploited by terrorists.

Negotiating global standards that restrict access to dangerous pathogens would reduce the threat of bioterrorism, while reinforcing the legal prohibitions on the development, production, and stockpiling of biological and toxin weapons contained in the 1972 Biological Weapons Convention (BWC). Since its inception, the credibility of the BWC has been undermined by its lack of formal mechanisms for monitoring and verification, and efforts over the past decade to strengthen the treaty have been largely unsuccessful. Although the BWC review conferences in 1986 and 1991 introduced politically binding confidence-building measures (CBMs) to increase transparency and improve compliance, only a minority of member states have submitted annual CBM reports. More recently, a six-year effort to negotiate a legally binding inspection protocol to supplement the BWC collapsed in July 2001 when the United States rejected the draft text.

The Bush administration views the terrorist acquisition and use of biological weapons as a more urgent threat than state-level proliferation, and it is also skep-

tical about the utility of legally binding multilateral agreements. Accordingly, the U.S. government has sought to bolster the BWC by urging member states to pass national legislation mandating domestic measures to counter bioterrorism. In November 2002, under U.S. pressure, the Fifth Review Conference of the BWC adopted a work program consisting of three annual meetings of experts groups and states-parties in 2003-2005, prior to the next review conference in late 2006. The aim of these meetings is to “promote common understanding and effective action” on five measures that could be taken at the national level to strengthen the BWC: penal legislation, pathogen security measures, enhanced international procedures to investigate and mitigate the alleged use of biological weapons or suspicious outbreaks of infectious disease, improved mechanisms for global disease surveillance and response, and scientific codes of conduct.²

The first experts meeting in Geneva on August 18-29, followed by the first meeting of BWC member states November 10-14, will address two issues: national implementation measures for the enactment of penal legislation and best practices for the security and oversight of pathogenic microorganisms and toxins. This article addresses the latter topic, which has come to be termed “biosecurity.”

Defining “Biosecurity”

Although the terms “biosafety” and “biosecurity” are often used interchangeably, they refer to different issues. Biosafety technologies and procedures aim to prevent accidental infections of biomedical researchers and releas-

Table 1 Characteristics of Fissile Materials and Pathogens

Fissile Materials	Biological Pathogens
<ul style="list-style-type: none"> • Do not exist in nature • Nonliving, synthetic • Difficult and costly to produce • Not diverse: plutonium and highly enriched uranium are the only fissile materials used in nuclear weapons • Can be inventoried and tracked in a quantitative manner • Can be detected at a distance from the emission of ionizing radiation • Weapons-grade fissile materials are stored at a limited number of military nuclear sites • Few nonmilitary applications (such as research reactors, thermo-electric generators, and production of radioisotopes) 	<ul style="list-style-type: none"> • Generally found in nature • Living, replicative • Easy and cheap to produce • Highly diverse: more than 20 pathogens are suitable for biological warfare • Because pathogens reproduce, inventory control is unreliable • Cannot be detected at a distance with available technologies • Pathogens are present in many types of facilities and at multiple locations within a facility • Many legitimate applications in biomedical research and the pharmaceutical/biotechnology industry

es of dangerous pathogens from research laboratories that could endanger public health or the environment. These objectives can be achieved through “biocontainment,” which involves placing impermeable barriers or filters between the infectious agent and the researcher and between the laboratory and the outside world. Four levels of increasingly stringent biocontainment—referred to as Biosafety Levels (BSL) 1 through 4—are keyed to the lethality and contagiousness of pathogens and the availability of protective vaccines or therapeutic drugs.

Biosecurity, in contrast, denotes policies and procedures designed to prevent the deliberate theft, diversion, or malicious use of high-consequence pathogens and toxins. (A third term, “biosurety,” refers to the integration of biosafety and biosecurity.) In thinking about biosecurity, it is important to note some fundamental differences between biological and nuclear weapons materials (mainly plutonium and highly enriched uranium) that determine the effectiveness of controls. First, dangerous biological agents exist naturally in the environment. (The sole exception is the smallpox virus, which was eradicated from the wild in 1977 and is stored officially in only two repositories.) Second, since microorganisms will reproduce rapidly under the right conditions, large quantities can be grown from extremely small samples. Finally, biological materials have numerous civilian uses. (See Table 1.) Given the unique charac-

teristics of pathogens, they cannot be controlled to the extent that nuclear weapons materials can be. As a result, it is necessary to develop a new security paradigm that is specifically tailored to microorganisms.

Although it is not possible to measure precisely the level of risk associated with poor security at microbiological laboratories, some recent incidents in the United States and elsewhere have hinted at the magnitude of the problem. A report in May 2002 by the inspector-general of the U.S. Department of Agriculture found that many of the department’s 124 research laboratories were vulnerable to theft and could not account accurately for their stocks of animal and plant pathogens.³ Similarly, investigations of the Pentagon’s leading biodefense facility, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Maryland, found chronic problems with laboratory security during the 1980s and 1990s, including repeated failures to account for samples of pathogens because of poor internal controls and record-keeping.⁴

If such concerns over laboratory security persist, the Bush administration’s plan for a massive increase in funding for biodefense research and development could prove counterproductive. The U.S. federal budget for fiscal year 2003 allocated more than \$1.5 billion to the National Institutes of Health for work on bioterrorism countermeasures—a fivefold increase over the previous year. If the Bush administration

gets its way, additional appropriations on this scale will continue for the next several years.⁵ Much of this money would be spent on the construction of new or expanded high-containment laboratories and related infrastructure for basic and applied research on dangerous pathogens. Ironically, the rapid expansion of biodefense research could create new security problems by multiplying many-fold the number of people with access to hazardous biological materials.

The Threat of Diversion

Until quite recently, controls on biological pathogens were driven more by concerns over safety than security. In contrast to the strict safeguards placed on nuclear weapons materials, dangerous pathogens and toxins have typically been stored in unprotected research laboratories and shipped across national borders with minimal precautions. University-based researchers have a long tradition of sharing microbial cultures informally through the mail, and few countries restrict who is granted access to infectious agents.

One reason for this laxity was that biological threats were not recognized to be as dangerous as nuclear threats, particularly in the pre-September 11 environment. Another reason is that most pathogens and toxins can be obtained from natural sources. A skilled microbiologist can isolate a bacterium or virus from diseased animals, clinical specimens, and even from soil (in the case of anthrax spores). Nevertheless, reliance on these sources entails certain drawbacks. Since natural strains of pathogens vary widely in virulence, or the degree to which a microbe can cause disease, many of the strains isolated from nature could not be developed into effective weapons.

Given the technical difficulties associated with acquiring virulent microorganisms from natural sources, terrorists might well have a higher probability of success if they stole well-defined strains from a research facility, a clinical laboratory, a commercial supplier, or a state-owned culture collection or purchased such strains under false pretenses. The Ames and Vollum strains of anthrax, for example, are known to be highly virulent. Thus, the main purpose of biosecurity standards and procedures is to make it harder for terrorists to acquire deadly pathogens by making sure that legitimate activities and facilities are off-limits. Determined terrorists will then be forced to isolate virulent strains from natural sources, which are considerably less reliable.

Research laboratories working with dangerous pathogens face two main threats of theft or diversion: from outsiders and from insiders. In addition to criminal gangs and terrorist cells, outsiders could include visiting scientists, students, and short-term contractors who might attempt to steal pathogens covertly during a visit or stay at the facility. Insiders, in contrast, are trusted members of the scientific or technical staff who have been granted unescorted access and are familiar with laboratory security procedures and equipment. Such individuals might be motivated to steal dangerous pathogens for a variety of reasons, including resentment over being reprimanded or passed over for promotion, financial pressures, blackmail threats and other forms

of external pressure, psychological or personal problems such as divorce or substance abuse, or recruitment by a terrorist organization.

The temptation to divert pathogens for sale on the black market might be particularly strong in the ex-Soviet states, where former bioweapons scientists currently receive only a fraction of their previous salary and perks. Traditional approaches to facility security such as “guns, gates, and guards” cannot prevent a covert outsider or a trusted insider from stealing a small sample of a pathogen and cultivating it in large quantities for illicit purposes. To prevent such misuse, biosecurity systems require an integrated approach that includes physical protection, access controls, materials accountability, and personnel screening.

The International Dimension

The United States currently leads all other countries in the extent and detail of its biosecurity legislation. (See sidebar.) Yet, even as the U.S. government implements the new regulations, the international dimension of the problem remains to be addressed. Several countries outside the United States have passed domestic laws that contain provisions on biosecurity, including Canada, France, Germany, Israel, Japan, and the United Kingdom. Nevertheless, many other countries conduct research on infectious disease agents such as anthrax and plague, maintain collections of microbial pathogens, and operate maximum-containment laboratories that handle the most deadly and incurable disease agents. (See Table 2 on next page.) Relying exclusively on nationally developed guidelines would result in an uneven patchwork of regulations, creating pockets of lax implementation or enforcement. For this reason, any effective campaign to restrict terrorist access to dangerous pathogens will have to be global in scope. Roughly 1,500 state-owned and commercial culture collections worldwide maintain, exchange, and sell samples of microbes and toxins for scientific and biomedical research. These organizations vary widely in size and content, from large nonprofit organizations such as American Type Culture Collection to “boutique” collections based at universities, federal agencies, and private companies. About a third of the culture collections outside the United States might possess dangerous pathogens that are not adequately secured and controlled, making them vulnerable to theft or diversion.⁶ Trade in microbial cultures is also poorly regulated, both within countries and among them. In the United States, the Commerce Department licenses exports of pathogens and toxins on a list of “select agents,” and the Centers for Disease Control and Prevention authorizes imports. In many other countries, however, culture collections routinely ship dangerous pathogens with few questions asked.

The security situation in states with former offensive biowarfare programs is particularly troubling. During the late 1980s, some 60,000 scientists and technicians in the Soviet Union worked on biological weapons at more than 50 research institutes and production plants around the country. After the breakup of the Soviet Union in 1991, the old structures of authority and control collapsed, putting pathogen

U.S. Biosecurity Legislation

The U.S. Congress first introduced controls on dangerous pathogens after a 1995 incident called attention to the lack of government regulation in this area. Larry Wayne Harris, a licensed microbiologist and neo-Nazi sympathizer in Columbus, Ohio, used a forged letterhead to order three vials of freeze-dried *Yersinia pestis* (plague) bacteria from American Type Culture Collection. After Harris' repeated calls to check on the status of his order aroused suspicion, he was arrested and later convicted of one count of mail fraud.

In response to the Harris case, the Senate Judiciary Committee held hearings on how to prevent the unauthorized acquisition of dangerous pathogens by criminals and terrorists. The following year, Congress passed the Anti-Terrorism and Effective Death Penalty Act of 1996, which included a section imposing new controls on facilities that ship or receive dangerous pathogens and toxins.

Pursuant to this legislation, federal regulations that went into effect April 15, 1997, required anyone shipping or receiving agents on a list of hazardous microbial pathogens and toxins (termed "select agents") to register with the U.S. Centers for Disease Control and Prevention (CDC) and file a report on each individual transaction. But the regulations contained a major loophole: laboratories that possessed or worked with listed pathogens or toxins but did not transfer or receive them were not required to register. In the aftermath of the 2001 anthrax letter attacks, the Senate Judiciary Committee held hearings at which FBI officials testified that because of the regulatory loophole, the U.S. government did not have a comprehensive list of facilities or scientists in the United States that possessed or worked with anthrax.

In an effort to close this loophole, Congress included two provisions on select agents in an anti-terrorism bill (the so-called USA PATRIOT Act) signed into law October 26, 2001. Section 817 makes it a crime to knowingly possess any biological agent, toxin, or delivery system that cannot be "reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." In addition, Section 175b specifies several categories of "restricted persons" who are prohibited from shipping, receiving, transporting, or possessing select agents. One

such category covers nonresident aliens from countries on the State Department's list of states that support international terrorism. (The list, which is subject to change, includes Cuba, Iran, Libya, North Korea, Sudan, and Syria.)

On June 12, 2002, President George W. Bush signed a second piece of legislation called the Public Health Security and Bioterrorism Preparedness and Response Act. Title II of this act, "Enhanced Controls for Dangerous Biological Agents and Toxins," requires all entities in the United States that possess, use, or transfer one or more of the 39 pathogens and toxins on the Select Agents List to register with the CDC and implement safety and security measures. In addition, all scientists seeking to work with select agents must undergo an FBI background check. The Bioterrorism Preparedness Act also grants authority to the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) to develop a separate list of pathogens and toxins that pose a severe threat to animal health or to animal or plant products. The CDC and APHIS coordinate in regulating 16 so-called overlap agents that appear on both the human and animal lists. An estimated 1,469 facilities in the United States that possess, work with, or transfer listed agents are covered by the new rules; clinical laboratories are exempt unless they retain samples of pathogens for long periods. Laboratory security plans must be prepared by June 12, 2003, and each registered entity must be in full compliance with the new regulations by November 12, 2003.

The main objective of the biosecurity regulations is to track "who, what, and where"—who has access to listed pathogens and toxins, what agents have been accessed, and where in a facility they are in use. Because of the wide variety of facilities working with listed agents, the guidelines are not highly prescriptive. Instead, each institution is required to conduct threat and vulnerability assessments and develop a comprehensive plan to ensure the security of areas containing listed pathogens and toxins. Once the security plan has been developed, it must be submitted to the CDC or APHIS, performance tested, and updated periodically. Officials from the two federal agencies may also conduct unannounced inspections of declared sites.

collections in the newly independent states of Russia, Kazakhstan, Uzbekistan, and Georgia at risk of theft or diversion by terrorists or criminals. In November 2002, authorities in Almaty, Kazakhstan, arrested a man who entered the Scientific Center for Quarantine and Zoonotic Diseases with the apparent intent of stealing samples of dangerous pathogens. Fortunately, the intruder was arrested before penetrating the second layer of physical security, which had only recently been upgraded with U.S. government assistance.⁷

Another former biowarfare program that poses a proliferation threat is that of South Africa. Known as "Project Coast," this program began in 1981 and focused on developing small-scale, custom-made weapons to terrorize and kill opponents of the apartheid regime. Project Coast scientists collected hundreds

of deadly strains, including the causative agents of anthrax, brucellosis, cholera, and plague. After the program was dismantled in 1993, former Project Coast scientists secretly retained samples of virulent strains to continue work on vaccines and antidotes with commercial potential. They also attempted to sell cultures of deadly pathogens, including genetically engineered varieties, to the United States and possibly to other countries.⁸

Although the World Federation for Culture Collections (WFCC) has urged its members to restrict the distribution of sensitive materials to third parties, the organization lacks the funding and authority needed to enforce compliance. Moreover, more than two-thirds of culture collections worldwide do not belong to the federation.⁹ Even if the WFCC recommenda-

tion could be enforced, it does nothing to set a minimum security standard and hence does not address the problem that weak regulations in some countries undercut more stringent efforts in others.

Since international terrorist organizations are likely to seek biowarfare materials from the most accessible source, international biosecurity standards would reduce the risk that terrorists could obtain dangerous pathogens from foreign laboratories and culture collections. Harmonized guidelines for transferring pathogens would also facilitate collaborative research and development on biodefense vaccines and drugs. Joint U.S.-Russian research projects on defenses against anthrax and smallpox, for example, have been hampered by incompatible national regulations on the export of dangerous pathogens.¹⁰

Developing a Biosecurity Regime

An effective biosecurity system requires the integration of technologies and procedures. The global guidelines should include, as a minimum, the registration and licensing of facilities that work with dangerous biological agents, based on an agreed list

of pathogens and toxins that can be readily updated; physical security and access controls at laboratories and culture collections that possess such agents; systems for the control and accounting of listed pathogens and toxins, both in storage and during experiments; background checks on laboratory personnel; and an emergency plan for responding to breaches in security. In view of the wide variety of facilities that work with hazardous biological materials, ranging from pharmaceutical companies to academic research labs, biosecurity measures cannot be developed on a “one size fits all” basis. According to a “white paper” by the American Biological Safety Association, guidelines for laboratory security should consist of functional requirements that the affected entities can implement in a tailored manner.¹¹

It is also important to balance the complexity and cost of biosecurity measures introduced at a facility against the threats posed by the pathogens and toxins that are actually held or used at the facility. To develop a tailored biosecurity plan, each entity that possesses or works with biohazardous materials

Table 2 Maximum-Containment (BSL-4) Laboratories Worldwide

Country	Name of Laboratory	Location
Australia	National High Security Quarantine Laboratory	Geelong
Australia	Victorian Infectious Disease Reference Laboratory	Melbourne
Belarus	Research Institute for Epidemiology and Microbiology	Minsk
Brazil	Universidade Estadual Paulista, Campus de Botucatu	Sao Paulo
Canada	Canadian Science Centre for Human and Animal Health	Winnipeg, Manitoba
France	Jean Merieux Laboratory	Lyons
Gabon	International Center for Medical Research	Franceville
Germany	Bernhard Nocht Institute for Tropical Medicine	Hamburg
Japan	National Institute of Infectious Diseases	Tokyo
Russia	Institute for Viral Preparations	Moscow
Russia	Vector Laboratory	Novosibirsk, Siberia
Spain	Center for Investigations of Animal Health	Madrid
South Africa	National Institute of Virology	Johannesburg
Sweden	Institute for Infectious Disease Control	Solna
United Kingdom	Centre for Applied Microbiology and Research	Porton Down
United Kingdom	Central Public Health Laboratory	London
United Kingdom	Chemical and Biological Defence Establishment	Porton Down
United Kingdom	National Institute for Biological Standards and Control	Potters Bar
United Kingdom	National Institute for Medical Research	London
United States	Centers for Disease Control and Prevention	Atlanta, GA
United States	Maximum Containment Lab, National Institutes of Health	Bethesda, MD
United States	U.S. Army Medical Research Institute of Infectious Diseases	Frederick, MD
United States	Southwest Foundation for Biomedical Research	San Antonio, TX
United States	University of Texas Medical Branch	Galveston, TX

Source: American Society for Microbiology

should conduct a threat assessment of what assets need to be protected and the most likely diversion scenarios. Having identified the greatest risks, the facility should then do a vulnerability assessment based on how and where the pathogens or toxins are employed in research protocols, the security conditions under which they are stored and used, and how they are moved within the facility or transferred to outside locations. Given the impossibility of protecting all assets against all conceivable threats, laboratories must prioritize risks. Cost is an obvious limiting factor in the choice of security measures, since small university laboratories cannot afford state-of-the-art systems such as biometric identifiers and computerized inventory systems.

Physical security poses the greatest challenge to academic institutions, which are the least familiar with it. Most commercial pharmaceutical firms have already implemented extensive site security measures to protect intellectual property and valuable business secrets. In general, the level of security should be commensurate with the level of risk, so that the most dangerous agents and strains—from the standpoint of public health impact and suitability for weaponization—are subjected to the highest levels of physical protection and access control. Nevertheless, biosecurity requirements do not always track directly with biosafety levels: some agents that require lower levels of biocontainment, such as toxins, might pose a significant bioterrorist threat.¹² Reynolds Salerno and his colleagues at Sandia National Laboratories have also identified a number of “secondary assets” at biological research facilities that warrant protection, including detailed information about regulatory compliance and biosecurity programs, personnel records, and computer databases.¹³

To augment physical security, facilities should establish procedures for the accountability of pathogens during their storage in a central repository and their utilization in laboratory experiments. Such procedures include conducting inventories and audits of sample collections, documenting the “chain of custody” of dangerous pathogens outside the access-controlled area, and verifying the destruction of working stocks at the end of an experiment. Any pathogen accountability system is unfortunately not foolproof; because microorganisms reproduce, a scientist who has access to a pathogen could covertly remove a small amount (taking steps to ensure that the organism remained alive and viable under the transport conditions) and later mass-produce it.

Academic and industrial facilities working with dangerous pathogens should train scientists and technicians in appropriate laboratory practice, including elements of both biosafety and biosecurity. Because scientists are not security experts, however, each facility that houses dangerous pathogens should employ a security professional to assess threats and vulnerabilities and develop a tailored biosecurity plan. Should a theft or diversion be detected, the incident must be reported promptly to the responsible government agency.

Given the inherent limitations on the ability of physical security and inventory control measures to prevent insider diversion or theft, any biosecurity system ultimately depends on the personal integrity and reliability of the laboratory staff. Background investigations are a critical element of any biosecurity program, including verifying an individual’s references and checking government or Interpol databases for a criminal history or links to terrorist organizations. Because reliability problems might not emerge until long after an individual has been hired, staff members who work with dangerous pathogens should be subjected to periodic reinvestigation, particularly before they are granted unescorted access to secure areas.

The final element of a biosecurity plan involves controls on transfers of dangerous pathogens, both domestic and international. Each country that ships listed pathogens and toxins across national borders should establish regulations for the safe and secure transportation of hazardous goods, controls on imports and exports, and verification of the declared end-use. A national export-control body should be established to enforce these regulations if one does not already exist. In addition to complying with permit and licensing requirements at the local, state, and federal levels, suppliers of biological pathogens should keep detailed records of each transaction, including strain and batch numbers, method and date of shipment, and name and address of each recipient. Suppliers should also establish reliable mechanisms to verify that recipients of pathogens and toxins have a legitimate need for the requested materials and that all necessary safety and security policies are in place.

Negotiation and Oversight

In preparation for the upcoming August meeting of the BWC experts group in Geneva, the U.S. government has circulated four short papers, two describing U.S. domestic legislation on penal legislation and biosecurity and two outlining how the BWC states-parties might proceed in these areas. The U.S. position on biosecurity is that the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE) are the expert bodies most capable of formulating guidelines for national legislation. Accordingly, Washington has asked the WHO to take the lead in this effort by working with the FAO and the OIE to prepare a report for the experts group.

Since the experts will have only one week in which to discuss biosecurity issues, it is likely that a follow-on negotiation among BWC member states will be required to develop an appropriately detailed set of technical guidelines for the protection, control, and accounting of dangerous pathogens. Recently, a few international organizations have launched initiatives in the biosecurity field. (See box on next page.) Drawing on the best practices identified by these efforts, BWC member states should establish a technical experts group that

International Biosecurity Initiatives

Organization for Economic Cooperation and Development

The Organization for Economic Cooperation and Development (OECD), a group of 30 advanced industrial countries headquartered in Paris, has undertaken the most ambitious international effort to date to regulate dangerous pathogens. The OECD has long been interested in "biological resource centers" (BRCs), defined as government, industry, or academic facilities that house, control, test, or use biological materials. BRCs are a key element of the research infrastructure for the life sciences and the biotechnology industry, but many valuable culture collections are disappearing as governments withdraw financial support. In response to this problem, the OECD is organizing a global network of BRCs that will function as a "virtual lending library" to permit the free exchange of microbial cultures among its members.

In mid-2001, the OECD established a Task Force on BRCs to begin negotiations on the global network. In addition to the 30 members of the OECD, several non-member countries were invited to participate as nonvoting observers. Establishing the BRC network requires the harmonization of national rules for accreditation, quality control standards for the composition and purity of cultures, and funding arrangements. After the terrorist attacks of September and October 2001, the United States asked that the mandate of the BRC Task Force be expanded to include biosecurity measures.

The current plan is for the OECD Task Force to negotiate a set of regulatory guidelines for the BRC network, which will be presented for approval at a meeting of science ministers from the participating countries, scheduled for January 2004. Given the tight deadline, the task force is unlikely to develop detailed technical security standards but instead broad guidelines, and the final rules will not be legally binding. Nevertheless, because the free exchange of pathogens among facilities within the BRC network will be possible only if all the participating facilities are secure, countries that do not meet the agreed minimum standards of quality, safety, and security will be excluded from the network. To certify and enforce the standards on a national basis, each participating government must select an accrediting agency, which will conduct periodic checks of biosafety and biosecurity measures at the participating BRCs.

Although negotiation of the BRC network currently involves the 30 OECD member states plus roughly a dozen observers, member countries are conducting regional consultations with other states, with a view to creating a global network of BRCs. Eventually, the network might be spun off from the OECD and a small, stand-alone international secretariat established to serve as gatekeeper.

Group of Seven Plus Mexico

In response to the events of the fall of 2001, health ministers from the G-7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States) plus Mexico met in Ottawa, Canada, November 7, 2001, to forge a new partnership called the Global Health Security Initiative. Among the stated goals of this partnership is "to improve linkages among laboratories, including level four [Biosafety Level-4] laboratories, in those countries which

have them." Directors of maximum-containment laboratories from participating countries met in Lyons, France, March 12, 2002, to discuss the establishment of a Level 4 Laboratory Network that will develop standard protocols for the transfer of pathogens among BSL-4 facilities.

Australia Group

The United States and 32 other like-minded countries "harmonize" their national export controls on dual-use materials and equipment that could be involved in the production of chemical and biological weapons through an informal coordinating mechanism known as the Australia Group. This body was established in 1985 in response to the widespread use of chemical weapons by Iraq during the Iran-Iraq war. The Australia Group initially developed a "control list" of chemical weapons precursors that were to be denied to countries assessed to be seeking a chemical warfare capability. In 1990, in response to growing concern over the proliferation of biological weapons, the Australia Group added measures to tighten export controls on dangerous pathogens and dual-use biotechnology equipment.

Although the primary aim of the Australia Group has been to impede state-level proliferation, in June 2002 the group placed greater emphasis on bioterrorism by adding eight toxins of possible terrorist interest to its biological control list. One drawback of the Australia Group is that its membership does not include a number of important countries, such as China, Russia, India, Pakistan, and Iran. Several developing countries also oppose the group's existence on political grounds, claiming that it is discriminatory and unfairly impedes the economic development of targeted states.

Other International Organizations

The Organization for Security and Co-operation in Europe (OSCE) supports proposed standards for licensing and enforcement procedures related to dangerous pathogens and dual-use biotechnology equipment. The World Customs Organization has started sharing information with Interpol and the World Health Organization to combat the smuggling of biological, chemical, and radioactive materials. The International Maritime Organization plans to negotiate an agreement to halt the shipping of biological agents for hostile purposes.

Biotechnology and Pharmaceutical Industry

Although most work with dangerous pathogens takes place in university and government laboratories, elements of the biotechnology and pharmaceutical industries have begun to address biosecurity issues. In 2002 the Swiss pharmaceutical trade association Interpharma developed a draft code of conduct titled "Biosafety and Biosecurity—Industry Best Practices to Prevent Use of Biohazardous Material." It calls on companies to establish internal regulations and procedures for handling dangerous pathogens, including detailed inventories of materials stored and transferred, transparency in the acquisition of pathogens and toxins from commercial sources and scientific collaborators, security measures to prevent access by unauthorized individuals, safe transport of biohazardous materials, and treatment of wastes to avoid discharging infectious agents into the environment.

—Jonathan B. Tucker

would meet on a regular basis to negotiate a set of detailed functional standards that can be implemented through national laws and regulations.

Biosecurity standards would be promulgated and enforced on a national level by existing or newly established governmental entities. To ensure a degree of uniformity and accountability in national implementation, however, it might be necessary to create an international oversight mechanism. One model is provided by the Nuclear Safety Convention, which was adopted in Vienna on June 17, 1994, to establish basic safety guidelines for the location, design, construction, and operation of civilian nuclear power plants.¹⁴ The Nuclear Safety Convention is an “incentive instrument” in that it does not enforce compliance through formal verification measures but rather through the common interest of the parties in achieving higher levels of nuclear safety. Member states are expected to submit periodic reports on the steps they are taking to implement the agreed guidelines. At regularly scheduled review meetings, each participating country has an opportunity to discuss its own actions and to seek clarification of the reports submitted by others. Political pressure and the need for governments to appear responsible create incentives to join the regime and to comply with the agreed standards.

In much the same way, BWC member states that have voluntarily accepted international standards for the protection, control, and accounting of dangerous pathogens could agree to participate in annual review meetings, which might be organized by a small international secretariat staff. At these meetings, countries would report on the implementation of their national biosecurity regulations and answer questions from other delegations. States that failed to implement or adequately enforce the agreed measures could be subjected to probing questions and political pressure. Participating countries could also exchange information to facilitate implementation of the biosecurity standards. For example, if one country refused to grant a scientist access to select agents because of suspected links to a terrorist organization, the intelligence supporting this decision could be shared with other countries so that they could avoid undercutting one another.

Recommendations

Efforts by BWC member states to develop and implement global biosecurity standards will involve a number of policy choices to ensure that the resulting guidelines are workable and cost effective. Key issues to be addressed include the following:

Focus on strengthening the weakest links.

Highly demanding and expensive standards for laboratory security will be counterproductive if developing countries are technically and financially unable to implement them. Instead, the primary aim of global biosecurity standards should be to strengthen the “weakest links”—those states whose research

laboratories and culture collections are so poorly secured that terrorists could penetrate them easily. A realistic goal would be to negotiate a set of minimum performance benchmarks that can be met through a variety of different means, either labor intensive (such as armed guards) or capital intensive (such as electronic surveillance technologies).

Engage the international scientific community.

The ultimate success of global biosecurity standards will depend on “buy-in” and voluntary cooperation from microbiologists and laboratory administrators around the world. For this reason, the regulatory guidelines should not be imposed from the top down but rather developed cooperatively from the bottom up with the active participation of leading scientific organizations, such as the International Union of Microbiological Societies.

Balance flexibility and uniformity.

Global biosecurity standards should be flexible enough to be tailored to individual research facilities, yet specific enough to ensure a reasonable degree of consistency and uniformity in their implementation. Overly rigid standards could force universities and other research centers to purchase costly security equipment that is unnecessary or inappropriate to their needs, but standards that are too vague would enable institutions to evade their basic obligations, creating areas of lax implementation that could be exploited by terrorists. Another problem is that regulations tend to be fixed and static, whereas biological science and technology are in constant flux. Thus, a workable system of biosecurity standards must contain a mechanism for periodic review so that the list of regulated agents and the functional guidelines could be revised and updated in response to ongoing advances in scientific knowledge and security measures.

Encourage compliance by using “carrots” rather than “sticks.”

The best way to promote international compliance with biosecurity standards is through positive incentives rather than punishments. Creating mechanisms to “incentivize” compliance is generally easier and cheaper than attempting to establish an international policing mechanism. One precedent is the Organization for Economic Cooperation and Development (OECD), which is developing voluntary security guidelines that must be adopted by all states seeking to participate in a planned global network of biological resource centers. The OECD network will effectively create an exclusive “club” whose benefits can be accessed only by meeting the requirements for membership. This arrangement will provide a strong incentive for countries to comply with the agreed biosecurity rules. Similarly, the WHO and other international scientific bodies might make compliance with global biosecurity standards a prerequisite for research grants involving work on dangerous pathogens.

Avoid creating perverse incentives.

Experts developing global biosecurity standards should try to anticipate their downstream consequences, both positive and negative. Since many scientists have a deep aversion to paperwork, regulations that are too burdensome and costly to implement might simply drive microbiologists and laboratory administrators to circumvent the rules by engaging in informal transfers of pathogens that are not reported to government authorities. It is also essential that biosecurity standards not be so onerous that they deter academic and industrial scientists from pursuing legitimate biomedical or biodefense research on dangerous pathogens or drive research institutions to destroy valuable culture collections in the hope of avoiding regulatory burdens or legal liability. To prevent such negative outcomes, biosecurity procedures should be designed to minimize paperwork and ease compliance.

Integrate national biosecurity regulations with international arms control objectives.

Ensuring that pathogens are used only for peaceful purposes would help strengthen the legal and ethical norms enshrined in the BWC against the development, production, and stockpiling of biological weapons. At the same time, biosecurity standards, which focus primarily on the threat of bioterrorism, should be linked to efforts to bolster state-level compliance with the convention. For example, biosecurity measures should be designed so that they do not adversely affect the perception of national biodefense programs, which are permitted under the BWC. The line between defensive and offensive work on biological weapons is unavoidably blurry because researchers must use dangerous pathogens to assess threats and to test the effectiveness of defensive systems, such as detectors and protective equipment. Given this inherent ambiguity, excessive security at biodefense laboratories could arouse suspicion that supposedly defensive research activities are being used as a cover for the development of new biological weapons. For this reason, it is essential that countries not invest in biosecurity technologies or procedures that unduly reduce the transparency of biodefense research. At the same time, states should not be forced to reveal critical vulnerabilities that could render the defenses ineffective.

In conclusion, the negotiation of global biosecurity standards would represent a departure from arms control as it has been traditionally practiced. Rather than creating a legally binding treaty that is subject to intrusive verification by an international inspectorate, as in the case of the Chemical Weapons Convention, the biosecurity regime would consist of a set of agreed guidelines implemented through national legislation. To ensure a reasonable degree of uniformity and accountability in implementation, a small international secretariat might be established to provide oversight and to organize annual review meetings. Further, instead of focusing on state-level proliferation of biological weapons, global biosecurity standards would reduce the risk of theft or diversion of dangerous pathogens by terrorists and criminals—a problem that

the BWC does not explicitly address. Although biosecurity standards would not directly strengthen state-level compliance with the treaty, they would reinforce the basic norms enshrined within it. **ACT**

ENDNOTES

1. For useful comments on an earlier version of this paper, I am indebted to Gerald L. Epstein of the Defense Threat Reduction Agency, Reynolds M. Salerno and colleagues at Sandia National Laboratories, Janet Shoemaker of the American Society for Microbiology, Frank P. Simione of American Type Culture Collection, and Gregory J. Stewart of the U.S. Department of State.
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Will the New Biology Lead to New Weapons?

Biology is in the midst of what can only be described as a revolution. It began in the mid-1970s with the development of recombinant DNA technology. Slowly at first but with increasing speed, related technologies have been developed that have dramatically expanded the experimental capabilities of modern research biologists and that are rapidly being adopted in such areas of applied biology as drug development. These new technologies include genomics, proteomics, microarray technology, high-throughput screening techniques, combinatorial methods in both chemistry and biology, site-specific mutagenesis, knock-out mice, and many others.¹ Collectively, these technologies are referred to as genomic sciences, or the “new biology.”

This technology will have great power both for peaceful and hostile uses. Peaceful applications will include a wide range of new therapeutic agents of much greater specificity and safety than are currently available; hostile applications could include a wide range of new biochemical weapons that could transform the nature of combat in unprecedented ways.

Yet, policymakers have paid little attention to the new biology and its potential hostile applications, even though human physiology might be altered in ways that will raise a broad range of ethical, legal, political, and military issues. Policymakers need to consider these issues now before undesirable applications develop a momentum that will narrow the options for control.

The New Biology

Until recently, attempts to manipulate natural processes were largely unsuccessful as scientists were stumped by the fiendish complexity of physiological systems. The newly detailed understanding of the physiology of living organisms, however, is paving the way for breakthroughs in biology and biotechnology. By any measure—number of professional scientists, number of publications, new journals, funding level, etc.—the growth of this field is extremely rapid, with no sign of leveling off.

There has been a related growth in relevant computer and instrumentation technologies. For example, an

entirely new discipline, bioinformatics, has evolved to manage the collection and analysis of massive amounts of new data. Likewise, a major instrumentation industry has developed to provide the sophisticated technology on which the new biology depends. Instrumentation technology has matured quickly: slow, crude prototypes requiring skilled operators have given way to highly sophisticated equipment that can be operated with minimal technical expertise. Additionally, experiments that needed milliliters or milligrams of material a few years ago now require only microliters or micrograms.

The result has been the swift production of new knowledge. This knowledge and related technologies have spread quickly around the globe as these commercially-available tools have become easier to use, more reliable, and increasingly affordable to individual laboratories.

Soon, scientists around the world will be able to tailor pharmaceutical agents to enhance or block specific physiological pathways. This will be a great boon for medicine but will also allow the development of a wide range of novel biochemical agents for hostile purposes.

Two aspects of the new biology have particular potential for military application: our new understanding of the nervous system and our greater comprehension of the mechanisms by which disease-causing microbes interact with humans, animals, and plants.

Manipulating the Nervous System— for Good and Ill

The nervous system is of great interest to biologists, for intrinsic reasons and because there is a huge economic market for the development of new pharmaceutical compounds for the treatment of mental illness, pain, and other medically important nervous system disorders. As we come to understand the detailed mechanisms that underlie such phenomena as pain, depression, panic attacks, post-traumatic stress, anxiety disorder, schizophrenia, and sleep disorders, we will be able to design new medications that will offer much greater effectiveness and specificity than current ones and that will have greatly reduced side effects. A combination of humanitarian and economic incentives ensures that progress will be very rapid.

Of course, the capabilities that emerge, like all advanced technologies, will be capable of hostile as well as peaceful exploitation.² Hostile applications include the manipulation of humans to increase their effectiveness as soldiers; the creation of novel weapons for combat use, including a range of non-lethal, incapacitating biochemicals; and new agents for interrogation.

Designer Soldiers

For at least half a century, militaries have used amphetamines as stimulants for pilots or soldiers on long missions. In the future, we can anticipate that at least some countries would use forced medication to produce troops who are not only alert and energetic for days at a time, but who have heightened sensory awareness, enhanced aggressiveness, decreased fear, decreased sensitivity to pain, and a dulled moral sense. The beginnings of the understanding of the chemical bases of all of these attributes is already emerging, and to anticipate the development of drugs that can provide such capabilities is not much of an extrapolation. Further into the future, it might be possible to make soldiers stronger and quicker than normal; the “superhuman” strength conferred by some street drugs is a common experience among law enforcement personnel and suggests that a biochemical basis for enhancement of physical capabilities might emerge. Selective memory erasure may also be possible, once we understand the molecular basis of repression. Briefing and debriefing sensitive missions could include erasure of selected memories.

Designer Biochemical Weapons

The new knowledge about the nervous system will also make new biochemical weapons possible. It is worth remembering that the most potent, existing chemical weapons—the nerve agents—are analogs of acetylcholine, a neurotransmitter used in a number of different neural and neuromuscular circuits. As we learn the details of neural circuitry, there is every reason to believe that even more toxic agents will become available. Of even greater significance, it will likely be possible to develop a completely new range of disabling biochemical weapons.

Biochemicals for Interrogation

New pharmaceuticals could also be of great interest to interrogators who are willing to ignore legal restrictions on interrogation methods. Although a genuine “truth serum” may not be possible, many pharmaceuticals would substantially reduce the ability of a captive to resist providing information. Chemical agents that cause submissiveness and eagerness to please are on the horizon and would be effective on many captives. Pharmaceutical forms of torture could also be highly effective in reducing the ability of captives to retain secrets—techniques in which depression, delirium, panic, and submissiveness are manipulated and perhaps alternated with euphoria and pleasure— would likely prove irresistible.

New Vaccines or New and Deadly Viruses and Bacteria

The mechanisms by which pathogenic (disease-causing) bacteria or viruses cause disease are complex. Yet, very rapid progress is being made in understanding these processes, known as pathogenesis, promising greatly enhanced public health and agricultural benefits.

The tools are rapidly becoming available that will produce improved vaccines (more efficient, longer lasting, and safer), produce new antibiotics and antivirals, enhance defenses against diseases, and protect against damage from overreaction of defensive systems. The same benefits may be realized in veterinary medicine, and better understanding of plant diseases can be expected to provide increased yields and improve nutritional quality.

However, as with our greater understanding of the nervous system, greater understanding of pathogenesis also opens the door to potential military applications. Within the next decade, some possible military uses include:

- genetically engineered pathogens that evade diagnosis and treatment
- pathogens that are exceptionally lethal
- pathogens intended to disable permanently
- pathogens with enhanced contagiousness
- pathogens with enhanced environmental stability

Evading Diagnosis and Treatment

The first of these is not new. The ability to create antibiotic-resistant pathogens has existed for decades, and the idea of using mutant forms of a virus or bacterium to confuse diagnosis is also not new. The new technologies, however, make the construction of such altered pathogens easier and faster and provide a range of new options. Until now, the development of such pathogens has been limited by the interconnectedness of virulence with other traits, such that, if scientists changed one property in a pathogen, such as surface proteins to defeat vaccines or diagnostics, they would commonly reduce virulence. Soon, their new understanding will allow them to manipulate agent properties while avoiding such undesirable secondary effects.

Increasing Lethality or Causing Disability

In nature, the virulence of pathogens is the result of a complex selective process that often limits virulence in favor of transmissibility: a pathogen that kills its host so quickly that it has little chance to transfer to a new host will quickly die out.³ Microbes perpetuated in the laboratory, however, are free of such selection, and thus genetically engineered organisms might reach a level of lethality that is exceptionally high and rapid compared to existing pathogens. This is not speculation; it has already been achieved inadvertently: a benign mousepox virus with very low lethality became highly lethal when a mouse gene related to the immune system was incorporated into its DNA. The development of such potentially highly lethal bioweapons agents poses a significant risk of a renewed biological arms race and also raises serious biosafety concerns, as an accident in a military laboratory could lead to the inadvertent release of extraordinarily dangerous pathogens.

Researchers will not be limited to transforming benign viruses into lethal agents. Perhaps more disturbing, they could also engineer viruses to produce pharmaceutically active compounds, causing a wide range of disabling effects, from mild disorientation to severe psychosis. Such viruses could be contagious and could persist for years in the body (like herpes viruses and retroviruses), causing permanent, contagious, mental or physical disability.

Making Diseases Spread Faster and Live Longer

Currently, many pathogens only have a limited capacity to spread from host to host. That could change with the new technology. It should thus be possible, at least for some pathogens, to create variants with increased (or decreased) contagiousness. Of course, this property could be combined with increased lethality. For instance, the monkeypox virus could be engineered to be contagious among humans and also feature increased lethality, creating a fearsome weapon, perhaps worse than smallpox.

One of the obstacles to transforming naturally occurring microbes into military weapons has always been the limited persistence of many when released, a persistence that was sometimes measured in minutes. Plague, for instance, has a fearsome lethality in the pneumonic form but is transmissible only over very short distances (a few feet), in part because it is short lived in aerosol form. For this reason, it was not successfully weaponized by the United States during its offensive biological weapons program, although the Soviet Union was able to do so. Better understanding of the reasons that some bacteria persist for long periods while others do not will very likely allow the modification of pathogens to persist longer and thus become candidates for weaponization.

The Danger of “Nonlethal” Weapons

When Russian forces used a derivative of the anesthetic fentanyl to knock out 50 Chechen hostage-takers in a Moscow theater in October 2002, they provided a glimpse of what may happen with the development of a new class of “nonlethal” pharmaceutical weapons. These calmatives, or “knockout gases,” are intended to cause rapid sedation or unconsciousness and are viewed by many militaries as a less-than-lethal means to limit civilian casualties. The Moscow incident, however, also showed the downside of these new pharmacological weapons and the need for countries to pause and reflect before racing to embrace this new technology.

In the Moscow confrontation, the hostage-takers were holding 800-900 hostages and were threatening to blow them up if their demands for a Russian withdrawal from Chechnya were not met. After a standoff of several tense days, Russian authorities tunneled into the basement and fed the fentanyl derivative into air conditioning ducts. The male hostage-takers, armed with automatic weapons, immediately left the theater for surrounding hallways in order to defend against the impending attack. The female hostage-takers were left inside and were soon overcome by the anesthetic, still holding the bombs they had threatened to detonate to kill the hostages.

Half an hour later, Russian special forces stormed the theater, killing the male Chechens in a firefight and executing the comatose female ones. The unconscious hostages were removed from the theater

and taken to local hospitals. Unfortunately, nearly 130 died of overdoses, and an undisclosed number were left with permanent disabilities.

Whether it was necessary for the Russian military to use fentanyl remains unclear. The hostage-takers had sufficient time to detonate their bombs before the anesthetic took effect, but for some reason did not.

Still, this event is seen by advocates of such weapons as a model. They regret the loss of more than a hundred innocent hostages, but they point to the saving of more than 600. Additionally, they look to advances in pharmaceutical sciences to provide safer agents that might truly deserve the term “nonlethal.”

On the other hand, opponents of these weapons say that the theater episode points to a number of disturbing implications of these weapons.¹

The first is safety. It may indeed be possible to develop an anesthetic agent that would technically be as safe as tear gas (which does cause occasional deaths).² Yet, when used under realistic conditions, such an anesthetic weapon would likely cause significantly more fatalities because there is always a risk of death from airway obstruction or of accident when people are rapidly made unconscious without medical supervision.

Second, critics point to the erosion of the Chemical Weapons Convention. That pact prohibits the development, production, stockpiling, and use of all chemical weapons, defined as weapons that depend on direct chemical toxicity for their

Long-Term Dangers

In the longer term—20 years or more—we can expect not only the further development of the aforementioned technologies, but additional technologies as well. Likely capabilities will include:

- synthetic viruses and prions
- synthetic cellular pathogens of exceptional virulence
- synthetic, nonreplicating cell-like entities as vectors for biochemical agents
- stealth pathogens
- genotype-specific pathogens of crop plants and domestic animals
- ethnic-specific human pathogens
- pathogens that cause ethnic-specific autoimmune diseases with effects such as sterility

Synthetic Life

One of the most dramatic developments of the new biology is the impending capability to create synthetic living systems—living in terms of being able to replicate themselves using known life processes involving nucleic acids and proteins. Synthetic replicas of existing viruses

effects. This ban explicitly applies to nonlethal as well as lethal chemicals. It has a significant loophole, however: it permits the use of these weapons for law enforcement. For this reason, most analysts consider the Russian use of a fentanyl derivative to have been legal. Yet, it would be clearly illegal for such an agent to have been developed, produced, stockpiled, or used for military combat. The fact that the Russian special forces appear to have had a stockpile of this agent suggests a military as well as law enforcement interest. It is also clear that the U.S. military has been interested in calmatives for some time.³ Whether the United States has gone beyond permitted research into prohibited development remains an open question. Unfortunately, recent U.S. work appears to be classified, and it is not possible to determine how far the U.S. military has progressed.

Military interest in such knockout gases is understandable in a time in which military forces are commonly deployed for nontraditional roles, such as peacekeeping, counterterrorism, and others in which combatants and noncombatants are intermixed and in which minimizing civilian casualties is politically important. An unfortunate side effect may be the development of considerable pressure to relax the ban on chemical weapons, which is rightly seen as an important milestone in arms control. Because calmatives in combat will inevitably cause casualties, it may be very difficult to maintain a distinction between them and traditional lethal chemical weapons when the ranges of lethality overlap. For instance, mustard gas, the most heavily used and most ef-

fective chemical weapon in World War I, was lethal only in a few percent of casualties. It will not be long before completely novel synthetic viruses are produced. The capability to produce effective, synthetic, new viral pathogens will surely follow. Such agents could have significant utility in biocontrol of pests such as weeds, rodents, or insects, so their development is likely to be pursued vigorously. Yet, the lessons could easily be transferable to the construction of weapons. Synthetic viruses could be designed to be contagious or noncontagious, lethal or disabling, acute or persistent, and so on; and they could be invisible to the immune system and resistant to existing forms of anti-viral therapy. They would be very hard to diagnose on first use. Similarly, as understanding deepens of the biology of self-perpetuating prions, which are infectious protein agents, it will be possible to develop novel, synthetic forms of these agents.

Living synthetic cells will likely be made in the next decade; synthetic pathogens more effective than wild or genetically engineered natural pathogens will be possible sometime thereafter. Like synthetic viruses, such synthetic cellular pathogens could be designed to be contagious or noncontagious, lethal or disabling, acute or persistent, etc. They could lack the usual targets of antibiotic therapy, be invisible to the immune system, and be very hard to diagnose on first use.

fective chemical weapon in World War I, was lethal only in a few percent of casualties.

It will also be impossible to confine pharmaceutical weapons to responsible states that will use them with due respect for human rights and humanitarian law. Despotism, terrorists, and criminals will be sure to find unpleasant uses for nonlethal chemical weapons, perhaps more so than responsible states: They will be less constrained to use them in a way that would minimize fatalities or respect human rights. This is especially likely because it is so easy for a prepared terrorist, soldier, or criminal (with gas masks or with chemical antidotes) to defend against the effect of such weapons while it is virtually impossible for an unsuspecting civilian population to do so.

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It will also be possible to create novel, cell-like entities that could be used to target biochemical agents to specific tissues. They would have great utility in medicine by allowing pharmaceuticals to be targeted to specific tissues, but they would have equal potential for facilitating the delivery of weapons agents.

Stealth Pathogens

It might also be possible to engineer stealth pathogens, the microbial equivalent of sleeper cells. These would be pathogens, either natural or syn-

thetic, that are engineered to become latent after a period of mild or asymptomatic replication, to be reactivated later for symptomatic replication in response to a particular stimulus. Such a pathogen would spread unnoticed through a susceptible population, and all those infected could at a later time be induced to display symptoms in response to, for instance, an otherwise benign chemical compound added to such things as water supplies and imported food materials. The resulting symptoms could be lethal or disabling.

Inside the New Biology: Cellular Communication

The new biology has resulted in an increasingly detailed understanding of how the billions of cells within the human body communicate and coordinate their functioning, using chemical messenger molecules known as bioregulators.

Neurotransmitters, for example, are bioregulators that mediate communication within the nervous system. These free-floating molecules are released from the terminus of a nerve cell, or neuron, and diffuse across tiny gaps between neurons called synapses. They then bind in a lock-and-key fashion to large globular proteins called receptors, which are embedded in the outer membrane of the target cell. Examples of neurotransmitters are small molecules such as acetylcholine and serotonin and short protein chains such as endorphins.

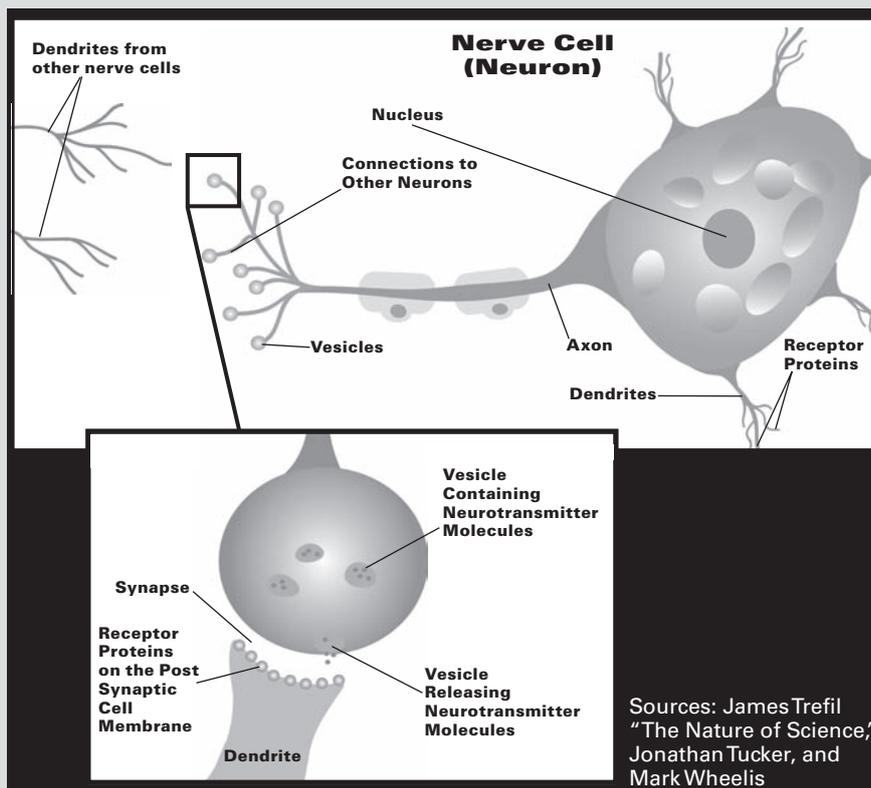
Hormones are a different type of bioregulator. They are produced at one site in the body and act at another. For instance, a hormone released in the brain causes the pancreas to release insulin (another hormone), which in turn regulates sugar metabolism in the liver and other tissues.

Regarding both hormones and neurotransmitters, when a bioregulator binds to its corresponding receptor protein, the protein changes its shape, triggering a sequence of biochemical events that results in a physiological response of some kind within the target cell (see inset). For example, the bioregulator-receptor interaction may result in the excitation or inhibition of a receiving neuron, the contraction of a muscle cell, or the release of a hormone from an endocrine cell.

Each cell has many different types of receptor proteins embedded in its outer membrane, each corresponding to a different bioregulator. Some of the receptors are common to most cells, but others are specific to the particular tissue or organ in which the cell is located and even to a group of cells within a specific tissue. In recent years, scientists have gained a much better un-

derstanding of the wide variety of receptor proteins in the human body and their role in intercellular communication. Approximately one-third of the 30,000 to 50,000 genes in the human genome (total complement of DNA) are believed to code for receptors, indicating the great importance of this class of proteins. The tools of the new biology allow scientists to identify this genetic sequence for receptor proteins and determine their three-dimensional structure, as well as the structure of their binding sites.

Most therapeutic drugs work by mimicking or blocking the action of natural bioregulators at their specific receptor sites in the body. For example, anesthetics, analgesics, tranquilizers, stimulants, and anti-depressants all have molecular structures closely related to those of natural neurotransmitters. In addition to beneficial applications of such drugs for the treatment of physical and mental illnesses, however, the growing understanding of bioregulators and their receptors brings with it the potential for misuse: the development of new bio-warfare agents that can kill or modify the function of the brain and nervous system to induce fear, sleep, pain, or passivity.



Sources: James Trefil
"The Nature of Science,"
Jonathan Tucker, and
Mark Wheelis

Ethnic Weapons

There has been much talk of ethnic-specific or genotype-specific biological weapons, and they are likely to become technically feasible. Their development will be easiest for agricultural targets because cultivated plants and domestic animals tend to have very little genetic variability. Such genotype-specific weapons could, for instance, specifically target a cultivar of corn widely planted in the United States but not in other countries. The rapidly increasing use of genetically engineered crop plants in the developed world provides genetic targets for such designed pathogens, or natural genetic sequences unique to specific types of crops or breeds of animal could be targeted.

Engineering an ethnic-specific weapon targeting humans is much more difficult, as human genetic variability is very high both within and between ethnic groups. Nevertheless, it is possible to find combinations of traits, no one of which alone correlates highly with ethnicity, that together do. Using such combinations as a basis for pathogen specificity makes for a formidable problem in genetic engineering, but there is no reason to believe that it will not eventually be possible. If so, pathogens could be designed that are essentially restricted to one race or ethnic group; however, they would only infect a limited proportion of that group (perhaps on the order of 10 percent or so of the targeted group).

If such weapons are ever contemplated, it is likely that the sought-after effects would include sterility, mental illness, or other disabilities that are not obviously the result of biological attack. Mental illness could be produced by designing the pathogen to produce bioregulators, as described above. Sterility could be induced by causing autoimmune reactions to sperm or egg proteins, an approach that is already being actively pursued for biocontrol of pest animals. Such infectious sterility, if coupled with ethnic-specific targeting, could go undetected for a long time, as fertility rates in the target group gradually fall.

As a final long-term prospect, the likely merger of the new biology with nanotechnology, artificial intelligence, and microrobotics will lead to a hybrid technology of enormous power, for good and ill.

Policy Responses to the Prospects of the New Biology

The preceding analysis has outlined some possible hostile applications of the revolution in the biological sciences. It is far from exhaustive; many other applications can be imagined, and others that we cannot yet imagine may soon emerge. These are all logical applications of knowledge that will be acquired as the inevitable result of peaceful medical, veterinary, and agricultural efforts. There is no way to avoid the knowledge that will make new hostile applications possible while still enjoying the benefits of the peaceful applications. Thus, if we wish to enjoy the benefits and avoid the perils offered by new biological knowledge, we need a coherent policy to control the applications.

Clearly it will be desirable to prevent many, perhaps all, of the hostile applications of the new biology. Even a country such as the United States, whose technological capabilities will likely keep it in the lead in the development of such new weapons, would eventually conclude that these weapons reduce, rather than enhance, its security. Without effective restrictions on development and proliferation, terrorists and states that do not respect international humanitarian laws will gain access to this technology, constituting a serious threat to more scrupulous states.

Many of the international legal tools to prevent the development of these weapons are already in place, notably the Biological Weapons Convention (BWC) and the Chemical Weapons Convention (CWC), which together ban military use of all of the weapons imagined here. Nevertheless, these may prove insufficient to prevent proliferation, and we should not shy away from new international treaties as necessary. Foremost among the new treaties that should be considered, or reconsidered, are those that would:

- add a compliance regime to the 1972 BWC;
- make development, possession, or use of chemical or biological weapons a crime over which nations may claim universal jurisdiction (like piracy, airline hijacking, and torture)⁴; and
- impose a single control regime over the possession and transfer of dangerous pathogens and toxins.⁵

Consideration should also be given to a new convention that would prohibit the nonconsensual manipulation of human physiology, to support and extend the provisions of the CWC, BWC, and international humanitarian law.

Even with sustained political commitment to ensuring compliance, treaties by themselves will be insufficient to prevent determined nations from secretly developing prohibited weapons. A variety of other means must supplement the international legal regime. Many of these are already in place, such as export controls. Others will be needed. Perhaps foremost would be a system of review and prior approval for potentially dangerous experiments, whose results might be readily applied to weapons development.⁶ Such a system would usefully begin as national programs in the United States and other countries with strong biomedical research communities. Ultimately, they would have to become international, or at least be widely implemented in a harmonized fashion, to truly address the problem. The United States has taken the first step by establishing the National Science Advisory Board for Biosecurity to advise federal agencies and departments that conduct and support research in biology and to develop guidelines for oversight of research. However, there is a long way to go, and substantial political commitment required, to transform these first steps into an effective system.

One of the most significant factors usually spurring interest in new weapons is the suspicion that other na-

tions may be developing them. The development and production of chemical and biological weapons has an increasingly small footprint and may become nearly invisible to national technical means of intelligence. It is thus increasingly difficult to have confidence in the compliance of many countries with the BWC and the CWC. This problem will worsen as the technology becomes more sophisticated; production facilities decentralized, miniaturized, and robotically controlled; and the potential weapons more potent. For this and other reasons, serious consideration should be given to making transparency in biodefense and chemical defense a central component of U.S. efforts in counterproliferation. This would allow the United States to take a leadership role in encouraging others to be transparent, to offer incentives to those that do, and to impose sanctions on those that do not. A world in which biology and chemistry are transparent to the maximum degree without betraying important vulnerabilities or clues to offensive technology is much more likely to deter proliferation of biological and chemical weapons and to allow detection of cheaters than one in which military biology and chemistry are shrouded in secrecy.

Making transparency a central pillar of biological weapons disarmament policy will clearly require a major transformation of current U.S. attitudes and policy. In reality, however, this would be less a radical departure and more of a return to a prior philosophy. After President Richard Nixon renounced offensive biological and toxin weapons programs in 1969 and 1970, the U.S. biodefense system was for 20 years nearly completely unclassified, with vulnerability assessments the only significant exception. There is no evidence that this openness caused adverse security consequences. However, the United States now has the world's most aggressive biodefense program and is moving rapidly in the direction of increased classification. For instance, the recently announced Biothreat Characterization Center at Fort Detrick, Maryland, part of the National Biodefense Analysis and Countermeasures Center of the Department of Homeland Security, is expected to engage in a wide range of exploratory activities, including developing new pathogens by genetic engineering; developing new methods of packaging and delivering agents; developing techniques for enhancing environmental stability of pathogens; and assessing the suitability of bioregulators as weapons. Although this research will be carried out in the interest of better understanding the hypothetical threat to the United States, it constitutes a de facto program for the development of a sophisticated offensive bioweapons capability. As such, it will by necessity be classified. Such activities are clearly incompatible with transparency, as well as quite provocative. An independent review is urgently needed to assess the relative benefits and disadvantages of transparency versus such aggressive threat analysis and the consistency of the latter with U.S. treaty commitments under the BWC and the CWC.

Conclusion

The revolution in the biological sciences is making it possible for biology, especially medical and pharmaceutical sciences, to become a full-fledged military technology. This raises the specter of a new genera-

tion of biological and chemical weapons, as well as a sophisticated capability to manipulate the physiology of human beings for military purposes. Designing and weaponizing these agents would require a substantial investment of time, expertise, and money; it is not a feasible activity for terrorists, although with time some terrorist groups might be able to develop some of the simpler alternatives. However, these new weapons will lie well within the capabilities of any country with a biomedical research community—an increasingly large number of states that includes most that are suspected of current or past interest in biological and chemical weapons. The implications for weapons proliferation are thus grave.

Clearly, such a prospect deserves careful analysis and wide-ranging debate. National and international security are not well served by ignoring the issues and allowing the world to creep toward new biochemical and biological weapons, as departments of defense and justice in the developed world continue to explore their utility for short-term tactical goals. We owe it to our children and grandchildren to consider our choices carefully, rather than thoughtlessly allowing momentum to carry us forward, irreversibly, down one fork in the road ahead. **ACT**

ENDNOTES

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Biotechnology and the Challenge to Arms Control

Advances in biotechnology pose grave challenges to arms control for the coming decades. The increasing capabilities of the biological sciences and the global spread of the underlying technologies raise the prospect of misuse of these technologies by small groups or individuals with the necessary technical competence. The challenges lie both in the mismatch between the rapid pace of technological change and the comparative sluggishness of multilateral negotiation and ratification, as well as the questionable suitability of monitoring and inspections to a widely available, small-scale technology. But this is not a counsel for despair. Rather, this international and human-security dilemma should serve as a spur to construct an appropriate web of prevention and response that allows the world to benefit from this technology while minimizing its dangers.

There is now a well-known list of recent experiments conducted by legitimate researchers that illustrate the dangers inherent in modern biological research and development.¹ One such experiment was the synthesis of the polio virus at the State University of New York (SUNY) using readily purchased chemical supplies.² Therefore, even if the World Health Organization succeeds in its important task of eradicating polio worldwide, the virus could still be reconstituted in laboratories throughout the world. Another experimental signpost was work at the Australian National University involving genetic modifications of the mousepox virus, a smallpox-analog virus that infects rodents. The researchers spliced into the mousepox DNA a gene for making a signaling protein that inhibits the mouse immune response to viruses. The unanticipated effect was to make the virus deadly both to mice that had previously been naturally immune and to those that had been vaccinated against mousepox.³ The experiment inadvertently pointed the way for attempts to make other viruses far more lethal.

These experiments illustrate the potential for misuse of work in molecular biology, immunology, and other forefront areas of research. Techniques developed, systems investigated, and manipulations performed for legitimate medical, food security, commercial, or other reasons may also show the way for extremely danger-

ous modifications that could cause harm to humans, animals, crops, or species in the natural world.⁴ Of course, a dual-use hazard has accompanied technology development since the invention of fire and the domestication of the horse. In the last century, the development of nuclear technology likewise married enormous power with enormous dual-use implications. What is different about biotechnology is its exponential growth, the speed of its spread around the globe, its potential for the creation of agents that could reproduce in the natural world, and its increasing availability and utility to small groups or even individuals.

Exponential Growth

The capabilities of biotechnology have increased at exponential rates in recent years, in some ways akin to the evolution of computer power. The capabilities of computers have exploded over the past several decades because the number of transistors per computer chip—a measure of how much computation can be done in a volume of a given size—has doubled every 18 months or so. This is the famous Moore's Law, after the co-founder of Intel Corp. who first called attention to the phenomenon in 1965.⁵ Moore's law is the reason that a single laptop today contains more computer power than was once found in entire halls of mainframe computers.

Although biotechnology's growth began decades later than that of computers, what is striking is that the rate of increase, as measured, say, by the time required to synthesize a DNA sequence of a certain length, is as fast or even faster than Moore's law.⁶ Just as Moore's law led to a transition in computing from extremely expensive industrial-scale machines to laptops, iPods, and microprocessors in toys, cars, and home appliances, so is biotechnological innovation moving us to a world where manipulations or synthesis of DNA will be increasingly available to small groups of the technically competent or even individual users, should they choose to make use of it.

There are ever more anecdotes illustrating the power and pace of the biotechnology explosion. The synthesis of the polio virus, completed in 2002, took the SUNY team three years of work. A year later, a research group at the Institute for Biological Energy Alternatives in Maryland manufactured a virus of comparable genomic length in just two weeks.⁷ In 2005 a group at the U.S. Armed Forces Institute of Pathology completed and published the determination of the genetic sequence of the 1918 human influenza virus that had killed tens of millions of people.⁸ Using this sequence, a research team from the Centers for Disease Control and Prevention and three other institutions recreated the complete 1918 virus and used it to infect mice in order to better understand what made the virus so deadly.⁹

Other technologies have appeared almost out of nowhere, moving rapidly from fundamental research to applications. These include RNA interference, which allows researchers to turn off certain genes in humans or other organisms, and synthetic biology, a fledgling field recognized only since about 2002, intended to allow engineers to fabricate small "biological devices" and ultimately new types of microbes.

Between 1990 and 2000, the speed of DNA synthesis increased more than 500 times. Moreover, laboratory processes have become more automated and black-boxed so that less and less tacit knowledge is needed to employ the technologies. By contrast, multilateral arms control treaties can take a decade to negotiate and ratify; a proposed protocol to the Biological Weapons Convention (BWC) took most of the 1990s to develop, reach the stage of a bracketed text, and have a chairman's text proposed for final discussion. In the end, no agreement was reached. The BWC protocol was not intended to deal with the biotechnology revolution; the comparison is simply to illustrate that the pace of technological change in some fields is outstripping that of the global political tools available for addressing the resulting implications.

The dilemma is being recognized internationally. Earlier this year, UN Secretary-General Kofi Annan called the use of biological weapons "the most important under-addressed threat relating to terrorism" and warned of the potential development of "designer diseases and pathogens."¹⁰ He asserted that an approach is needed as ambitious as the one developed at the dawn of the nuclear age for harnessing nuclear power while minimizing the spread of nuclear weapons. Finding such an approach that makes sense and that does more good than harm is the biotechnological challenge to arms control for the coming decades.



Roslan Rahman/AFP/Getty Images

Corporate scientists conduct research at Paradigm Therapeutics' Biopolis laboratory in Singapore. Singapore's government lauds biotechnology as the fourth pillar of its manufacturing industry, along with electronics, chemicals, and engineering.

Framing the Issue

Any effort to find solutions to the security dilemma posed by biotechnology should be informed by key features of the biological challenge. The problem requires urgent attention, but those urging action must avoid apocalyptic dramatization, which will attract interest initially but will risk undermining the credibility of the issue in the long term. Gregg Easterbrook has published a sarcastic and garishly illustrated piece titled "We're All Gonna Die!" as a reminder that scientists can readily make long lists of possible disasters for civilization.¹¹ The examples of dual-use biological research just mentioned, as well as a comprehensive recent U.S. National Academies of Sciences study of the issue,¹² demonstrate that the problem is real, not hype, but care is required to maintain perspective and avoid stirring opposition to possible solutions when cooperation is badly needed. Besides biotechnology's exponential growth, there are at least four key aspects of the issue.

Contrast With Infectious Disease

About 14 million people die annually from infectious diseases.¹³ Most of these deaths are in the developing world where infectious disease is the leading killer; in the developed world infectious disease typically ranks much lower, well behind heart disease and cancer. Five people died in the 2001 anthrax attacks in the United States. Any approach to the dual-use challenge that significantly curtails the use of biotechnology to counter disease runs the risk of being seen by much of the world as sacrificing actual Third World lives in the service of heading off hypothetical risks. An African meeting on these issues in October 2005 issued the Kampala Compact, which declared that although "the potential devastation caused by biological weapons would be catastrophic for Africa," it is "illegitimate" to address biological weapons threats without addressing infectious disease and other key public health issues.¹⁴

Few Actual Biological Attacks

For all the attention paid to bioterrorism, there have been very few actual biological attacks by nonstate groups. Apart from the still mysterious 2001 anthrax attacks, there were the nonlethal food poisonings by followers of Bhagwan Shree Rajneesh in 1984 and the unsuccessful efforts by Aum Shinrikyo to attack Tokyo with anthrax in 1993. Beyond these, there is evidence that al Qaeda made use of one doctoral-level microbiologist and perhaps several with undergraduate degrees in a quest for biological weapons. It is difficult from the open literature to determine the level of sophistication of their program, but what is currently available suggests it may have been more aspirational than effective at the time al Qaeda was expelled from Afghanistan.¹⁵

The rarity of modern bioterrorist attacks emphasizes the importance of understanding why there have been so few, the extent to which this has been due to capabilities or motivations, and how we might work to preserve whatever inhibitions have been at play.¹⁶ It is certainly true that modern travel will mean that a biological attack with a contagious agent could rapidly spread the resulting disease globally. Under what conditions this globalization of an epidemic would prove a deterrent to the use of contagious agents is unclear; an apocalyptic group such as Aum Shinrikyo might view global catastrophe as an incentive, whereas others might be reluctant to loose a plague that would boomerang against their own populations. The greatest damage might well be done in the developing world, regardless of where the initial target of the attack was located, because of the weak disease surveillance and response capacity of many developing countries.

It is striking to compare the focus on capabilities in many threat assessments with the tenor of one of the most successful threat assessments in U.S. history, that of George Kennan's famous "X" article in *Foreign Affairs* in 1947.¹⁷ Kennan's analysis was a keystone to the establishment of the successful decades-long Cold War policy of containment of the Soviet Union, yet in re-reading that piece today, one is struck by how little of it addresses Soviet capabilities. Instead, nearly all of it concerns Soviet motives and intentions, informed by a deep knowledge of Russian and Soviet history and culture.¹⁸ Similar sophistication must be brought to the biological threat posed by modern terrorist groups.

The WMD Continuum

In 1948 the Commission for Conventional Armaments of the UN Security Council defined "weapons of mass destruction" (WMD) to mean "atomic explosive weapons, radio-active material weapons, lethal chemical and biological weapons, and any weapons developed in the future which have characteristics comparable in destructive effect to those of the atomic bomb."¹⁹ This definition has the great virtue of specificity, in contrast to the loose way in which "weapons of mass destruction" and "WMD" are often used today. However, few now would want to include radiological weapons under the WMD label, and lumping biological weapons together with nuclear weapons is greatly misleading.

The strengthened monitoring and inspection regime implemented by the International Atomic Energy Agency in the nuclear realm can be reasonably effective because of the significant industrial bottlenecks (barring nuclear theft) through which any would-be nuclear weapons program has to pass: uranium conversion and enrichment or plutonium production and reprocessing. The weaponization of biological agents presents far less severe bottlenecks. The trajectory of advances in biotechnology will only reinforce these differences.

There is an argument among some nuclear experts that tacit knowledge, the real-world engineering experience of actually having worked with nuclear weapons design and explosive materials, is a tremendous asset that mere blueprints or articles cannot convey.²⁰ However true this claim might be for nuclear weapons technology, the thrust of biotechnological development is to make powerful applications increasingly black-boxed so that key procedures are available to be used by a broad audience. Undergraduates at a ten-week Synthetic Biology Jamboree in 2004 made use of "BioBricks" from an MIT database for students²¹ and, in the words of one senior observer, "did world-class work, yet their level of training was embryonic."²²

This is not to say that weaponizing biological agents—going from the laboratory organism to a treatment ready to be sprayed or otherwise spread—is not challenging. In fact, Aum Shinrikyo, despite substantial financial resources, ran into trouble in this step, among others. Yet, if the terrorist group's approach were to create a contagious agent such as smallpox or influenza, sophisticated spray preparations might not be necessary.

Globalization Requires Global Response

The biotechnology explosion is being driven by academic, private, and government research. The allure of biotechnology for public health, food security, and commercial applications is so great that its globalization is unstoppable. Singapore is establishing biotechnology as the "fourth pillar" of its economy; China's Office of Genetic Engineering Safety Administration approved more than 250 genetically modified plants, animals, and microorganisms for field trials between 1996 and 2000; India claims 96 biotechnology companies; Mexico has established a new Institute of Genomic Medicine; the Pakistani Atomic Energy Commission has committed itself to training scientists from Muslim countries in biotechnology; South Africa is working to develop a national biotechnology sector; Nigeria is considering a \$5 billion endowment for science and technology, with agricultural biotechnology a major focus; and the list goes on.²³

To be effective, any attempt to address the dual-use biotechnology challenge must be global in scope and therefore must find common ground among the developed and developing world on the issue. There is simply no way to duck a global approach to this problem, and the fact that many contagious organisms have incubation times longer than international flight times means that isolation is an insufficient strategy.

The nuclear Nonproliferation Treaty establishes a bargain between the nuclear-weapon states and the non-nuclear-weapon states. Under Article IV, the non-nu-

clear-weapon states have an “inalienable right” to nuclear energy in exchange for living up to their obligation not to pursue nuclear weapons. The dual-use biology dilemma should not be understood as requiring an analogous bargain. Although the BWC’s Article X calls for the sharing of biological science, the convention is an arms control treaty, not a nonproliferation treaty: all signatories are banned from the acquisition of biological weapons. Similarly, all countries have a stake in preventing and fighting pandemic diseases, whether due to natural emergence or laboratory creation. The developing world may have the most to gain from these technologies and therefore the most to lose if misuse or inadvertence leads to biological accidents that then curtail their use worldwide.

Five Categories of Risk

One reason that solutions to the biotechnology misuse dilemma are so difficult is that any proposed response must be attentive to at least five categories of risk. These are naturally occurring diseases; illicit state weapons programs; nonstate actors; hackers; and laboratory accidents or other inadvertent release of disease agents. Particular measures may well address only one or two of these concerns, but they must be judged according to their impact, positive and negative, across the board. This kind of overall strategic assessment is largely missing.

Nor should a measure’s failure to address all aspects of the biological challenge necessarily be held against it. For example, the BWC is primarily an instrument for addressing state programs. The likelihood that inspections will not be a successful strategy against small-scale laboratory genetic engineering does not negate the value of transparency and inspections for the “high end” of large-scale production programs. Attention to preventing the misuse of biotechnology should not compromise the continuing need to avoid a state-based biological arms race. Similarly, so-called science-based threat assessment that explores novel pathogens to determine potential terrorist or state threats must be assessed strategically to weigh defense advantages against dangers of feeding a perception among other governments that something resembling an offensive program is underway, thereby risking fueling the state-program threat even while preparing for other levels of threat.

Within these risk categories, there are important further distinctions. The nonstate actor category, for example, should really be divided into substate actors and nonstate actors. The latter, such as Aum Shinrikyo, receive no state support, in contrast with the former. “Hackers” is used by analogy to computer hackers that launch cyberattacks, for example, by releasing “worms” or viruses over the internet. Bio-hackers could be included in nonstate actors but are separated here to emphasize the possibility that, were dangerous biological manipulations to become sufficiently black-boxed, then careless, mischievous, or hateful individuals might individually pose a substantial risk.

We may not yet have entered a realm where the ability of individuals to do highly consequential biological hacking is widespread. Biological hackers at this point would still need to be sophisticated scientists. In coming years, however, we must worry not only about the rare “evil genius” but also about the intellectual hangers-on. The analogy here is to “script kiddies” in the

cyber realm, those who are insufficiently knowledgeable or motivated to create their own sophisticated computer viruses but who make use of online postings of virus computer scripts and then unleash these derivative creations.²⁴ In the biological case, as the technologies permit increasing ease of use, hackers or nonstate groups will not need to conduct their own sophisticated biological research programs. They will simply have to follow, perhaps with modifications, the steps published by legitimate researchers.

Addressing the Threat

Is it possible to fashion an effective international control regime in the face of exponentially expanding biotechnology? The answer to this question carries important implications for our biological future and also for how the world will cope with other technologies, such as nanotechnology, that may pose similar dilemmas further down the road.

The good news is that there is tremendous ferment now with respect to this question. Scientists, lawyers, policy analysts, scientific societies, international nongovernmental organizations (NGOs), and the UN secretary-general have all weighed in with thoughts on the issue. It would be impossible to survey comprehensively this entire landscape of remarks and proposals, but it will be useful to highlight some of the main threads of the discussion, their weaknesses, and possible paths forward.

An Endless Arms Race?

If an effective global system for security in the face of biotechnology cannot be put in place, the world could enter a kind of endless offensive-defensive arms race, where bad actors, not just state programs, endeavor to engineer around new antibiotics, antivirals, vaccines, or other defenses against disease-causing agents. The arms race metaphor should be used with caution because, unlike the Cold War arms race, the primary driver for the biological arms race is the ongoing advance of biological research. The hope would be that the defenses arrayed against the rare bad actor by the vastly larger biomedical community would prove sufficient. Nevertheless, although the resource advantage will lie overwhelmingly with the defense, defensive measures also require a series of steps—for example, drug development and distribution—that the offense need not master. The words of the Irish Republican Army after it just missed assassinating the British cabinet in the 1984 Brighton bombing should be recalled: “Today we were unlucky, but remember we have only to be lucky once—you will have to be lucky always.”²⁵ Rather than concede that this grim and disheartening view of the human future is what biotechnology holds for us, the scientific and arms control communities should try to do better.

Formal Treaties

The cornerstones of efforts to control the misuse of biology are the 1925 Geneva Protocol prohibiting the use of “bacteriological methods” of warfare, and the 1972 BWC, which prohibits the development, production, stockpiling, or other acquisition of biological agents for nonpeaceful purposes. The BWC also calls on states to prohibit such acquisition anywhere within territory under their control so that signatories have an obligation

to prevent the offensive misuse of biology. Perhaps a major contribution of the BWC besides setting a global norm against biological weapons is its potential for increasing international transparency and decreasing the mistrust that could drive new state-sponsored weapons programs.

Although a verification protocol even for the largest production facilities is not now a realistic possibility, other mechanisms based on the BWC, in particular, mutual declarations and other confidence-building measures (CBMs), would further transparency and should be strengthened.²⁶ Efforts to maintain transparency between states will be increasingly important if biodefense research continues to expand with an eye to the terrorist threat.

The biological challenge is unprecedented with respect to the power it will place in the hands of small groups of the technically competent. The pace of technological advance is daunting and risks outstripping the pace of political response.

Other Current Multilateral Approaches

There are multilateral approaches outside the BWC process. Most striking among these is UN Security Council Resolution 1540, by which the Security Council required all UN member states to develop and maintain controls over biological weapons materials and their export. It is too soon to be sure of the outcome of this extraordinary experiment in Security Council lawmaking, but it is important that Resolution 1540 not come to be seen as just a hollow set of aspirations. The Australia Group suppliers' regime and the Proliferation Security Initiative (PSI) are further, more specialized examples of multilateral (but far from global) approaches to biological security. To interdict illicit biological shipments, however, PSI members would need precise intelligence.

Disease Surveillance and Response

Over the past several decades, the world has faced annually a newly emerging disease. Severe Acute Respiratory Syndrome (SARS) spread around the world in 2003 but was nevertheless contained despite its novelty and an absence of vaccines or antiviral drugs targeted against it. This emphasizes the great importance of the early recognition of and response to disease outbreaks, whether natural or human engineered. The World Health Organization (WHO) recognizes that its global disease surveillance systems, including its Global Outbreak Alert and Response Network, will be at the forefront of detection and response either to human-caused or natural disease outbreaks.²⁷

Despite WHO efforts within its limited budget, there remains great scope for improving international disease surveillance and response. Because flight travel times to the United States are shorter than many disease incubation times, it is strongly in the self interest of the United States to buttress disease surveillance overseas, even apart from humanitarian reasons for doing so.

Yet, the United States has failed repeatedly to act. The Global Pathogen Surveillance Act has been introduced in Congress in 2002, 2003, and 2005, with similar language

in the Foreign Assistance Authorization Act in 2004, 2005, and 2006. The current bill authorizes \$35 million to be spent to improve capacity for disease surveillance and response in developing countries, through training, improvements in communications and public health laboratory equipment, and the deployment of U.S. health professionals. It is sponsored by Senate Majority Leader Bill Frist (R-Tenn.) and supported by Secretary of State Condoleezza Rice. Despite some success in the Senate, the bill has never passed the House.

Facing a world where novel microorganisms can emerge or be invented, there should be a strong incentive to budget tens of millions of dollars to improve and sustain

international disease surveillance and response. Yet, over and over, it seems imagination stops at the border. Although atmospheric sampling within our cities and buildings may prove a powerful tool, recognizing and shutting down disease outbreaks overseas must be a high priority. The failure to pass, then adequately fund the Global Pathogen Surveillance Act is an extraordinary ongoing failure of U.S. national security policy.

Formal International Oversight of Research

The National Research Council has recommended a variety of oversight mechanisms for research conducted with federal research grants.²⁸ John Steinbruner and his colleagues at the Center for International and Security Studies at Maryland (CISSM) have proposed a global system of internationally agreed rules for the oversight of potentially high-consequence pathogens research.²⁹ Of course, devoted terrorists would not likely be captured by such a system. Most nonstate groups are unlikely to conduct forefront research, but they might attempt to implement discoveries and techniques reported in the scientific literature. By overseeing certain high-consequence research and its publication, we might therefore head off some of the worst misuse. The WHO's international advisory committee that oversees smallpox research provides a limited model of what oversight of the highest consequence biological research might look like. It is important that that committee demonstrate that such bodies are capable of real oversight.

The CISSM oversight system would require an International Pathogens Research Authority with an appropriate administrative structure and legal foundation to set requirements for its states-parties. It is unlikely that such a system could be negotiated and ratified at the present time, although perceptions of what is possible could change rapidly subsequent to a first human-engineered major pandemic.

Yet, careful thinking is better done before an attack. Other international approaches to provide some level of oversight have also been envisioned, in-

cluding the creation of additional UN bodies or the establishment of an International Biotechnology Agency (IBTA). An IBTA could be established in a modular way, with modest initial goals, such as helping BWC states-parties meet their CBM requirements and fostering best practices in laboratory safety. However, even establishing such a limited body might look too much like an effort to revive some of the BWC protocol and may not be politically achievable at this time.

“Soft” Oversight

At the other end of the spectrum from the CISSM oversight scheme are efforts at what might be called “soft” oversight of potentially hazardous research. Perhaps most common among these are efforts to promulgate codes of ethics, or the more demanding codes of conduct or codes of practice, for scientists working in the relevant fields. Many national and international groups have made efforts in this direction.³⁰ The issue was also the focus of the 2005 BWC intercessional meeting. Such codes, coupled with education about the prospects for the misuse of scientific research and the national and international legal framework, would help give the scientific community a better capacity to police itself, a kind of “societal verification.” A National Academy panel has gone further, recommending establishing a global internet-linked network of informed scientists “who have the capacity to recognize when knowledge or technology is being used inappropriately.”³¹ The scientific community would conduct its own self-surveillance and initial intervention to prevent malevolent behavior within its ranks.

A more specific kind of community surveillance has been proposed by the participants in the Second International Meeting on Synthetic Biology held in Berkeley, California, in May 2006. They note that DNA synthesis is one obvious pathway toward the creation of hazardous biological systems, but most DNA synthesis companies do not systematically check their orders to ensure that they are not synthesizing DNA for human disease organisms or other hazards. Those that do such screening use existing software tools that are unable to identify novel hazards and that have a high false-alarm rate. The participants called for all companies to screen their synthesis orders, including customer validation, and created a working group to create better software screening tools.³²

Governance Without Treaties

There is a growing body of international relations literature concerned with the mismatch between the importance of global problems and the absence of international mechanisms to address them in a timely and effective way.³³ The World Bank’s J. F. Rischard advocates the creation of “global issues networks” that bring together representatives of governments, NGOs, and business for “rapid norm production and rapid activation of reputational effects.” The networks would quickly reach a rough consensus and then pressure states, through rating systems and naming and shaming, into performing better on the

issue in question. The objective is to effect change within years rather than the longer multilateral treaty and ratification process.

How such an approach might work in the biotechnology realm might be seen by analogy to concrete examples from an altogether different field, that of human rights and transnational corporations.³⁴ The UN Global Compact is the world’s largest corporate social-responsibility initiative, with more than 2,300 participating companies. These companies publicly advocate the compact and its 10 principles in the areas of human rights, labor, environment, and anti-corruption and share best practices.³⁵ There are other, overlapping initiatives including the Business Leaders Initiative on Human Rights.³⁶

In the absence of an international organization established by treaty to regulate biotechnology research, an initiative analogous to these efforts might begin to fill the gap. As one concrete example, Harvard biologist George Church suggested that all new DNA synthesis machines manufactured be licensed, tagged with electronic locators, and programmed to forbid the synthesis of dangerous DNA sequences.³⁷ An initiative analogous to the UN Global Compact could, with the support of governments and civil society, put strong pressure on the still-small number of companies manufacturing DNA synthesis machines to adhere to such principles on the grounds of global security. Broader principles to which all member companies would adhere could be explored, as could expansion to academic, governmental, and other biological research entities. The International Council for the Life Sciences is one newly formed membership-based organization that is beginning to assume this role.

Reasons for Optimism

The biological challenge differs greatly from the nuclear challenge and is unprecedented with respect to the power it will place in the hands of small groups of the technically competent. The pace of technological advance is daunting and risks outstripping the pace of political response, but there are reasons for optimism. The biological science community has a strong tradition of recognizing the potential for misuse of their work and calling for self-regulation.

Whereas the atomic scientists led by Leo Szilard failed in the 1930s to impose self-censorship in the publication of research in nuclear fission, the biologists succeeded in the early 1970s to restrict their own research in recombinant DNA, the predecessor of today’s far more powerful genetic engineering techniques. One reason for the biologists’ comparative success was that from the outset they enlisted support from prestigious scientific academies. This continues to provide a powerful tool.

The greater challenge is for the policy world. Neither Cold War arms control nor nonproliferation treaties provide good models for how to cope with the nonstate aspects of the biotechnology dilemma. It is unclear whether the international system will be nimble enough to respond effectively. If it cannot, we will simply have to cope with, rather than shape, our biological future. Before we accept that outcome, it is time for the creative exploration of rapid and effective international means for addressing the worst dangers. **ACT**

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The Biological Weapons Convention (BWC) At a Glance

The Biological Weapons Convention (BWC) is a legally binding treaty that outlaws biological arms. After being discussed and negotiated in the United Nation's disarmament forum¹ starting in 1969, the BWC opened for signature on April 10, 1972, and entered into force on March 26, 1975. It currently has 155 states-parties and 16 signatory states.

Treaty Terms

The BWC Bans:

- The development, stockpiling, acquisition, retention, and production of:
 - i. Biological agents and toxins "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;"
 - ii. Weapons, equipment, and delivery vehicles "designed to use such agents or toxins for hostile purposes or in armed conflict."
- The transfer of or assistance with acquiring the agents, toxins weapons, equipment, and delivery vehicles described above.

The convention further requires states-parties to destroy or divert to peaceful purposes the "agents, toxins, weapons, equipment, and means of delivery" described above within nine months of the convention's entry into force. The BWC does not ban the use of biological and toxin weapons but reaffirms the 1925 Geneva Protocol, which prohibits such use. It does not ban biodefense programs.

Verification

The treaty regime mandates that states-parties consult with one another and cooperate, bilaterally or multilaterally, to solve compliance concerns. It also allows states-parties to lodge a complaint with the UN Security Council if they suspect other member states are violating the convention. The Security Council can investigate allegations, but this power has never been invoked. Security Council voting rules give China, France, Russia, the United Kingdom, and the United States veto power over Security Council decisions, including those to conduct BWC investigations.

Membership and Duration

The BWC is a multilateral treaty of indefinite duration that is open to any country.

Compliance

The convention has been flagrantly violated in the past. The Soviet Union, a state-party and one of the accord's depositary states, maintained an enormous offensive biological weapons program after ratifying the BWC. Russia says that this program has been terminated, but questions remain about what happened to elements of the Soviet program. Indeed, the U.S. government declared in an August 2005 treaty compliance report that "Russia continues to maintain an offensive BW program."² Moscow refuted the charges.

Iraq also violated its treaty commitments in the past. After the 1991 Persian Gulf War, Iraq initially denied having an offensive biological weapons program to international arms inspectors, but admitted otherwise in July 1995. But inspectors never resolved all outstanding issues surrounding the Iraqi program and could not verify Iraqi claims that the program had been eliminated. Some governments, led by the United States and the United Kingdom, charged up until the March 2003 invasion of Iraq that the country maintained an active biological weapons program, even though international inspectors had no evidence supporting these allegations. U.S. post-invasion inspections found the charges of an illicit program to be false.

In its 2005 treaty compliance report, the U.S. government listed, in addition to Russia, BWC states-parties China, Iran, and North Korea, as well as BWC signatory Syria, as possessing offensive biological weapons programs in violation of the treaty. Washington also raised concerns about Cuba's compliance with the convention.

Meanwhile, the United States maintains extensive biodefense programs that some independent analysts and foreign government officials have contended could be perceived as crossing the line between permitted and outlawed activities.³

Efforts to Enhance Compliance

States-parties have convened a review conference about every five years to review and improve upon the treaty's implementation. In an effort to enhance confidence and promote cooperation among states-parties at the second treaty review conference in 1986, member states agreed to implement a set of confidence-building measures. Under these politically binding measures, states are called upon to:

- Exchange data on high-containment research centers and laboratories or on centers and laboratories that specialize in permitted biological activities related to the convention.
- Exchange information on abnormal outbreaks of infectious diseases.
- Encourage the publication of biological research results related to the BWC and promote the use of knowledge gained from this research.
- Promote scientific contact on biological research related to the convention.

At the third BWC review conference in 1991, the scope of the first measure was expanded to include national biodefense programs and the second and fourth measures were slightly modified. In addition, member states added the following three measures to the list:

- Declare legislation, regulations, and “other measures” pertaining to the BWC.
- Declare offensive or defensive biological research and development programs in existence since Jan. 1, 1946.
- Declare vaccine production facilities.

These endeavors have been largely unsuccessful; the vast majority of states-parties have consistently failed to submit declarations on their activities and facilities.

The 1991 review conference also tasked a group of “governmental experts” to evaluate potential verification measures for use in a future compliance protocol to the BWC. The group subsequently considered 21 such measures and submitted a report to a special conference of states-parties in 1994. Building off this report, the conference tasked a second body, known as the Ad Hoc Group, with negotiating a legally binding protocol to strengthen the convention.

The Protocol Regime and Negotiations

The Ad Hoc Group met from January 1995 to August 2001 and aimed to finish its work before the fifth review conference scheduled to begin in November 2001. During the negotiations, the group developed a protocol that envisioned states submitting to an international body declarations of treaty-relevant facilities and activities. That body would conduct routine on-site visits to declared facilities and could conduct challenge inspections of suspect facilities and activities as well.

However, a number of fundamental issues, such as the scope of on-site visits and the role export controls would play in the regime, proved difficult to resolve. In March 2001, the Ad Hoc Group’s chairman issued a draft protocol containing language attempting to strike a compromise on the disputed issues. But in July 2001, at the Ad Hoc Group’s last scheduled meeting, the

United States rejected the draft and any further protocol negotiations, claiming such a protocol could not help strengthen compliance with the BWC and could hurt U.S. national security and commercial interests.

The fifth BWC review conference, which many experts thought could resolve the fate of the Ad Hoc Group, was suspended on its last day, Dec. 7, 2001, after the United States offered a controversial proposal to terminate the Ad Hoc Group’s mandate and replace it with an annual meeting of BWC states-parties. The United States is the only country that publicly favors revoking the group’s mandate. Despite resuming the fifth review conference in November 2002, the states-parties still failed to agree on any verification measures, including the proposed protocol. Instead, they agreed to hold annual meetings before the next review conference in 2006. No decision was taken regarding the Ad Hoc Group, and its future remains unclear.

The New Process

During the subsequent annual meetings, member states discussed various nonproliferation measures each state-party can implement to prevent the spread of biological weapons. Each of the meetings, which included experts and state representatives, had a special focus:

- In 2003, improving national legislation and better national oversight on dangerous pathogens.
- In 2004, enhancing international capabilities to deal with alleged cases of biological weapons use and strengthening and broadening national and international disease surveillance.
- In 2005, developing of codes of conduct for scientists.

Due to U.S. opposition, the agenda of these meetings did not include any discussion of verification measures and participants were not allowed to issue formal recommendations to member states on more effective nonproliferation instruments. It will be up to the sixth review conference, taking place Nov. 20, 2006 to Dec. 8, 2006 in Geneva, to take action on the issues discussed the past three years and agree on a new set of meetings.

ENDNOTES

1. The forum, the Committee on Disarmament, is now known as the Conference on Disarmament.
2. U.S. Department of State, *Adherence to and Compliance with Arms Control, Nonproliferation and Disarmament Agreements and Commitments*, August 2005, pp. 108.
3. Brugger, Seth, “International Reaction to Secret U.S. Bio-Weapons Research Muted,” *Arms Control Today*, October 2001, p. 22, and Yang, Jonathan, “U.S. Biodefense Plans Worry Nonproliferation Advocates,” *Arms Control Today*, September 2003, p. 43.

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