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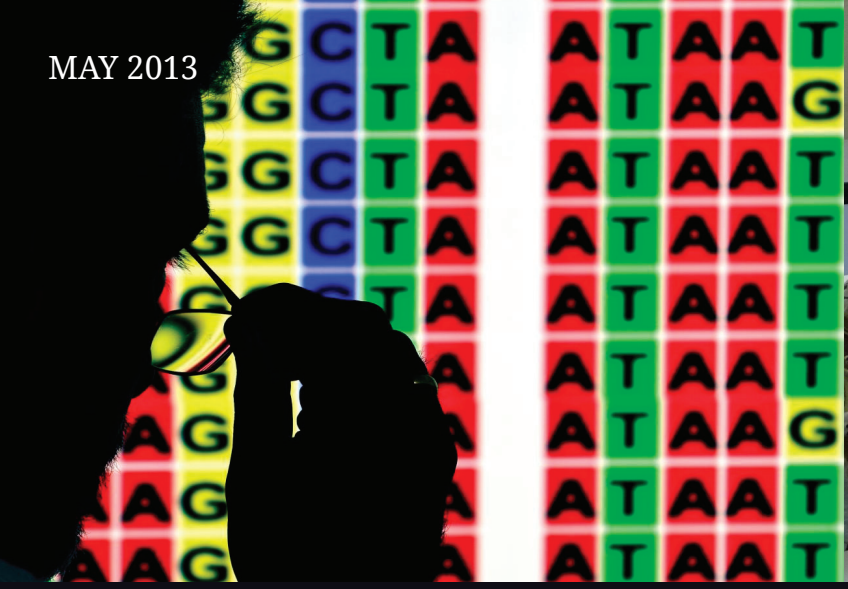

A Biological Threat Prevention Strategy

Complicating Adversary Acquisition and Misuse of Biological Agents

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Carol Kuntz

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A Report of the CSIS Defense and National Security Group

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Foreword

This report was inspired by three roundtable discussions, hosted in the fall of 2012 by the Center for Strategic and International Studies (CSIS) and funded by the Nuclear Threat Initiative (NTI). Throughout these meetings, a group of senior government officials and non-governmental subject-matter experts discussed the range of biological threat prevention tools, their costs and benefits, and techniques for integrating them into optimal policies. The authors are grateful to NTI for their support and to the roundtable participants for their insights and comments, which have been integral in shaping this report. A list of these participants is included as the second appendix to this report.

This report represents only the views of its listed authors. It does not represent the views of individual roundtable participants, nor does it represent the views of the U.S. government, the Department of Defense, Sandia National Laboratories, the Center for Strategic and International Studies, or the Nuclear Threat Initiative.

Executive Summary

A contradiction sits at the core of U.S. biological threat prevention policy. Despite the U.S. government (USG) accepting the scientific and industrial costs of a domestic biosecurity system, it has not committed the diplomatic and financial resources needed to successfully promote the global adoption of similar systems. While the safety and security of biological pathogens within the United States are important national goals, their pursuit has the potential to impede another crucial goal: a robust research and commercial enterprise. To make matters worse, domestic policies are insufficient to fully protect U.S. citizens, since they provide limited protection from attacks launched with pathogens brought into the United States from abroad. Biosecurity has become a global problem. With the rapid spread of technology and know-how, attacks that originate from less-regulated locales outside the United States are becoming increasingly serious risks to U.S. national security. This means that the United States is bearing the full costs of domestic bio threat prevention without attaining the benefits of a thorough global prevention system.

The USG must correct this imbalance by reevaluating its policies both at home and abroad. This reevaluation should take the form of three action steps. First, the administration should direct a thorough assessment of the safety and security benefits of current or potential alternative national bio threat prevention systems compared with their scientific, industrial, and public health costs. Second, the National Security Council should use this assessment to define the optimal content of domestic and global bio threat prevention efforts. Third, the National Security Council should establish a tactical plan for committing high-level resources to speed the adoption of appropriate domestic and global measures.

The stakes are high. The USG must commit to a balanced global safety and security policy that maximizes the tremendous benefits of modern life sciences while minimizing the risk of their misuse. If the United States fails to act now, it will risk enduring the worst of both worlds: a domestic research enterprise entangled in regulations and bureaucratic procedures, and an international counterpart unfettered and ever more widely distributed and capable.

A Biological Threat Prevention Strategy

Complicating Adversary Acquisition and Misuse of Biological Agents

The risk of a biological attack is ever-present. The relevant knowledge and material are becoming more widely available because of the global dispersion and rapid advances of technology, combined with its inherent dual-use nature.[1] While technical challenges remain to a successful large-scale, high-impact biological attack, such an attack could kill tens of thousands of innocent civilians.[2]

Significant efforts have been devoted to strengthening a national strategy to counter biological attacks. This report focuses on the prevention portion of these efforts. Prevention seeks to prevent an adversary or a potential adversary from acquiring, developing, or misusing the biological materials, delivery technologies, and expertise needed to launch an effective biological attack. This examination focuses on biological materials and expertise.[3] Although effective delivery would be essential to significantly increase the number of deaths in an attack, this report does not focus on preventing the acquisition of delivery systems.

Prevention strategies constitute only a portion of an overall national strategy to counter biological threats. The other aspects of a national strategy are deterrence and defense. Deterrence seeks to affect the calculation of an adversary, leading him to conclude that the costs of launching an attack would be greater than the benefits he would accrue. Defense seeks to mitigate the consequences of an attack through response measures, such as deploying vaccines and therapeutics, which reduce the severity of the attack on the defender's population or military forces. Both deterrence and defense are critically important to overall national strategy.[4] They are not, though, the subject of this report.

Costs and Benefits: At Home but Not Abroad

Current U.S. prevention policy contains a contradiction at its core: federal enforcement of a domestic biosecurity system that is unmatched by other nations with leading research or industrial life science sectors. As a result, the United States incurs the full cost of implementing its domestic bio threat prevention measures—potentially including impediments to scientific progress and industrial strength—but remains vulnerable to gaps in international bio threat prevention. For instance, pathogens at home may be more secure,

Current U.S. prevention policy contains a contradiction at its core: federal enforcement of a domestic biosecurity system that is unmatched by other nations with leading research or industrial life science sectors.

but many abroad have been secured less comprehensively and could be carried into the United States and used to launch an attack. This contradiction should be resolved. If prevention efforts are worth the costs of implementation at home, they are worth a much more concerted effort by high-level U.S. officials to catalyze the global adoption of bio threat prevention practices.

The United States has constructed an extensive domestic structure of controls and guidance. The U.S. Select Agent Program specifies the conditions under which facilities and individuals can have access to biological select agents and toxins (BSAT), and requires these facilities to create performance-based safety and security plans. The U.S. government (USG) also has established official guidance on a variety of issues, including biosafety, recombinant DNA, and, most recently, government-funded and government-conducted dual use research of concern (DURC).[5] Further, the USA PATRIOT Act expanded Title 18 of the United States Criminal Code to criminalize the use of biological agents and toxins as a weapon and the possession of biological materials without prophylactic, protective, bona fide research, or other peaceful purpose. Licenses are required for exporting, and permits required for importing, select agent pathogens and toxins. FBI outreach to scientific communities aims to facilitate awareness and enforcement of these regulations.

Such controls seem to provide safety and security benefits at home. They can increase *safety* by raising awareness and establishing procedures that reduce the probability of unintentional exposure to harmful agents—both inside and outside the laboratory. Reducing the risk that pathogens could leak from labs based in the United States without imposing unreasonable scientific or industrial costs is an important goal. Controls can increase *security* by making it more difficult for adversaries or potential adversaries to acquire components of a biological weapons capability, or by more efficiently targeting law enforcement resources on individuals or groups that demonstrate high-risk behavior. Since the means to develop a biological weapon are widespread, preventing adversary acquisition or misuse of a biological

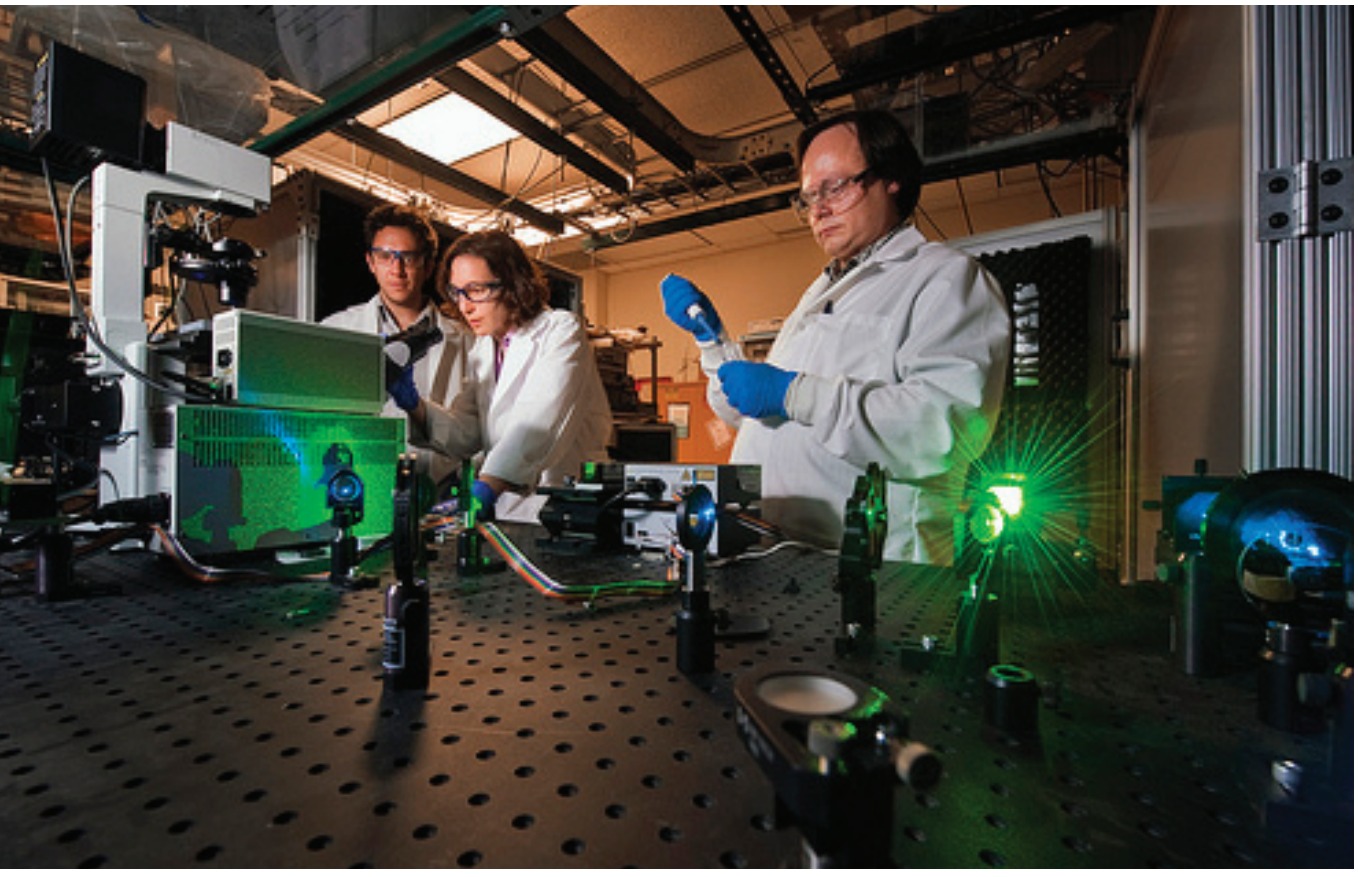
agent with 100 percent confidence is impossible. However, a well-conceived set of practices could help manage these circumstances and mitigate risk.

Despite these potential benefits, U.S. policies leave a major security gap: pathogens and technologies delivered from abroad. Despite calls by the Biological Weapons Convention and United Nations Security Council Resolution 1540 for each party nation to pass laws to prevent the illicit acquisition of biological agents and technologies that a non-state actor could misuse for harm, international progress toward implementing these agreements has been slow and uneven. It would be possible for an individual to surreptitiously carry a dangerous pathogen into the United States and, subsequently, manipulate the pathogen for malicious use in a private room. It also would be possible for an individual to release a pathogen in the United States that was acquired and weaponized abroad. U.S. controls provide minimal protection against such scenarios.

Further, the means to acquire such a pathogen abroad are increasing. Public health infrastructure is growing around the world. Advanced biological research is becoming ever more globally diffuse and booming in China and India in particular. Costs for DNA segments and genome sequencing are dropping at a rate faster than predicted by Moore's law,[6] and high-end equipment capable of synthesizing new or modifying existing organisms is becoming increasingly accessible.[7] These developments are unquestionably positive overall. For example, they enable production of better medical diagnostics and therapeutics, improve agricultural productivity, and allow production of molecules that can consume carbon dioxide emissions. At the same time, however, this trend toward reduced entry barriers to increasingly sophisticated technology may make it easier for a terrorist to acquire a bioweapons capability.

The USG has allocated significant resources to international bio threat prevention. However, despite pursuing some whole-of-government initiatives, U.S. efforts to promote prevention abroad have proceeded primarily at a program-by-program level. The U.S. Department of Defense (DoD) has by far the greatest share of available funds; the Department of State has an analogous but smaller program.[8] The bio components of the DoD Cooperative Threat Reduction (CTR) program, created by the 1991 Nunn-Lugar Act, focus on (1) consolidating pathogen collections and constructing labs for centralized pathogen storage so agents are no longer held in far-flung and unsecure public and animal health labs; (2) providing technical training and assistance in biorisk management and disease surveillance; and (3) supporting transparent and ethical research practices in the biosciences.[9] DoD, the Department of State, the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), and other government agencies have programs that seek to build relationships between the United States and foreign bioscience and biotechnology communities and encourage the adoption of best practices abroad. These programs offer partner nations a variety of engagement options, including training, education, and other resources to consolidate pathogen collections and manage risks in public and animal health facilities.

However, despite efforts to pursue whole-of-government initiatives, U.S. efforts to promote prevention abroad have proceeded primarily at a program-by-program level.



Unfortunately, this work is largely bilateral, leaving the majority of countries unengaged. Although the 2009 *National Strategy for Countering Biological Threats* identifies the importance of transforming international dialogue on this issue,[10] the global components of U.S. policy are less well resourced compared to bilateral outreach. The clearest example of U.S. global efforts is the United States' engagement with the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP).[11] This initiative seeks to extend the efforts of Cooperative Threat Reduction beyond the former Soviet Union, creating a coordinated global network of providers and recipients of assistance. While U.S. work in the GP is well conceived and laudable, the Global Partnership is a relatively new effort with a limited track record, and it appears to lack top-level commitment within the U.S. government. In brief, U.S. bio-engagement policy is global in both strategy and concept, but not in resources or execution.

U.S. bio-engagement policy is global in both strategy and concept, but not in resources or execution.

These U.S. policies have undoubtedly achieved meaningful tactical advances—securing facilities; establishing positive relationships; and encouraging better integration of biosecurity, human health, veterinary, and agricultural disease communities in some countries. However, these policies do not seem likely to produce efforts that will persist and generate, over time, a broadly accepted, self-reinforcing global framework. For example, USG-funded reference labs in Georgia and Kazakhstan, which consolidate pathogens of concern located in each nation, are valuable but expensive to operate and maintain, much less to construct in additional countries. This approach may prove neither sustainable nor widely replicable, given U.S. partners' lack of capacity and the limitations of future funding outlays in the United States. Further, this model is likely unworkable in some of the countries where bio threat prevention is arguably most important—those with large, highly capable academic and commercial life science sectors.

The trajectory of U.S. efforts to prevent misuse lags behind the global advance of the life sciences. A sustainable solution that does not hamstring the U.S. scientific enterprise requires

a reprioritization of global initiatives. Although the United States cannot compel adoption of its biosecurity agenda—and must avoid the perception that it is trying to work unilaterally—a sustained high-level U.S. commitment could succeed in raising bio threat prevention on the global agenda and would likely spur useful change at a faster rate.

A variety of nongovernmental groups have pursued and advocated such global prevention efforts, but these groups lack the funding and top-level political support necessary to leverage their initiatives into system-wide changes. They generally focus on one professional group (e.g., lab technicians, top scientists) or one part of the problem (e.g., laboratory containment). While these efforts reflect well on the tenacity and determination of the individuals and organizations involved, the efforts seem too limited to advance a global consensus on a prevention framework on any reasonable timeline, absent more funding and senior-level support.

The result of these uncoordinated efforts on the part of both government and civil society is a patchwork of international bio threat prevention policies and programs. A few countries have constructed domestic control systems similar to that in the United States. Singapore and Denmark are among the countries with significant regulatory systems, although neither has a bioscience enterprise approaching the size of that in the United States. The European Union is working to implement coordinated standards, but progress is slow and uneven. Several countries with burgeoning bioscience sectors—such as Brazil, China, and India—have weak legal and regulatory systems that, in some cases, are plagued with local corruption.

Such a system could complicate regulation of the life sciences, driving portions of these communities out of the field, overseas, or underground, where regulation is impossible.

This inconsistency among national regimes harms the United States. By regulating access to particular materials and facilities and increasing compliance costs, prevention measures probably create at least some inefficiencies in U.S. scientific, pharmaceutical, and public/animal health research.[12] It is plausible that these inefficiencies are worth the benefit of reducing the risk that pathogens leak or become diverted from U.S. labs, threatening the safety of those in surrounding communities. However, it also could be the case that the costs of such a system do not justify their safety benefits, or that the safety benefits could be achieved through less costly alternative policies. Making prevention policies too onerous could be counterproductive. Such a system could complicate regulation of the life sciences, driving portions of these communities out of the field, overseas, or underground, where regulation is impossible. Some analysts argue that U.S. policies have reached this level.[13]

Although U.S. bio threat prevention policy may be valuable in the absence of comparable global efforts, the extent of global implementation should play a role in deciding the appropriate degree of domestic regulation. Specifically, the benefits to the United States and its life science community of a prevention framework seem almost certain to be increased by its broader global adherence, while costs to the United States and its life science community seem likely to be commensurately reduced. In any case, if the safety and security advantages of U.S. policy truly outweigh their efficiency downsides, shouldn't the USG be playing a much more active role in catalyzing global activity to develop and implement similar bio threat prevention measures?

To answer this question, the USG must decide: what bio threat prevention efforts are worthwhile? This requires weighing costs and benefits—an extremely difficult task given the wide range of variables, the difficulty of quantifying the benefits of particular biosecurity efforts, and the wide array of potential bio threat prevention tools and enforcement nodes.[14] Although advocates argue strenuously on both sides of the issue, no integrated, high-level assessment has been conducted that systematically weighs the trade-offs—or potential synergies—between biosafety and biosecurity on the one side and science, industry, and public/animal health on the other. Such an analysis could, for example, study the number of U.S. patents and publications, the amount and quality of research, and the incidence of accidents before and after the enactment of dual-use research guidance, Select Agent regulations, and other changes in bio threat prevention policy. It could determine the costs—both direct and indirect—of compliance for individual facilities. It also could evaluate the number of known criminals, terrorists, or other restricted persons that the new policy has denied access to high-risk pathogens, and coordinate with intelligence communities to assess the contributions of these restrictions to public safety and security. It could delve into the qualitative experiences of researchers in these areas to determine whether they have redirected their research to avoid being subject to these rules. It also could seek the views of trade and international economists to evaluate what, if any, have been the repercussions of these rules on U.S. industry. The study also should consider the robustness of its findings given different levels of foreign adoption and observance—such as a lack of regulatory strength or cheating.

Although advocates argue strenuously on both sides of the issue, no integrated, high-level assessment has been conducted that systematically weighs the trade-offs—or potential synergies—between biosafety and biosecurity on the one side and science, industry, and public/animal health on the other.

Admittedly, these are challenging issues to evaluate, especially in a single study. But even multiple analyses of these various questions would contribute to shaping more informed U.S. policy at home and abroad. Working to develop a clear understanding of the costs and benefits of each component of U.S. domestic bio threat prevention system and U.S. priorities in balancing these costs and benefits will aid U.S. efforts to identify and persuasively promote a suite of global bio threat prevention initiatives.

Action Step: *Systematically weigh costs and benefits.*

The administration should direct that a high-level analysis or analyses be conducted—including life science researchers, public/animal health experts, nonproliferation experts, economists, and trade experts—to weigh the costs and benefits of current and potential alternative U.S. bio threat prevention policies. The study should make this calculation assuming different levels of global adoption and observance.

Content: Optimizing Prevention Measures

After completing the assessment, the USG will need to decide if the implications call for altering the U.S. system and/or pursuing a global one. Assuming that the net assessment calls for pursuing a global initiative, the next two steps are *content* and *tactics*: defining the optimal set of prevention measures and shaping a tactical plan to secure these measures' broadest possible adoption. More plainly, the USG needs to figure out what to do and how to do it. A reasonable first step is to consider the content that such an initiative should seek to promote.

Twenty-first century bio threat prevention must be equal to the enormous number and diversity of relevant actors. These actors work in conditions ranging from poorly funded public health clinics to do-it-yourself biology experiments to university research labs to large biopharmaceutical companies.

It seems clear that a traditional arms control approach cannot be the centerpiece of such an effort. Inspection regimes, such as those envisioned in previous Biological Weapons Convention (BWC) proposals, are highly problematic given the dual-use nature of the relevant research[15] and the risk that inspections could compromise proprietary information. Export controls can be helpful in complicating the efforts of some state programs to acquire sophisticated technology, but they have limited utility, particularly against non-state programs, since biological agents and technologies are widely dispersed internationally, inherently dual-use, and constantly changing, and export control laws are nationally (not universally) imposed. Discussions at the BWC, United Nations, and in forums such as the Australia Group (created to harmonize export controls) can stimulate interest and build expertise in biosecurity among foreign bureaucracies, but they are not a complete solution to the challenges posed by 21st-century bio threats.

Twenty-first century bio threat prevention must be equal to the enormous number and diversity of relevant actors. These actors work in conditions ranging from poorly funded public health clinics to do-it-yourself biology experiments to university research labs to large biopharmaceutical companies. These sites are not systematically organized by professional associations or via government processes; such organization is likely impossible. The entry costs for the creation of new

operations are so low that maintaining a list of relevant facilities is probably a poor use of resources.[16] Within these facilities, the vast majority of actors have the most public-spirited of intentions, hoping to save lives and secure research advances. The difficulty is separating these actors from those with malign intent.

There are two major issues in shaping the content of measures equal to this challenge: (1) the optimal mix of global bio threat prevention measures, and (2) whether these measures should be enforced by a comprehensive global regime or left to voluntary national implementation of best practices with little or no global enforcement.

There is broad agreement about the prevention measures that could be promoted. Experts disagree, however, about how far down this list of prevention measures to proceed. At the top of the list would be challenging but relatively easier issues, including laboratory biosafety practices that aim to prevent accidental exposures and releases. Next would likely be laboratory biosecurity practices that reduce the risk of misuse by limiting access to dangerous pathogens to certain individuals. Further down the list might be certification of professional competencies in the life sciences. Particularly contentious topics, such as limiting dual-use research and publication, might fall toward the bottom of this list.

The second choice is determining whether the enactment of these measures should proceed top-down or bottom-up. A top-down approach, for example, could involve a binding global treaty or United Nations Security Council resolution that requires countries to adjust their national laws and regulations. A bottom-up approach could engage individual communities, reaching out to scientists, law enforcement, and other nations. Such an approach could result in national regulation, but it would include little to no global enforcement.

There are arguments for all of these outcomes. The right answer may entail a suite of bio threat prevention initiatives, each with different levels of enforcement. One example of such a solution could be a series of global standards, coordinated through an international standards organization. Each group of standards would target different components of the life sciences enterprise—for example, laboratory biorisk management, professional competencies, and managing dual-use research.

These standards gradually could become more widely and stringently enforced. For instance, the standards could initially be established as international best practices. Economic pressures may prompt the community to pursue the creation of accreditation or certification systems to validate that a particular facility meets a certain standard or element of a standard. Prestigious journals could decide to publish only research that complies with appropriate bio threat prevention standards. Although an international verification regime seems unlikely, certain countries may independently decide to implement some standards as national regulations.[17]

These standards gradually could become more widely and stringently enforced.

At all points along the path toward more robust enforcement, standards could complement and enhance international outreach and assistance efforts. The commitment of

high-level resources could generate interest in bio threat prevention among foreign bureaucrats, nudging governments with a wide range of interests and priorities toward renewed prevention efforts that are coordinated with the emerging global norm. In addition to changed policies, invigorated interest on the part of foreign governments could produce new opportunities for coordination, such as sharing intelligence related to the implementation of new biosecurity policy.

Further, the process of negotiating a set of standards could facilitate awareness and build productive partnerships between security and scientific communities. On the security side, this discussion can increase the sensitivity of regulators and law enforcement to the demands of scientific research and facilitate the collection and coordination of information regarding known or potential adversaries with an interest in bio threats. On the scientific side, this discussion can raise awareness regarding the risk of misuse of biological agents or technologies. Partnership between the security and research enterprises is necessary to revise and update government policy, and identify where regulation is inappropriate. Absent such efforts, regulation will be neither well enforced nor up-to-date with rapid changes in the life sciences. Informed scientific communities seem open to cooperation as long as standards are not unduly onerous or expensive.[18] Outreach efforts are underway—the U.S. FBI, among other agencies, has advanced cooperation with relevant scientific communities—but, in order to produce widespread global change, these programs need the top-down support that would come from a whole-of-government commitment to global bio threat prevention standards.

The process of negotiating these standards must be attentive to the differences among affected communities. At the same time, the significance of these differences from the perspective of bio threat prevention should not be overstated. Some types of standards—such as those concerning dual-use research with infectious agents—would affect only a relatively specialized subset of life sciences activities. Further, although day-to-day procedures are vastly different between small public health clinics and multinational pharmaceutical companies, commonalities exist in the conditions required to manage the risks of working with dangerous materials at these disparate sites, and all major life sciences groups have a professional interest in avoiding the misuse of biological agents. As a result, there exists significant space for a meaningful agreement.

Action Step: *Identify an optimal mix of domestic policies and global initiatives.*

The National Security Council should direct the development of a paper for principals-level review, six months after completion of the cost-benefit assessment, outlining in light of the assessment's findings (1) how the United States should alter its total set of bio threat

prevention measures (if at all) to better balance their costs and benefits; and (2) the content and specific enforcement plans (if any) for a global bio threat prevention initiative.

Tactics: Mapping a Path Forward

The negotiation of a global bio threat prevention initiative would be complicated. A successful effort probably needs reinforcing (or at least not counterproductive) efforts at several levels, including: (1) the international level (United Nations, Biological Weapons Convention, World Health Organization, etc.); (2) the national government level including security, counterterrorism, public/animal health, and life science research officials; (3) the professional community level (life science researchers, public/animal health professionals, lab technicians, etc.); (4) the private-sector level, both large pharmaceuticals and emerging biotech companies; (5) the "thought-leader" or champion level to spur progress across both formal and informal domains; and (6) the individual facility and the principal investigator level. None of these levels can individually implement a comprehensive solution, so awareness of the others' actions and perspectives and a commitment to cooperative progress are imperative in the long term.

There are many viable tactical paths to advance this initiative. Selecting and refining one should be a first order of business. If the USG decides to pursue the development of a global bio threat prevention initiative, one tactical approach would be to identify industries and nations that would support such an effort. An international, public-private partnership, including representatives from the public/animal health community, the pharmaceutical and biotech industries, the security community, and other key stakeholders, could work together to develop a consensus on content and method of implementation. This partnership could convene representative technical experts from around the world, and specific technical committees could be tasked with developing standards in specific disciplines of relevance to biosecurity—including, for example, standards for laboratory biorisk management, professional competencies, and managing dual-use research. This process would create groups of experts who, under the framework established by the convening organization, could update and refine the standards as the scientific and technical context rapidly progresses.

Once the technical committees have agreed to a set of standards in their respective areas, the representatives involved in creating them, along with the foreign ministries involved in their development, could advocate for their global adoption. This group would need to work closely with relevant international organizations, including the United Nations, the World Health Organization, the World Organization for Animal Health, and the Biological Weapons Convention.

Current efforts to develop such global standards are limited, and encountering difficulties. One example is the European Committee for Standardization's (CEN's) CEN Workshop Agreement (CWA) 15793 on Laboratory Biorisk Management.[19] This document provides performance-based risk management standards for life sciences laboratories. Related guidance documents also have been created and updated by the World Health Organization (WHO)

Standards that can genuinely contribute to global bio threat prevention need to be broader in scope and duration, developed in a much more transparent and participatory process, and adopted globally with the support of significant political bodies and professional organizations.

and the U.S. Department of Health and Human Services (HHS).[20] Although CWA 15793 goes further than WHO or HHS guidance in describing expectations for a management structure to implement biosafety and biosecurity, it also has some significant limitations. First, it was created by a relatively small group of technical experts from only 24 countries. It was not subject to the broad international scrutiny and consensus of a formal global standard. Second, it is a temporary document that is due to expire in September 2014. Third, since it is not an official standard, an accreditation or certification system cannot be created to sustain it. Fourth, it is often incorrectly perceived to be "European" guidance and not internationally relevant. Finally, this CWA is limited in both scope and ambition. It is directed at traditional laboratory operations and does not address the wider biomedical/bioscience community, nor does it contain guidance on key issues, such as dual-use research or professional competency.

Standards that can genuinely contribute to global bio threat prevention need to be broader in scope and duration, developed in a much more transparent and participatory process, and adopted globally with the support of significant political bodies and professional organizations.

Significant tactical judgment calls would be required. What group or organization should have the day-to-day responsibility for moving the initiative forward? Should all components of the initiative be negotiated simultaneously, or should a separate working group craft each distinct component? How are the members of that group connected to the foreign ministries of the nations seeking to advance the initiative? How should international organizations be included? Who are the stakeholders and, given their extreme diversity, how could they practicably be included in a negotiating or consultative process? How large a coalition of the willing is necessary to make the initial adoption of the standards meaningful? Should potential "tough cases" be engaged at the outset, or after a consensus begins to take shape? What degree of confidence is needed that other avowed members of the coalition are actually following the standards?

As global standards further develop, the United States should consider normalizing U.S. rules and guidance with the emerging global norms.

Action Step: *Knit together and secure commitment from diverse communities.*

The National Security Council should task the development of a paper, within two months of the policy review, that outlines a specific plan to commit high-level resources to pursue the review's recommended initiatives. The plan should identify, for example, governmental staff to dedicate to the initiative; scientific, public/animal health, and industry representatives to serve as advocates; like-minded or influential states to approach early on; and international forums to push the initiative.

Conclusion

The biosciences are growing increasingly global and complex, producing both great opportunities and grave dangers for society. The United States must navigate these rapidly changing dynamics, working to minimize the risk of devastating bioattack while maximizing the potential of its research enterprise. This is no easy goal. It will require a reevaluation with three components: (1) a high-level assessment of the costs and benefits of bio threat prevention; (2) identifying the optimal content of domestic policies and global initiatives; and (3) a robust, broadly supported tactical plan to pursue these measures. These three action steps must go together. Without the first, the United States risks an overburdened life sciences sector. Without the second, the United States may pursue only ad hoc global efforts. And without the third, U.S. bioscience will disproportionately shoulder the costs of desirable safeguards while threats continue to grow abroad.

The path forward is difficult and complex, but it is also worthy and important. Anyone who has closely studied the impact of an effective biological attack on a civilian population would vastly prefer to stop the attack before it was launched. The type of analyses and initiatives urged here may show the path to such a strategy and help generate the momentum to pursue it.

Endnotes

1. See Gardiner Harris, "China and India Making Inroads in Biotech Drugs," *New York Times*, September 18, 2011, http://www.nytimes.com/2011/09/19/health/policy/19drug.html?pagewanted=all&_r=0; Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism* (New York: Vintage Books, 2008); and National Research Council of the National Academies, *Biotechnology Research in an Age of Terrorism* (Washington, DC: National Academies Press, 2004).

2. Richard Danzig and Pamela B. Berkowsky, "Why Should We Be Concerned about Biological Warfare?" in *Biological Weapons: Limiting the Threat*, ed. Joshua Lederberg (Cambridge, MA: MIT Press, 1999), 9–10; and National Security Council, *National Strategy for Countering Biological Threats* (Washington, DC: National Security Council, 2009), 1.

3. Biological materials can be acquired in a number of ways. The most basic are isolating the pathogen from nature (five of the six most dangerous pathogens can be found in nature; the Centers for Disease Control and Prevention, CDC, lists 6 "Category A" agents—anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers—all of which can be found in nature with the exception of smallpox; see http://www.bt.cdc.gov/agent/agentlist-category.asp) or taking the pathogen from a public health lab or other life sciences facility. A more advanced adversary could create that same naturally occurring pathogen from de novo synthesis, or genetically modify a naturally occurring pathogen, increasing its lethality or infectiousness. In high-end labs, a novel pathogen could be constructed, potentially giving rise to new disease functions and mechanisms. Such a pathogen would present a particularly difficult challenge to defend against; it could defeat a stockpiled medical countermeasure, for example.

Expertise is harder to define and control. It can be acquired through activities ranging from basic life sciences training at universities to high-end publications about the effects of genetic manipulation on lethality and infectiousness. Both abstract and tacit, experiential knowledge are necessary to successfully construct and disseminate a biological weapon.

4. There are important interactive effects between the various strategies of prevention, deterrence, and defense. For example, a demonstrably stronger defense capability would reduce the "benefits" that an adversary could anticipate accruing from an attack and hence should on balance strengthen deterrence.

5. The DURC policy was developed too late to apply to the NIH-funded Dutch laboratory whose research controversially identified mutations that enhance the transmissibility of H5N1. See National Institutes of Health, *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern* (March 29, 2012), http://oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf.

6. Robert H. Carlson, *Biology Is Technology: The Promise, Peril, and New Business of Engineering Life* (Cambridge, MA: Harvard University Press, 2011).

7. For instance, Chinese scientists built the torque teno virus (TTV) from scratch in 2011. See Zheng Hou and Gengfu Xiao, "Total chemical synthesis, assembly of human torque teno virus genome," *Virologica Sinica* 26, issue 3 (June 2011): 181–89.

8. See U.S. Defense Threat Reduction Agency, "Biological Threat Reduction Program," http://www.dtra.mil/Missions/Nunn-Lugar/BiologicalThreatReductionProgram.aspx; and U.S. Department of State, "Biosecurity Engagement Program," http://www.bepstate.net.

9. Defense Threat Reduction Agency, *Fiscal Year 2012 Budget Estimate: Cooperative Threat Reduction Program* (February 2011), http://comptroller.defense.gov/defbudget/fy2012/budget_justification/pdfs/01_Operation_and_Maintenance/O_M_VOL_1_PARTS/O_M_VOL_1_BASE_PARTS/0134_CTR_OP-5_FY_2012.pdf.

10. National Security Council, *National Strategy for Countering Biological Threats*, 19–20.

11. See U.S. Department of State, "G8 Global Partnership Agrees to Biosecurity Deliverables Document," 2012, http://www.state.gov/t/isn/gp2012/rls/docs/196021.htm. The United States was the chair of the GP in 2012.

12. There are exceptions to this rule. It is possible to create "win-win" outcomes that align seemingly disparate goals. For example, developing medical diagnostics that could enable public health labs to diagnose diseases without culturing disease cells would both enhance the speed and precision of the medical diagnosis and eliminate the need to maintain collections of disease cultures in dispersed, poorly secured public or animal health clinics. Further, a compelling case can be made that improved biosafety and biosecurity can enhance a facility's efficiency and strengthen the quality of its results. Bio threat prevention strategy should identify and take advantage of these potential positive synergies.

13. David R. Franz and James W. LeDuc, "Balancing Our Approach to the Insider Threat," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 9, no. 3 (2011); and Robert Roos, "Changes in select agent rules concern public health labs," *CIRDAP News*, October 10, 2012, http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/oct1012select.html.

14. See Appendix I for a complete account of both domestic and international bio threat prevention efforts.

15. The differences between a legitimate public health program and an offensive military program could be slight. Signs that would seem to distinguish a weapons program—including the types of pathogens selected, the nature of any modifications made to these pathogens, or the development of specialized delivery capabilities such as aerosolization—could plausibly be components of biodefense or even pharmaceutical research. While difficult to prove the existence of an offensive program, it is also extraordinarily difficult for an inspection team to verify or validate that such work is not underway. Does passing an inspection mean that all of a facility's work is legitimate? Could an inspection falsely accuse a legitimate facility of pursuing illegitimate weapons work? These difficult questions complicate international acquiescence to any inspection regime.

16. The Government Accountability Office (GAO) recently advocated that a single U.S. agency be given responsibility for tracking the expansion of high-containment facilities. Government Accountability Office, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-574 (September 2009), http://www.gao.gov/new.items/d09574.pdf, 66–69.

17. The Global Food Safety Initiative (GFSI), which has proven quite effective in working to standardize food safety issues internationally, is an example of how such a process can succeed. See http://www.mygfsi.com/.

18. See, for example, Brian Rappert, "A teachable moment for biological weapons: The Seventh BWC Review Conference and the need for international cooperation in education," *Bulletin of the Atomic Scientists* 67, no. 3 (2011): 19–23.

19. This document was created initially in 2008 and renewed in 2011, and a guidance document published in 2012 provided notes to facilitate implementation. See CWA 15793:2011, *Laboratory biorisk management* (September 2011), http://www.uab.cat/servlet/BlobServer?blobtable=Document&blobcol=urldocument&blobheader=application/pdf&blobkey=id&blobwhere=1345644148300&blobnocache=true; and CWA 16393:2012, *Laboratory biorisk management—Guidelines for the implementation of CWA 15793:2008* (January 2012), http://www.su.uzh.ch/activities/bio/links/16393.pdf.

20. See U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, DC: HHS, December 2009), http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf; World Health Organization, *Laboratory Biosecurity Guidance* (Geneva: WHO, September 2006), http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf; and World Health Organization, *Laboratory Biosafety Manual*, 3rd ed. (Geneva: WHO, 2004), http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf.

Appendix I

Bio Threat Prevention "Toolbox"

A Summary of Current Efforts

Tool Category	Tools	Definition and/or Example	Candidate Enforcement Nodes					
			International enforcement	International treaties	International coalition of the willing	National laws and regulations	Norms and codes	Person-to-person
Nationally or supranationally imposed initiatives	Inspections	Historical BWC proposals; similar to OPCW/IAEA in concept						
	National Criminalization	BWC/UN1540 adherence						
	Export Controls	Australia Group adherence; national measures						
	National Biosecurity System	Registration or licensing regime; Select agent rule-type legislation						
	Monitoring and Interdiction	Cooperative and non-cooperative monitoring; PSI is an example of interdiction						
Facility operations based initiatives	Consolidation	Reduce number of facilities with dangerous agents						
	Biorisk Management Standards	Biorisk management (biosafety and biosecurity) from cradle to grave						
	Training of Professionals	Potential certification of technical biorisk management competencies						
Science and knowledge based initiatives	Disease Surveillance	Identifying, characterizing, and controlling outbreaks of dangerous diseases to make acquisition from environment more difficult						
	Technical Constraints	Proliferation-resistant biotechnology - e.g. to prevent undesirable gene combinations						
	Industry Standards	Intervention to monitor networks of high-end equipment; Gene foundries verifying legitimacy of genomic sequence orders and tracking shipments and receipt						
	Technology Transfer/Capacity Building	Train/engage scientists to broaden security sensitivity of the technical community; to enhance specific technical capabilities; and to redirect weapons capabilities, and promote legitimate skills and professional status						
	Dual Use Oversight	Risk assessment and public communication tools; potential experiment pre-approval or cradle-to-grave management						

This appendix provides a summary of bio threat prevention activities that are underway. This cover chart displays a complete "toolbox" of bio threat prevention tools, each of which could be enacted via multiple enforcement nodes. Some of these nodes represent ongoing efforts; others are theoretical. The first step in revitalizing bio threat prevention policy must be to fill in these empty boxes. An understanding of the range of potential options is needed for a holistic, integrative assessment of the proper

A Deeper Look at the Tool Categories

Nationally or supra-nationally imposed initiatives

Tools	Ongoing Efforts
Inspections	• No ongoing efforts.
National Criminalization	• The Geneva Protocol is a post-WWI, No-First-Use agreement for biological (and chemical) weapons, ratified by the United States in 1975. Although there are no verification or enforcement provisions, the Geneva Protocol has contributed to the development of a norm against biological weapons use. • The 1972 Biological and Toxin Weapons Convention (BWC) requires signatories to prohibit and prevent the development, production, stockpiling, acquisition, or retention of agents, toxins, weapons, equipment and means of delivery related to biological weapons. The U.S. ratified it in 1974. The treaty seems to have created a meaningful but hardly foolproof norm against biological weapons. The Soviet Union/Russia is one of several states known to have pursued biological weapons after ratifying. The treaty has no inspection or verification provisions; such provisions are implausible given the difficulty of distinguishing offensive and defensive research. • The BWC Implementation Support Unit (ISU) provides support and assistance for implementation and confidence-building measures (self-reports on outbreaks, publications, legislation, and research efforts), but the ISU is small (3 full-time staff) and lacks a clear international mandate. • The 2001 USA PATRIOT Act criminalizes possession of biological materials of a type or quantity not reasonably justified by a bona fide research or peaceful purpose. The Bush administration envisioned an effort to criminalize biological weapons by countries throughout the world as a superior alternative to the one-size-fits-all BWC, whose strengthening would require onerous negotiations. This approach gives greater latitude to domestic law enforcement. However, its success has been limited by a lack of international political will; as of September 2002, ninety-eight BWC members had failed to report on progress towards criminalization. Some contend that such legislation unduly inhibits the pursuit of science. • United Nations Security Council Resolution 1540 (UNSCR 1540), adopted in 2004, imposes binding obligations on all States to adopt legislation to prevent the proliferation of weapons of mass destruction, including biological weapons, and their means of delivery, and to establish domestic controls over related materials to prevent their misuse. While it has been a useful vehicle for discussions, many states have not submitted required national reports on compliance, and measuring the effectiveness of implementation is difficult even with reports.
Export Controls	• The Australia Group (AG) is an informal coalition of countries which, through the harmonization of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons. The AG Common Control Lists include dual-use biological equipment and related technology and software, biological agents, plant pathogens, and animal pathogens. The AG is only a forum for discussion among participating states; it has no enforcement authority. Further, the coalition does not include a number of countries with rapidly-growing biotechnology sectors, such as China and India. • The United States requires export licenses for pathogens and toxins on the Commerce Control List (CCL) though Export Administration Regulations (EAR) and for pathogens and toxins controlled by the International Traffic in Arms Regulations (ITAR) under Category XIV of the US Munitions List (USML). Given the need to protect U.S. industry as well as bureaucratic difficulties, these lists are slow to change, and many other countries do not have particularly stringent export regulations.
National Biosecurity System	• The United States has a legal certification regime, granting individuals access to work with biological select agents and toxins (BSAT). The select agent rules affect: people, places, and agents. The institution must register with HHS Centers for Disease Control and Prevention (CDC) or the USDA Animal and Plant Health Inspection Service (APHIS). Individuals with access to BSAT must undergo a security risk assessment (SRA) performed by the FBI every three years. In order for individuals to be approved, they must be affiliated with an institution and a Principal Investigator who has registered with the CDC or APHIS. Required documentation includes background checks, security plans, laboratory inspections, and inventories. “Restricted persons,” as defined in the USA PATRIOT Act, are prohibited from working with BSAT. The U.S. recently increased the amount of protections required to work with 11 agents of particular concern. These laws are criticized by some for damaging the competitiveness of U.S. industry and limiting the ability of the Armed Forces, particularly the Army, to engage in cooperative public health research abroad. • A number of other countries have similar regimes. Canada has a legal licensing regime, which authorizes research ventures involving pathogens of concern. Israel provides legal authorization to institutions that possess disease-causing biological agents, which have institutional committees to oversee research. Denmark has a licensing and inspection procedure that permits research institutions, pharmaceutical companies, and hospital labs, to work with certain biological agents and dual-use components. Not all national biosecurity systems are select agent-based, however. China, for example, has a tiered, biosafety/containment-focused legal accreditation regime for work in government-funded labs with various pathogens. A large segment of Chinese biosciences – including private industry and hospitals – are not covered by these regulations.
Monitoring and Interdiction	• The Proliferation Security Initiative (PSI) is a global effort to stop trafficking of WMD. A coalition of more than 90 countries has committed to strengthening national interdiction capabilities and international information sharing. Although this framework could be used to interdict bioweapons components in theory, in practice its focus is almost entirely nuclear. China, for example, does not participate.

Facility operations based initiatives

Tools	Ongoing Efforts
Consolidation	• The Cooperative Threat Reduction (CTR) program, designed to secure WMD in the former Soviet Union (FSU), has shifted its focus gradually from fissile materials towards biosecurity. The DoD's Cooperative Biological Engagement Program (CBEP-formerly Biological Threat Reduction Program, or BTRP) was projected to receive over half of Congressionally-allocated CTR funding in FY 2012, or nearly $260 million. • One CBEP initiative continues CTR's emphasis on consolidation, or working to destroy or secure especially dangerous pathogens (EDPs) at their source. These efforts typically involve investment in costly facilities and capabilities, and are only feasible in countries with relatively small life science sectors. Given the global nature of the biological threat, these initiatives may prove difficult to sustain or replicate, as funding outlays may decline over time.
Biorisk Management Standards	• The development of codes of conduct spurs valuable discussions, but it's unclear whether these insights percolate down to the laboratories where they need to be heard. The discussions are the true strength of this approach, since raising awareness is crucial, but the documents themselves have no enforcement authority and tend to be vague. Specific examples of such efforts include: o The Royal Netherlands Academy of Arts and Sciences (KNAW) has published a code of conduct that seeks to inform and guide individual institutions. It is unclear if this model has been replicated in other countries, or seriously enforced by facilities located in the Netherlands. o The National Science Advisory Board on Biosecurity (NSABB), a federal advisory committee that consists of members from a broad array of professional communities, released a report on considerations for developing and disseminating a code of conduct for dual use research. o The InterAcademy Panel (IAP) convened National Academies from various countries to produce a statement outlining guidelines for codes of conduct. This statement and the discussions that produced it are unique in that they include representatives from countries with emerging bioscience sectors, including China and India. • Standards provide more specific guidance than codes of conduct, facilitating implementation of biosecurity practices. However, there exist no acknowledged global standards, and existing documents cover only a portion of biosecurity topics—excluding, for instance, dual use research. Examples include: o The Office of Safety, Health, and Environment (OSHE) at the U.S. Centers for Disease Control and Prevention (CDC) periodically updates two publications containing biosafety guidelines: *Biosafety in Microbiological and Medical Laboratories (BMBL)* and *Primary Containment for Biohazards: Selection, Installation, and Use of Biosafety Cabinets*. CDC hosts biennial international symposia on biosafety to promote these guidelines abroad. o The World Health Organization (WHO) published its most recent (third edition) *Laboratory Biosafety Manual* in 2004 and extended these principles into biosecurity guidelines in its *Laboratory Biosecurity Guidance*, published in September 2006. In 2010, it published an integrative guidance on research excellence, ethics, and laboratory biosafety and biosecurity, *Responsible Life Sciences Research for Global Health Security*. These guidance documents have no regulatory authority, but are intended to catalyze development of codes of practice. o The European Committee for Standardisation (CEN) created a standards document outlining the components of a biorisk management system in CEN Workshop Agreement (CWA) 15793:2008. This code was designed with the involvement of key stakeholders, including non-European representatives. However, CWA 15793 is frequently understood as a European standard; it has not secured the buy-in required of global standards.
Training of Professionals	• Biosafety associations are widely dispersed, which means that the biosafety community extends to some unexpected corners of the world, including for example Bangladesh and Morocco. Further, this community is fairly active, particularly in the United States and Europe. The major difficulties are generating that degree of activity in other parts of the world and, more importantly, ensuring that biosafety becomes an important component of the day-to-day operations of laboratories in places where biosafety associations are active. Examples of biosafety associations include: o The International Federation of Biosafety Associations coordinates and assists the efforts of other BSAs, with an emphasis on public and animal health. o The American Biological Safety Association, which holds an annual conference and gives credentials to trained professionals. o The Asia-Pacific Biosafety Association hosts conferences for biosafety professionals in the region. o The European Biological Safety Association hosts conferences in addition to lobbying on behalf of its members.

Science and knowledge based initiatives

Tools	Ongoing Efforts
Technology Transfer / Capacity Building	• DoD's Cooperative Biological Engagement Program (CBEP) and the State Department's Biosecurity Engagement Program (BEP) engage scientists to support safe, secure, and ethical work in the life sciences. Specific outreach is limited to a fairly small number of international partners. Sponsorship of events and attendance of individuals, while broader in reach, may be shallower in effect. • The Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP), pursued in the context of the G8, coordinates global bio-engagement and facilitates other countries' international biosecurity assistance, including outreach programs. Broadening international biosecurity efforts to include the international community could improve the sustainability of these programs—distributing the high cost among an increasing number of players. • The Federal Bureau of Investigation (FBI) Biological Countermeasures Unit (BCU) performs outreach to scientific communities to improve their security sensitivity and receive advice on emerging threats. These efforts include Regional FBI Academic Biosecurity Workshops at colleges and universities; funding the International Genetically Engineered Machine (iGEM) Competition; the Synthetic Biology Tripwire Initiative, which facilitates reporting of suspicious requests and mitigating risks for abuse; and outreach to Do-It-Yourself Biology (DIYbio). The FBI has WMD coordinators at each of its 56 FBI Field Offices who specialize in chemical, biological, radiological, and nuclear (CBRN) threats and incidents. It has shared best practices with other governments, including Canada and EU members such as Denmark and Germany. • Education efforts are numerous and diverse. They have achieved many important successes, but lack of awareness is so widespread that they are reaching their limit in the absence of further top-down support. Examples include NSABB outreach and education, an annual biosecurity meeting at the Biotechnology Industry Organization (BIO) sponsored by DHHS, biosecurity courses offered at universities (such as the University of Bradford), and dual-use education workshops run by the National Academy of Sciences.
Disease Surveillance	• The CBEP funds the development of partner capacity to develop and sustain effective disease surveillance systems. These systems have great public and animal health benefit and may prove useful for responding to natural and man-made outbreaks, but play a limited role in bio threat prevention. • Some GP assistance facilitates implementation of the World Health Organization (WHO) International Health Regulations (IHR). The IHR are designed to improve national, regional, and global public health security, with an emphasis on disease surveillance and response capabilities. They are legally binding on and should be implemented by the 194 State Parties to the IHR. The WHO recently launched an IHR implementation course to facilitate adherence. However, despite these efforts, many countries failed to meet the June 2012 implementation deadline and, given limited resources, competing priorities, and political challenges, enforcement is likely to remain difficult. • The Centers for Disease Control and Prevention (CDC) offers the Field Epidemiology Training Program (FETP) and the Field Epidemiology and Laboratory Training Program (FELTP). These are two-year training programs that seek to help foreign countries develop, set up, and implement dynamic public health strategies to improve and strengthen their public health system and infrastructure. These initiatives are focused on public health, not furthering bio threat prevention.
Technical Constraints	• The Defense Advanced Research Projects Agency's (DARPA's) Chronicle of Lineage Indicative of Origins (CLIO) funds a Gene Guards thrust area. This thrust area seeks approaches and methodologies to increase the safety of research involving dangerous pathogens and provide secure access to products of proprietary microorganisms used in biomanufacture. This objective would be achieved through the direct modification of the microorganism, with the goal of preventing genetic manipulation to enhance pathogen virulence. DARPA has led the development of many advanced technologies and, although Gene Guard is in its early phases, this venture has great potential. If developed, a second challenge would be effectively bringing this technology to market.
Industry Standards	• The International Association of Synthetic Biology (IASB) and International Gene Synthesis Consortium (IGSC) have developed protocols for screening sales of gene sequences. Screening attempts to determine whether the gene segments ordered by an individual could be used in combination to make dangerous pathogens. These groups cover at least 80 percent of the market for gene segments—an impressive accomplishment, although it would not be difficult to buy from the other 20 percent. • The United States Department of Health and Human Services (HHS) has issued "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA." This non-binding guidance includes customer screening (to establish the legitimacy of customers ordering synthetic dsDNA sequences), sequence screening (to identify when "sequences of concern" are ordered), and follow-up screening (to confirm that end-users are acting legitimately and within their authority). Guidance has both lower industry costs and greater flexibility than regulation—many think it should be the preferred approach to emerging technologies. Some have criticized this particular guidance for relying too much on automated review. • The NIH "Guidelines for Research Involving Recombinant DNA Molecules," created by the Recombinant DNA Advisory Committee (RAC), are research standards dating from the Asilomar Conference of 1975. They form the basis of the Institutional Biosafety Committee (IBC) system, which is employed to oversee recombinant DNA research by all federal research institutions and all other research institutions receiving support from NIH. These guidelines are periodically updated—most recently in October 2011.
Dual Use Oversight	• The United States Government (USG) recently released "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern" (or DURC). This policy requires federal funders to identify DURC and pursue a risk-mitigation plan that can include modifying research design or conduct, regularly reviewing research findings, or classification of research. This policy is significant since it applies to all federal agencies that fund life sciences research. Further implementation remains to come, however, potentially in the form of common compliance standards across agencies or requirements for researchers.

Appendix II
Roundtables

The following is a list of individuals who participated in at least one of the three roundtable discussions that generated this report. Although their contributions helped to shape an understanding of these complex issues, the views contained in this report are the authors' alone, and should not be understood to represent those of any individual listed below. The authors, though, want to express their gratitude to these individuals for their insights, suggestions, kindness, and work to strengthen bio threat prevention and hence international safety and security.

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Mr. Tim Trevan, Executive Director, International Council for the Life Sciences

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Author Biographies

Carol Kuntz was a visiting fellow with the CSIS International Security Program in 2011–2012, having served as a career professional in the U.S. Department of Defense (DoD) since 1988. Dr. Kuntz was the homeland security adviser to Vice President Dick Cheney for the five years after the 9/11 terrorist attacks against the United States and a member of the Homeland Security Deputies Committee. In these capacities, she played a key role in developing presidential initiatives to protect against biological terrorism as government biodefense expenditures increased from about $50 million in 2001 to some $8 billion in 2009. Dr. Kuntz also worked on grand strategy, helping to craft strategic guidance for DoD at the end of the Cold War and working to translate that strategy into the size and characteristics of the department's forces and programs. Dr. Kuntz received her Ph.D. from the Massachusetts Institute of Technology, her M.P.A. from Princeton University, and her B.A. from Cornell University.

Reynolds Salerno is senior manager of the International Cooperative Threat Reduction (CTR) programs in the Global Security Center at Sandia National Laboratories. Dr. Salerno's programs enhance U.S. and international security by reducing biological, chemical, and nuclear threats worldwide. Many different U.S. government agencies, as well as foreign governments and international agencies, sponsor the work of Sandia's CTR programs. His International Biological Threat Reduction team has done extensive international work on laboratory biosafety, biosecurity, biocontainment, and infectious-disease diagnostics and control. Dr. Salerno and his team have worked with the World Health Organization since 2004 to develop international laboratory biosecurity guidelines. Dr. Salerno has also served as a member of numerous working groups, including the U.S. delegation to the Biological Weapons Convention, the Dual-Use Biological Research Guidelines working group of the U.S. National Science Advisory Board for Biosecurity, the International Criminal and Police Organization's Counter-Bioterrorism Board of Experts, and the International Federation of Biosafety Associations. Dr. Salerno received his Ph.D. from Yale University and his B.A. from Middlebury College.

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