The Global Forum on Biorisks

Toward Effective Management and Governance of Biological Risks

A Report of the CSIS Homeland Security Program

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For more than 15 years, policymakers and security analysts have been concerned that governments, terrorists, or even a crazed individual would misuse the rapid advances in the life sciences to cause widespread death and disruption. Traditional proliferation concerns fostered by discoveries of illicit governmental biological weapons programs, together with novel worries provoked by emerging terrorist interest in such capabilities, elevated the issue of biological security on the policy agenda. In the autumn of 2001, following the tragedy of the 9/11 attacks, it seemed that people’s worst fears were to be realized as anthrax-filled letters resulted in five deaths and, more broadly, sparked extensive anxiety that disrupted the daily lives of countless individuals. As a result, between the time of the “Amerithrax” letters and today, the United States has spent, according to some estimates, more than $50 billion to protect itself from biological attacks.

The deliberate misuse of the life sciences and related technology for harm challenges existing policy mechanisms in a number of ways. Given the complexity of the issues and of the stakes involved, it is difficult to arrive at a common understanding of the threat, let alone the solutions. The speed at which dimensions of the risk are changing makes it difficult for slow-reacting governments to keep up and provide appropriate policy and regulatory responses. The expanding scope of the challenge has introduced a requirement for many more players to be involved in the process of managing biological risks. Traditional institutions and measures appear less and less able to provide adequate governance for an increasingly unfamiliar issue characterized by novel dynamics and fostered by a convergence of recent global trends.

This report addresses these concerns. It first considers the evolving challenges posed by naturally occurring disease as well as the potential misuse of the life sciences and related technology, including a number of trends whose convergence imbeds biosecurity challenges with unfamiliar dimensions. It then considers the variety of professional communities that are stakeholders in managing biological risks, presenting their different perspectives. It goes on to assess factors that must be incorporated into an effective strategy for countering this evolving challenge, and it concludes by introducing the Global Forum on Biorisks—a comprehensive, integrated, international, and multisectoral approach to dissuading, mitigating, interdicting, countering, and responding to biological threats of natural, accidental, or intentional origin.

This report is the culmination of several years of research, work, and collaboration with many individuals in many countries and in many institutions. Although there are far too many to list here, we would like to recognize a few individuals—Katherine Phillips, Megan Wilcox-Fogel, Ethan Wais, and Jacqueline Joliat, in particular—whose exceptional work on, and dedication to, this project made possible all we have accomplished. Many more also contributed to the discussions and research underlying the approach we present below, and we are indebted to them all. Finally, the authors gratefully acknowledge the John D. and Catherine T. MacArthur Foundation and the Carnegie Corporation of New York for their financial support of this project. We could not be more appreciative.
1. Increasing Biological Risks

The Challenge of Infectious Disease

Infectious diseases are responsible for more than one-fourth of global deaths.\(^2\) Yet despite their long-standing nature and notwithstanding the development of medical and public health technologies, the disease threat is constantly changing. Traditional diseases have greater impact in crowded societies that increase the opportunities for diseases to develop and spread. New diseases continually emerge as microorganisms evolve in ways that evade or overcome the human immune system and as humans spread into new environments and become exposed to formerly unfamiliar pathogens. Even as antibiotic and antiviral drugs are developed to fight disease, the pathogens targeted by these drugs mutate to defeat them.

In today’s highly mobile and interconnected society, people can spread disease to distant parts of the world before an outbreak is even recognized in its area of origin, much less contained. Recent examples include an outbreak of plague originating in Surat, India, in 1994, the SARS epidemic in 2002 and 2003, and most recently the global pandemic of novel H1N1 influenza in 2009. Trade and travel disruptions that result from ad hoc or coordinated attempts to control a disease’s spread can have severe economic impacts, as illustrated not only by human disease outbreaks but agricultural outbreaks such as foot and mouth epidemics in Taiwan in 1997 and the United Kingdom in 2001. Preventing, detecting, mitigating, and responding to natural disease outbreaks remains an issue of great concern—one that is very familiar to governments around the world, but one that poses new challenges as well.

The Challenge of Deliberate Misuse

Far less familiar to governments and policymakers is the threat that disease will be used deliberately as a weapon. In fact, few security threats facing society manifest as great a discrepancy between the potential for large-scale harm and the paucity of historical use as biological weapons and bioterrorism. More than half a century ago, nation-state biological weapons programs demonstrated the ability to produce and disseminate harmful biological organisms on a large scale. In the last 20 to 30 years, however, the development and diffusion of bioscience and biotechnology for fully legitimate reasons have created a situation in which what used to require national-level programs is now within reach of non-state groups and, perhaps, even individuals.

Growing and Diffusing Capabilities

The biological sciences and biotechnology are pervasively “dual-use,” meaning not only that they have both legitimate and illegitimate (i.e., harmful) applications, but also that the legitimate ap-

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Applications are ones that should be actively promoted, enhanced, and disseminated, and not just tolerated. Societies around the world deserve access to safe, cheap, and nutritious food, clean water, medical care, economic advancement, improved quality of life, and the other benefits that biological science and biotechnology can help provide, notwithstanding the potential harm that these capabilities can do if misused.

Practically every material, technology, or process necessary to produce and deploy biological weapons can be found in nature or is available for completely legitimate purposes in the civil economy and scientific sector. In the civilian world, this suite of capabilities would not normally be present in the same institution, and both effort and specialized expertise are necessary to draw on and integrate these elements for weapons purposes. But virtually no aspect of a biological weapons or bioterror program is unique to a military or terrorist application.

The relevant science and technology are expanding in three dimensions. First, bioscience and biotechnology are becoming ever more powerful as our knowledge about and ability to manipulate living systems advance. The world is witnessing a life sciences revolution, driven by an explosion of knowledge about life at the molecular level. What we know about life today is far greater than what we knew even a decade ago, and what we know about life today is far less than what we will know a decade hence.

A key dimension of this scientific and technological advance is the speed at which it is proceeding. Like science in general, the life sciences are moving at an incredibly rapid pace. Certain branches of the life sciences are advancing even faster than indicated by Moore's Law (which describes the incredible pace of change in information technology). The important point for this report is that in the face of such rapid change, it is difficult for legal, regulatory, or even ethical systems to keep up.

Basic scientific discoveries, initially attainable only by select experts using customized, state-of-the-art tools, are being translated at an increasing rate into “commodities,” or commercial products that can be reproduced by any competent practitioner using widely available components and materials. Many people, companies, and indeed governments believe the life sciences, and biotechnology in particular, will be a key driver of their future economic growth, and their goal is to transform cutting edge science into commercial products. One example of this “commoditization” is the worldwide explosion of “gene foundries” whose goal is to provide made-to-order DNA segments on request—for profit.

This accelerating rate of change combines with the surprise inherent in scientific discovery to generate phenomena that are unexpected and even unknowable. A 2006 National Academy of Sciences study makes the point that “new and previously unanticipated paradigm shifts are very

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3. “Moore’s Law” holds that the number of transistors on a microchip doubles approximately every 18 months. Robert Carlson has shown that equipment allowing individuals to read the sequence of a DNA molecule (the biological molecule that carries an organism’s genetic code) or to synthesize DNA molecules having an arbitrary sequence has been improving in capability even more rapidly than that, when measured by the number of base pairs (DNA building blocks) that can be sequenced or synthesized by one person in one day. Robert Carlson, “The Pace and Proliferation of Biological Technologies,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 1, no. 3 (2003): 1–3.

likely to occur . . . .”\(^5\) Given that history has shown that virtually all new science and technology is explored for its potential use in the security arena, some of those surprising outcomes could well come there. Moreover, innovations are likely to emerge from surprising quarters. Countries such as India and China are particularly well placed to achieve breakthroughs, given their wealth of scientific talent and the growing resources they are devoting to relevant research and development, but innovations with potential security implications could come from virtually any country or region of the world.

Another aspect of scientific and technological trends that will have a major impact on the future proliferation environment is the convergence of various scientific fields. Dramatic advances are made possible often as a result of their interaction. As analyst Alexander Kelle notes, “many of the products flowing from the biotechnology revolution . . . are basically chemical compounds.”\(^6\) The increasingly blurred lines between biology and chemistry are especially apparent in new processes for drug discovery using combinatorial chemistry and high-throughput screening to generate significant numbers of new chemical compounds, some of which may be highly toxic. Although those results would be rejected as new drug candidates, information about these toxic substances is maintained in corporate or other databases. Were those interested in doing harm able to access such information, they may be able to identify new opportunities.

Equally, if not more important, is the convergence of biology and chemistry with other scientific and technological disciplines, particularly information technology, materials science, nanotechnology, and imaging and sensor technology. This convergence is creating new fields such as “bioinformatics” and “bionanotechnology.” These new areas of study are also combining with other technology-related trends and patterns such as automation and miniaturization. In the minds of some people, the result of this process of convergence is a transformation potentially “as powerful as the industrial revolution.”\(^7\) Most important for this assessment, the previously cited National Academies report identified several major areas of advancing science and technology that “share important features that are relevant to their potential to contribute to the future development of biological weapons.”\(^8\)

The second dimension in which the relevant science and technology are expanding is that these capabilities are becoming more widely available as they diffuse throughout the world, in developing as well as developed countries. Biotechnology is knowledge-intensive, not capital intensive, and provides an arena in which all countries can participate. And they are increasingly doing so. The number of biotechnology enterprises around the world is exploding. Examples are almost endless:

- According to Ernst and Young, Asian biotechnology growth rates in 2005 outpaced those in all other parts of the world, including North America.\(^9\)

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8. Ibid., pp. 139–213.
In Brazil, the number of biotechnology companies increased from 76 in 1993 to 354 in 2001. There are reported to be as many as 1,700 groups in the public, academic, and private sectors working on biotechnology.\textsuperscript{10}

South Korea is expected to have invested more than $4.7 billion in biotechnology between 2000 and 2007.

India already has the twelfth-largest biotechnology sector in the world as measured by the number of companies,\textsuperscript{11} and New Delhi’s Department of Biotechnology hopes to expand the biotechnology sector fivefold in five years, creating ten new biotechnology parks by 2010.\textsuperscript{12}

What is emerging, then, is a more complex reality than the one captured by the distinction between technology “haves” and “have-nots” or “developed” and “developing” countries. One term that has been employed to identify those countries that should be of special concern is “innovative developing countries” (IDCs).\textsuperscript{13} China and India are perhaps the most notable members of this group, but several others, small and large, could also be included, such as Brazil, Argentina, Cuba, South Africa, Singapore, and South Korea. Others should be expected to join them in the future.

The process of globalization has also spurred the emergence of nongovernmental entities operating on a global basis. The impact of this growth and diversity is to increase the number of channels within and among societies through which action can be taken and influence exerted. More and more these increasingly empowered non-state actors are able to express their singular interests through the tools and channels that globalization provides, allowing them to operate beyond the control of any single government. The result is that actors who would otherwise be relatively weak can have a disproportionate impact both positively and negatively. This is as true with respect to the life sciences as any other arena.

It is not just the number of possible participants in the process of proliferation that has changed, however, but also the nature of their interaction. Traditionally, proliferation of weapons of mass destruction was seen largely as the product of a hierarchical top-down process that began with a government’s commitment to seek a given capability. Today, the process is much more free form. In particular, the emergence of networks of non-state entities is one of the key factors that have empowered the wide array of players now active in the security landscape, and it has facilitated the flow and exchange of not only critical materials and equipment, but also of the increasingly important element of scientific and technological knowledge that now resides at the core of the proliferation process.

The third dimension of science and technology development is that bioscience and biotechnology are becoming ever more useful as they penetrate the marketplace in an increasing array of


applications, including not only in the health, medicine, and agricultural sectors but also in sectors such as materials and energy. Biologically based processes are increasingly being used not only to manufacture pharmaceuticals, the objective of the first major biotechnology firms, but also an increasing number of products in sectors that traditionally have had little to do with the life sciences. Thus the pool of expertise, equipment, and supplies that might facilitate the malicious use of biology is becoming richer, more extensive, and more familiar to those who might have that objective.

Increased Motivation . . .

Concern about terrorist use of chemical and biological weapons significantly intensified following the sarin gas attack in the Tokyo subway by the Aum Shinrikyo in March 1995. In the investigations that followed the attack, Aum's efforts to use biological weapons also came to light. On multiple occasions, the cult tried to disseminate anthrax, attacking Japanese targets as well as against U.S. military facilities in Japan. None of the attacks, however, were successful because the strain they used was a harmless variety.

The September 11 attacks demonstrated the willingness of terrorist groups to commit mass destruction. Previously, terrorism scholars had generally argued that terrorists were ultimately in pursuit of political objectives and that they would not be particularly interested in catastrophic attacks that might alienate otherwise sympathetic constituencies whose support the terrorists need to accomplish their goals. One lesson from the September 11 attacks, therefore, seems to be that if such a limiting threshold of destruction exists, it is much higher than had been previously thought—particularly when recalling that the goal of that attack may have been to kill everyone in one or both World Trade Center towers, totaling not 2,700 individuals but up to 100,000.

In this context, revelations that al Qaeda has been, and continues to be, interested in biological weapons are particularly troubling. Osama bin Laden and his colleagues have provided an elaborate justification for use of weapons of mass destruction, including biological weapons, and evidence discovered in Afghanistan suggest that they have done more than express interest in these capabilities.

But Uncertain Capabilities

Since Aum Shinrikyo's 1995 attack, the question of whether terrorists could develop biological weapons has been the subject of intense debate. Some experts contend that terrorists are both unwilling and unable to exploit the life sciences. Other commentators directly disagree or at least are not so sure. Stanford University's David Relman argues, for example, that today, “anyone with a high school education can use widely available protocols and prepackaged kits to modify the sequence of genes or replace genes within a microorganism; one can also purchase small, disposable, self-contained bioreactors for propagating viruses and microorganisms.” Relman's conclusions are that the full potential of past programs was never unleashed and that biological weapon

14. Milton Leitenberg of the University of Maryland, for example, argues with respect to biological weapons that "advanced genetic engineering capabilities are not likely to become available to real world terrorist groups in the near future. Judgments based on the prevalence of genetic engineering competence in the general academic molecular research community are still not useful guides to terrorist capabilities." Milton Leitenberg, Assessing the Biological Weapons and Bioterrorism Threat (Carlisle Barracks, Pa.: Strategic Studies Institute, U.S. Army War College, 2005), p. 64.
use by small groups historically was relatively unsophisticated and "far from representative of what moderately well informed groups might do today."\textsuperscript{15}

Moreover, even if terrorists cannot exploit the most cutting-edge scientific and technological capabilities, it does not mean they are impotent. Terrorists do not need the most advanced capabilities. They do not demand the same operational performance from their technology that militaries require.\textsuperscript{16} Their science and technology has to be just "good enough."

Finally, as today’s state-of-the-art laboratory advances become tomorrow's commodities, terrorists need not operate at the scientific frontier to make use of the ever-increasing power of scientific advance.

**Little Empirical Basis for Threat Assessment**

Disagreement over terrorists’ capabilities is only one issue that makes it difficult to develop a widely shared assessment of current biological threats. Little historical evidence exists on which to base threat assessments for today and the future. The existence of large-scale national biological weapons programs did not ordain large-scale use, and except for a very few isolated and (in terms of human casualties) small-scale events, neither have terrorist groups yet exploited this technology on a significant scale to do harm.

Those who base future threats on projections of past experience, therefore, find little reason for serious concern. An alternative view, however, holds that the future need not resemble the past, particularly in light of significant and profound changes that continue to occur not only in the scientific and technological landscape but in the commercial environment, political situations, social networks, and conflict dynamics around the world.\textsuperscript{17} Neither side can prove that its assessment is correct, and there is room for considerable diversity of opinion regarding the nature and extent of the “true” biological threat.

In the end, it is impossible to know today’s true biological threat, much less tomorrow’s. As a consequence, wide disparities remain in biological threat reduction policies, practices, and priorities among various actors. Attention and investment across the globe devoted to biological threat reduction and efforts to respond to deliberate attacks remain a patchwork of fragmented, disconnected, and unharmonized approaches.


\textsuperscript{17} A recent high-level U.S. commission placed great emphasis on the biological threat in concluding that "unless the world community acts decisively and with great urgency, it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013." The commission went on to say that “terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon.” Although the analytical basis for this judgment was not presented, the commission explained that “the difficulty of quantifying the bioterrorism threat to the United States does not make that threat any less real or compelling.” Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk* (New York: Vintage Books, 2008), p. xv and p. 11.
Over the last decade and spurred by such problems as HIV/AIDS, SARS, and the potential for an influenza pandemic, increased concern about other biological risks has accompanied the growing attention to biological weapons. Biological weapons proliferation by states and terrorists, therefore, is only one element of what has come to be appreciated as a spectrum of biological risks (see figure 1).

At one end of this risk spectrum stand naturally occurring developments such as chronic disease and emerging or reemerging infectious diseases. The spectrum then runs through human-induced developments, including accident or misadventure (the unintended consequences of otherwise benign activities), to the other end (italicized in figure 1) at which stands deliberate misuse, whether for political power, ideology, or greed.

The two elements of this risk spectrum that have received the greatest attention from the policy community in recent years—particularly in the United States—are naturally occurring infectious diseases and deliberate misuse. Over the past several years, the relative emphasis given to these two issues has undergone a distinct change. Following 9/11, bioterrorism was the overwhelming focus. The argument was made that if effective bioterrorism preparations could be developed, they would also have utility in dealing with naturally occurring disease outbreaks. In the last two years, the priority given to these two elements has been reversed. Today, more attention seems to be given to infectious disease, particularly the risk of pandemic influenza; deliberate misuse in such forms as bioterrorism has become the “lesser included case.” And just as attention to the risk of global pandemic from a mutated form of avian influenza (H5N1) had begun to wane, an actual flu pandemic caused by a variant of swine flu (H1N1) reinforced the attention given to natural disease. There is no question that these issues are often considered together because many of the requirements for dealing with either contingency are the same. Even prior to the H1N1 flu pandemic, however, a cursory view of the media over the last year demonstrates that more stories have focused on flu than bioterrorism.

This shifting priority is not just an interesting intellectual point. It has repercussions for policy priorities and the allocation of limited resources, particularly the balance of investment in efforts to address infectious disease and those that are directed toward bioterrorism and biodefense con-

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**Figure 1. A Spectrum of Biological Risks**

<table>
<thead>
<tr>
<th>Chronic Disease</th>
<th>Accident</th>
<th>Misuse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious Disease/ Emerging Infectious Disease</td>
<td>Misadventure</td>
<td>Biocrimes &amp; Bioterrorism &amp; BW Attacks</td>
</tr>
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cerns. Moreover, the relative priority given to each of these components could be an issue of some disagreement between the United States and those in the international community with whom it wants and needs to work in combating proliferation.

**An Inherently International Challenge**

With respect to biological threats, all nations’ fates are intertwined. The SARS outbreak of 2002 and 2003 and the H1N1 influenza pandemic of 2009 dramatically illustrate the speed with which a local disease outbreak can become a global one—and how the trade and travel disruptions compound the effects on national economies of an outbreak’s health and medical consequences. With respect to deliberate biological attack, a national biological weapons program will have dramatic strategic and geopolitical repercussions, not only within the proliferator’s region but globally. Terrorist groups based in one country can acquire resources, facilities, or sanctuary in another to conduct an attack on a third. Moreover, harm from a successful bioterrorism attack anywhere in the world might extend widely. In addition, infected travelers or contaminated goods carry disease with them across national borders, perhaps remaining infectious and continuing to spread the disease.

The biological threat, therefore, is inherently an international one. No matter how unlikely a country may think it is to be attacked directly, it can suffer the consequences of an attack even if directed at someone else. And if a state fails to take biosecurity measures that impede national proliferation programs or terrorist groups from using its territory or its resources to commit biological attacks on others, the nations directly or indirectly affected may hold that state accountable. Therefore, all countries have a stake in biological risk management and threat reduction. At the same time, given the globalized nature of science and technology and the ease with which money, goods, people, and information can cross borders, any effective means of dealing with this problem must be international in scope. Although there are actions that individual states can take unilaterally to reduce the risks they face—such as procurement of medical countermeasures for their own populations—no nation can solve this problem on its own. Some form of international coordination is essential.

2. Disparate Communities and Stakeholders: Perceptions and Roles

An intentionally caused outbreak of disease overlaps with many more traditional problems that existing professional communities already face, but it equates to none of them. The deliberate use of biology for harm, therefore, is characterized by wide disparities in the way in which different professional communities view the problem.

Figure 2 illustrates the issue, albeit on a somewhat simplified basis. The biohazard symbol at the center represents a bioterrorist or biological warfare attack—the deliberate misuse of science and technology, often in the form of the introduction of disease to do harm. Each of the “petals” represents a professional community or communities whose expertise and responsibility bear on the prevention of or the response to such an attack. One of the “petals,” for example, represents the public health and medical communities, which must respond to deliberately caused disease outbreaks just as they would have to react to other disease outbreaks. Some of the traditional procedures that these communities would apply to natural outbreaks of outbreaks—such as disease
surveillance, prioritization of which patients to treat first, delivery of health care, and implementation of infection control procedures to mitigate transmission of a contagious disease—may still apply in the case of deliberate threats. However, many of their other tools—such as contact tracing to determine how and where an epidemic originated and traditional methods of estimating the population at risk—may be completely inappropriate for a disease that was deliberately spread by a mechanism (i.e., intentional aerosol production) completely different from natural propagation mechanisms.

In the same way, an intentional disease outbreak may be an act of terrorism, thus engaging the law enforcement or counterterrorism communities. Most of the effort of these communities, however, addresses crimes or terrorism activities that do not involve pathogenic biological organisms. In the wake of a bioterrorism incident, the involvement of communities with experience in investigating crimes and apprehending or neutralizing perpetrators may be necessary to prevent repeat attacks. Yet these communities typically deal with incidents that occur at definite times and places, using practices and procedures that may not apply to a biological attack that manifests throughout one or more extended geographic areas, and that reveals itself gradually over time. Unlike a bombing, the early stages of a bioterrorist attack may be difficult to notice at all, let alone distinguish from a natural disease outbreak.

Furthermore, some tools that law enforcement and counterterrorism officials might consider important during a biological event may conflict directly with requirements of other communities.
For example, public health officials may wish to maximize the dissemination of information about an incident in order to alert other health care workers and the public, and to solicit additional information relevant in reconstructing the incident and identifying who else may require treatment. In contrast, the law enforcement community may seek to withhold information about the case in order to minimize the chance of tipping off the culprit, and to avoid teaching him or her how to do a better job of covering his or her tracks. Similarly, law enforcement may place high priority on preserving the crime scene and securing evidence for a subsequent trial, which may conflict with the needs of health care workers who might have to destroy evidence in order to save lives.

The figure includes other communities with a role in responding to or preventing a bioterrorist attack. As with the health care and law enforcement communities, these actors also have “day jobs” or traditional missions quite distinct from bioterrorism. For example, a deliberate, high-consequence biological attack can constitute a disaster requiring the engagement of the disaster management community, a community more typically involved with the consequences of earthquakes, fires, hurricanes, or floods. If perpetrated by a nation-state or international terrorist group, a bioterrorist or biological weapons event might also constitute an act of war, and it would certainly engage the military, national defense, and intelligence communities, and other parts of the national security apparatus. These communities, however, at least at present are more familiar with conventional than biological weaponry, and they seem to give priority to nuclear issues over biological ones in the realm of unconventional threats.

If an unusual or novel organism were involved, as the SARS experience highlighted, the ensuing investigation would require the input of scientific researchers with appropriate expertise. Even in the case of better-understood pathogens, scientific research is required to develop medical countermeasures: the therapeutics, diagnostics, prophylactics, and vaccines needed to detect, prevent, or treat disease. However, prior to 1996, little attention was given to the possibility that pathogens used in research laboratories might be intentionally diverted to bioterror or bioweapons programs, or that those working in an ostensibly legitimate laboratory might actually be conducting or supporting malicious activity. Since then, the research community has had to evaluate how it might need to do things differently in response to security concerns. Similarly, commercial firms with access to dangerous pathogens have both a role in developing and manufacturing medical countermeasures and a responsibility to help ensure that they are not the source of the problem they are working to solve.

As mentioned, figure 1 is a simplified rendition that underlines the issue of different perspectives of multiple stakeholders. It could certainly be made more elaborate and complex. Some “petals,” for example, could be sub-divided, such as giving the public health and medical communities their individual place in recognition of the unique features of these respective

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18. The Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) for the first time instituted security controls over the transport of certain dangerous pathogens used in research laboratories; this law required that only preapproved facilities could ship or receive them. Following the September 11 terrorist attacks, this regulatory structure was extended by the USA Patriot Act (Public Law 107-56) and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), which regulated possession of certain biological organisms in addition to their transport and which requires those working with such organisms to be approved for that purpose by the U.S. government.

communities. Similarly, more “petals” or professional communities/“stakeholders” could be added whose participation would also be essential in responding to a biological incident, or to prevent future ones.

Figure 1 is sufficient, however, to underline two major characteristics shared by all the professional communities that must be involved in managing biological risks:

- Each community has a mission that goes well beyond dealing with infectious disease outbreaks, particularly those that may be deliberately induced. Each community has a “day job” to which it typically must devote the bulk of its attention and effort.
- In addressing biological risks, each community must work with others it traditionally has little experience working with.

Many communities must respond to aspects of this problem, but none can treat it as one that falls solely within its experience base, competence, or jurisdiction. Each community contributes only part of the response. This reality complicates the ability of the international community to elaborate and put into place an appropriate governance structure for risk management and threat reduction. In moving forward toward such a governance “regime,” it imposes on each of the communities two vital, yet perhaps unfamiliar requirements:

- Each community must decide which of its traditional approaches to preventing or mitigating risk applies to biological risk (including deliberate biological attack), which are less relevant or actually counterproductive, and which new approaches may be necessary.
- Each community responding to or seeking to prevent such incidents must understand the missions, cultures, assumptions, priorities, values, and constraints of other relevant communities to assure that all of them can do their own jobs without preventing each other from doing theirs.

Preventing or responding to a biological incident, therefore, requires that each professional community determine how these obligations relate to and can be integrated into its traditional responsibilities. Each community must also learn about the role each of the other communities plays, and each must develop some means of working together with other relevant communities so all can pursue their responsibilities without interfering with each other.

3. Critical Components of a Biological Risk Management and Governance Structure

The characteristics of biological risk, as well as the complex relationships among the multiple players involved, demand that three different dimensions be addressed by any governance regime to manage biological risks and reduce deliberate biological threats. It must be comprehensive, with measures spanning the complete timeline of a biological incident, from its origin to its consequences; it must be interdisciplinary, encompassing a diverse range of professional communities; and it must be international across countries, addressing both governmental and nongovernmental entities and activities.
Comprehensive

Unlike nuclear weapons, which require special materials (highly enriched uranium or plutonium) that do not exist in nature, that can only be produced at great expense and effort, and that have a very limited set of civilian applications, there is no single chokepoint at which biological risk can be controlled. Many diseases have been controlled, at least in developed countries, and some have been eliminated. Yet all countries suffer from disease, and those with poor public health and medical infrastructures and severe resource constraints suffer disproportionately. Even highly developed countries cannot eliminate outbreaks of chronic, emerging, and reemerging disease. With respect to deliberate disease threats, there are legitimate civilian or scientific applications for virtually any organism, material, piece of equipment, or skill set that would be needed to produce a biological weapon, just as there are multiple pathways to accomplish the technical steps that a weaponeer would need to master. It would be impossible, let alone undesirable, to control access to biotechnology so effectively as to eliminate the risk of its misuse.

The absence of singular, high-leverage opportunities to prevent disease or impede the development, use, or efficacy of biological weapons and bioterrorism means that no single policy measure or individual community can make decisive progress against today's broad and uncertain biological threat. Instead, a concerted and coordinated web of actions must be developed to minimize the likelihood and the consequences of natural disease outbreaks, and to counter terrorist and national activities to develop, acquire, produce, deploy, and benefit from biological weapons and bioterror. A comprehensive constellation of measures, each of which may be only partially effective, can aggregate to form a system that is more effective than any of its constituent parts.

Figure 3 characterizes the full-spectrum of potential policy measures to manage biological risk. The first two categories apply specifically to countering the planning and execution of a biological attack: dissuading malicious actors from seeking biological weapons, and denying them—to the extent possible—the knowledge, materials, knowledge, equipment, and expertise they need to succeed. Given the inherent dual-use potential of the technology, however, denial measures may be difficult to implement without unduly impeding legitimate activity. The third and fourth categories apply both to deliberate and natural outbreaks: detecting covert weapons programs before they can proceed to execution, as well as detecting the presence of pathogenic organisms, or the incidence of disease, at the earliest possible time; and defending society against the harm that a disease outbreak can cause. This task encompasses a wide range of measures including development and distribution of vaccination and prophylactic medication, application of post-exposure therapeutics, environmental remediation and restoration to prevent long-term contamination, and promotion of societal resilience. This “Four D's” framework opens up the possibility that policy measures applied at one point of the timeline of a biological incident can make biorisk management policies applied at other points more effective. For instance, the registration or declaration of some types of equipment might facilitate the discovery and identification of an illicit weapons effort even if it did nothing to impede the acquisition of that equipment.

Interdisciplinary

Biological risk management policies should also be designed to bridge the diverse set of professional communities that have a role in biological threat reduction and biosecurity risk management. Interdisciplinary issues are most salient for countering deliberate biological threats, since most of the professional communities that now find themselves engaged in preventing, mitigating,
Implement a Four D's Framework

- **Dissuade** malicious actors from pursuing biological weapons
- **Deny** them the materials, equipment, and expertise they need
- **Detect** covert weapons programs, sources of disease, and disease outbreaks
- **Defend** against the harm that disease can cause via effective consequence management and attribution

Figure 3. Potential Policy Measures to Manage Biological Risk

Although deliberate threats pose the greatest cross-sectoral challenges, managing the risk of natural and accidental biological incidents also requires interdisciplinary engagement. Public safety officials and disaster managers will be involved in responding to major epidemics. The scientific research and industrial communities must ensure that they manage dangerous pathogens responsibly; and military health care systems are best able to keep deployed forces free of disease if they are closely engaged with host nation medical and public health authorities. Providing a
framework in which all of these diverse communities can come together to address biological threats, and to see how effectively their respective roles complement—or interfere with—each other, is both challenging and necessary. No such mechanism exists today. Without understanding each community’s objectives, limitations, and constraints, members of professional communities cannot build the needed partnerships and relationships. Nor can they develop the cross-fertilizing activities that will also be essential to maximize the effectiveness of each community’s actions against the biological threat.

**International**

Just as biological risks are global in nature, so too must be biological risk management. Disease outbreaks anywhere in the world, including deliberate ones, can have widespread consequences. Moreover, in this globalized technical and threat environment, many if not most policy actions to counter biological threats must be undertaken multilaterally if they are to be effective.

This is not to say that all national biological risk management policies must be coordinated internationally. Although all countries are made somewhat more secure when any country procures therapeutics or vaccines, since that procurement increases the chances that an outbreak in that country will be contained, a country can benefit from an investment in medical countermeasures even if no other country follows suit. On the other hand, policies such as placing laboratory pathogens under greater security can be frustrated to the extent that pathogen sources elsewhere in the world remain unsecured. But even when (or especially when) international coordination is clearly desirable, an important role exists for national leadership and unilateral action in setting an example and encouraging other nations to follow suit.

The need for coordination or harmonization extends beyond national governments. Policies and actions of nongovernmental entities and professional communities must also be incorporated into an integrated, coherent strategic approach. Both informal coordinating mechanisms as well as formal diplomatic agreements will be required. Indeed, while the Biological Weapons Convention process provides an international forum in which diplomats have held useful discussions relevant to several aspects of this problem, a much richer suite of interactions among a more diverse array of actors, both governmental and nongovernmental, and both ad hoc and sustained, will be necessary.

**Implications for Governance**

Currently, no integrated governance structure exists for biological risk management that is at once comprehensive, international, and multisectoral. Intersectoral and international linkage mechanisms are weak and uncoordinated, and no effective way exists to take advantage of potential synergies between different layers of biological risk management and threat reduction (different “D’s”; see figure 2). Moreover, relatively few mechanisms exist to highlight and resolve tensions that may arise between biological risk management and other missions.

At the same time, centralized, hierarchical, top-down institutions—whether a traditional intergovernmental institution, an executive secretariat for a treaty or convention, or a multilateral organization—suffer from the same shortcomings in the face of the complex and multifaceted challenge presented by contemporary biological risk management. Not one has the scope of competence, the depth of legitimacy, or the range of authority to oversee or coordinate the full breadth of biological risk management activities. Current institutional mechanisms are poorly
suited to address complex global issues that require multidisciplinary, multi-actor, and transnational solutions. They are particularly weak at responding to risks that emerge suddenly and evolve rapidly, especially in response to scientific and technological developments. Perhaps most important, they are woefully inadequate and inexperienced in fostering the necessary relationships with nongovernmental actors, who are now as important as governments are in managing the risk and addressing the threat. This problem is too complex, with too many independent decisionmakers and lines of authority, too many relevant policy choices, too many coupled issues, too many diverse viewpoints, and too many country- or community-specific details for any existing institution to provide the solution or to manage a successful governance regime. Indeed, as has been pointed out, a centralized, hierarchical authority is probably not even appropriate: “The problem is no longer to ensure . . . control over a large and complex centralized system, but rather to determine how much governance is needed for a decentralized, distributed system and how we can accomplish this goal.”

Former United Nations secretary general Kofi Annan called for a “forum” that will bring together all of the key stakeholders to address the needs of biosecurity risk management and biological threat reduction. As worthwhile as such an effort would be, it is probably premature. All of the key players have yet to sort out their respective roles, and there is still little experience of working together. The “connective tissue” has yet to be created. Such a forum also represents an institutionalized response to a problem that is distributed and decentralized without a corresponding decentralized response mechanism on which it can rely.

For the moment, therefore, what is needed is a governance structure based on a network of communities—a bottom-up, decentralized, adaptive, and interactive process that provides the information and communications mechanisms for focusing attention on managing biological risks, promoting interaction among the many moving parts that are involved in pursuing it, and facilitating assessment and adaptation among each component of this complex system.

4. The Global Forum on Biorisks

The intent of the CSIS-initiated Global Forum on Biorisks is to create a governance structure that will produce the information and the incentives needed to promote decentralized actions and yield socially beneficial outcomes. Its goal is to facilitate interaction and engagement among individuals and institutions involved with all aspects of biological risk management—across the “D’s,” across professional communities, and across countries. These crosscutting approaches, of course, are not completely independent. Professional communities span national borders and have their own relationships with national governments, and working through these communities provides additional ways of reaching out internationally, complementing more traditional government-to-government engagement.

The assumption underlying the Global Forum on Biorisks is that governance is possible without a central decisionmaker. This is certainly true in the case of market economies, in which the decentralized activities of independent entities acting in their own self-interest serve to allocate resources and orchestrate the production of goods and services. Markets work because they

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provide two necessary factors: information in the form of price signals, which tell producers and consumers which products are in demand and which are in surplus, and incentives in the form of profits available to those who fill needs. Although markets, left to themselves, cannot be assumed to produce socially optimal results, given the many values and objectives that cannot be strictly translated into economic terms, price signals and profit incentives nevertheless do serve to inform and motivate individual actions in ways that serve collective interests.

This approach of engaging and linking professional communities around the world was validated by the CSIS Biological Threat Reduction (BTR) Consortium, a group that was created in an earlier stage of the project to bring together representatives with diverse perspectives, national backgrounds, and professional responsibilities. Members of the BTR Consortium are listed in figure 4 along with their institutional affiliations at the time they met. The consortium also benefited from strong liaison relationships with the World Health Organization and Interpol, the two principal international organizations associated with public health and law enforcement respectively. The consortium also worked with the World Federation of Public Health Associations.

**Global Forum on Biorisks Web Portal**

What makes the Global Forum on Biorisks necessary is the dispersed, decentralized nature of the many individuals, institutions, professional communities, and governments, and other entities who all have a role in managing biological risk and who must all engage and interact with each other to do so. What makes the Global Forum on Biorisks possible are new information, communication, and engagement tools that constitute a vital and heretofore missing component of an effective biorisk management architecture. The Global Forum on Biorisks has developed a Web
portal at http://virtualbiosecuritycenter.org/gfbr/ to serve as an ongoing, accessible, and interactive means of facilitating engagement among all parties involved. The portal will promote knowledge sharing, collaboration, and transparency among practitioners worldwide.21

Membership

Participants in the Web portal must apply to join, and they must register under their real names and provide some information about themselves. It is important that other participants know with whom they are interacting. At the same time, the forum sets a relatively low bar for admission in order to elicit widespread participation and engage as diverse a set of participants as possible. As the portal evolves, this "bar" can be raised or lowered to trade off diversity and access against familiarity and trust. Discussions within the Web portal are on a not-for-attribution basis and may not be cited outside the Web portal with out the permission of all participants. All portal members must feel comfortable sharing ideas with others without having to worry about how they might appear if publicized.

The Web portal is organized around professional communities, with the initial set including

- Public health
- Medicine and healthcare
- Law enforcement
- Academic and scientific research
- Veterinary medicine and agriculture
- Emergency response and management
- Diplomacy and international relations
- Industry and private sector
- Policy research and analysis
- Civic engagement
- National security

Each participant must select a “home” professional community, but is encouraged to select others as well to maximize cross-community interaction.

Functionality

The Web portal’s key features—some of which are in place now, some of which are under development, and some of which are future opportunities—include

21. After having been initially developed and produced by CSIS, the Global Forum on Biorisks Web portal has been incorporated within the Virtual Biosecurity Center (VBC), an international partnership among key individuals, entities, and organizations with a role in biosecurity (i.e., the prevention and mitigation of, preparation for, and response to biological threats, particularly ones of deliberate origin) that is being developed and operated by the Federation of American Scientists. The VBC will be an integrated central information hub for biosecurity and public health preparedness that will bring current developments in online Web technologies to the way the biosecurity community communicates and disseminates information.
Collaborative document development, such as position papers and policy proposals

Calendars of biorisk management–related events around the world, searchable by professional community and region

Discussion forums within and between professional communities

“Wiki”-like articles relevant to biorisks and their management that will be developed and maintained by all of the Web community’s participants. No Web site run centrally by any one organization can have the breadth or the currency of one for which all participants take collective responsibility.

Flexible permissioning that will enable participants to determine with whom they want to share works in progress. Some collaborative activities will be open to all to promote the widest possible engagement; others may be restricted to specific individuals who want to work out ideas privately before sharing them with others.

Text, voice, and multimedia communication capabilities to enable participants to interact in real time

Social networking capabilities that can introduce participants to information they may find useful and to other participants with whom they share interests.

These tools will facilitate functions such as

- Raising biorisk management policies for consideration by members of professional communities either in one region or with counterparts in different regions or countries;
- Providing a mechanism for members of different professional communities to understand others’ objectives and constraints as a way of identifying “win-win” relationships;
- Constituting an idea generator, posing and exploring answers to critical questions identified by community members as the most crucial;
- Raising tough issues for each community and promoting new approaches appropriate to the emerging and unfamiliar environment biological risks that must now be addressed; and
- Creating and reinforcing a sense of community among biorisk management professionals.

The goal, then, is a collaborative, community-driven platform in which experts from around the world engage and interact to share information, develop collaborative projects, and build partnerships. The need for such capabilities has been reinforced at many international conferences and symposia, including ones that predated the actual implementation of the Web portal as well as those in which an early version of the portal was demonstrated and participants enrolled.

Assessment

In addition to serving as a vital tool for communities’ awareness, engagement, and relationships, the portal will serve as a powerful diagnostic measure of intra-community and inter-community engagement. A virtual online community is well adapted to assess how its members utilize the Web site’s functionality; indeed, such evaluations are necessary for the Web site to optimize its own presentation and performance. In this case, the portal will provide data regarding usage and interaction that can be used not only to improve the Web site’s operation but also to evaluate how effectively cross-community and inter-regional or international interactions are being undertaken.
Engagement for Biorisk Management

Some specific proposals to manage or reduce biological risks are presented below, categorized by the “D” that each proposal would support. The ability to refine and implement any of them would benefit from dialogue, engagement, cooperation, and collaboration among parties. The examples chosen here are presented for illustrative purposes only; these discussions do not necessarily constitute recommendations for implementation, nor does mention here imply that these particular measures should be given highest priority.

Dissuasion

- **Biological Weapons Convention (BWC) process.** With its history of review conferences, the Ad Hoc Group’s negotiations, and the more recent intersessional activities, the BWC provides a forum primarily for diplomatic representatives of states party to the treaty. The intersessional work programs have been noteworthy, however, for involving a broad range of diplomatic and nondiplomatic government officials, and especially for their inclusion of nongovernmental representatives.

- **Government-to-government and law enforcement-to-law enforcement discussions on criminalization of biological weapons activities.** In addition to the general obligation imposed on member states by UN Security Council Resolution 1540 to criminalize proliferation-related activity, specific efforts to criminalize behavior prohibited by the Biological Weapons Convention are also important, especially for governments and law enforcement officials. Such action both strengthens the norm against use (“Dissuade”) and, by increasing the investigatory powers of law enforcement, improves the ability to detect covert programs (“Detect”). Having BWC states parties implement the obligation expressly stated in the treaty to pass such domestic legislation is a critical first step.

- **Scientific community discussions on codes of conduct.** Governments have some role in facilitating discussions among scientists regarding adoption by their respective peer groups of some kind of code of content. The primary actors here, however, are the scientific communities themselves, which are extensively connected internationally.

- **Scientific engagement programs with former biological weapons program scientists.** This is another area where scientist-to-scientist interactions should predominate, but government involvement is necessary both in terms of providing financial support (from the donor countries) and providing access to government laboratories and scientists (from countries whose scientists are the beneficiaries of these programs).

Denial

- **Controlling exports of pathogens and dual-use biological and biotechnological equipment.** Developing and administering export controls is the province of government. Participation from the scientific and industrial communities worldwide, however, will also be necessary to assure both that these controls are effective at impeding proliferation and terrorist activity and that they do not unduly penalize legitimate commercial and scientific activity. Controls can be imposed unilaterally, but they are more effective and engender greater respect among those who are subject to them if countries around the world adopt equivalent measures.
- **Restricting access to pathogens.** Given the ease with which pathogens can be transported, measures to secure pathogens in some countries may do little to impede terrorist access to them unless similar measures are enacted worldwide. This can be done by harmonizing versions of “select agent” rules; by harmonizing biosecurity standards at laboratories worldwide; by criminalizing inappropriate possession of agent, or through export controls. Involved in these discussions would be government officials, scientists, lawyers, and industry personnel.

- **Restricting access to information.** Decisions by government officials to restrict public dissemination of information thought to be useful to proliferators and terrorists are usually made unilaterally. Like export controls, however, the efficacy of any such action depends on whether other countries with equivalent information follow suit. Any such decision, however, would have to weigh the benefits of limiting the dissemination of information to those who might misuse it against the costs to scientific research, medicine, and other fully legitimate activities that could benefit from that same information.

- **Biosafety training.** As more high-containment biological laboratories are built in which dangerous pathogens are studied, those working in or having access to such facilities must be trained in how to keep themselves, their coworkers, and their surrounding communities safe from accidental exposures to infectious organisms.

**Detection**

- **Improving epidemiological surveillance.** Improving global epidemiological surveillance will require extended dialogue among the global public health community, national governments, and others around the world.

- **Improving environmental detection.** Improving environmental detectors for pathogenic organisms involves the above parties with the addition of the scientific community and certain vendors. International participation may be desirable, since many countries around the world have R&D budgets that could contribute to the development of environmental sensors. Best practices regarding detection will also be a valuable topic of discussion, as experience is gained with these systems.

- **Intelligence cooperation.** Although intelligence cooperation certainly takes place among governments, its occurrence is uneven because sharing is more extensive among some countries than others. This is always likely to be the case, but some thought should be given to whether and how some intelligence can be more widely disseminated. Another interesting topic is how effectively intelligence communities can engage with other professional communities to detect illicit activity. After all, professionals in these other communities, all of whom have an interest in preventing the misuse of the life sciences, will already be in more places than intelligence agencies would typically be able to obtain sources. Moreover, members of these other communities may be better able to spot potentially dangerous activity than intelligence agencies would be.

**Defense**

- **Research and development (R&D) into medical countermeasures.** World R&D capacity and R&D budgets exceed those available to any single nation, so all nations benefit if other countries are able to devote some of their capacity to developing medical countermeasures.
• **Development of nonpharmacological interventions.** Until vaccines or therapeutics can be developed for a newly emerging contagious disease, such as a pandemic influenza, the spread of disease can be checked only by the application of nonpharmacological interventions such as social distancing (lessening the risk of disease transmission by minimizing time spent in crowds or minimizing opportunities for crowds to form) and isolation (separation of sick individuals from healthy or asymptomatic ones).

• **Planning for procurement and distribution of medical countermeasures.** International cooperation and collaboration in distributing vaccines and other medical countermeasures in the aftermath of a major disaster or biological incident should be a key topic for international engagement.

• **Public health preparedness and local response.** This is a topic that would not seem as appropriate for international conversation, since effective response is location- and situation-dependent. However, both government and public health/medical community workers may be interested in sharing lessons learned and best practices.

• **Remediation/restoration.** There is a paucity worldwide of research on effective means of decontamination. To the extent other countries are sufficiently interested in this problem to fund work in the area, there is considerable potential for cooperation.

**Barriers to Biorisk Reduction**

Discussion among and within communities can generate or otherwise collect proposals for reducing, mitigating, countering, or responding to biological incidents or outbreaks. In each case, parties can seek to determine whether a given proposal should be implemented, and if so, why it has not been. Reasons why sound proposals have not been implemented could include:

• **Information limits.** Those in a position to enact a given proposal have not thought of it yet, and nobody else has brought it to their attention. Coming up with an idea, or telling it to the right people, may be all that is needed.

• **Analysis limits.** A suggested policy may not have sufficient detail or scope to be implementable. Additional study and analysis may be necessary before an approach to implementation can be designed. Relevant parties can identify what studies need to be done, if not take some of those studies on.

• **Dialog limits.** One party or group may seek to implement a proposal, but they may not be able to get the attention of others with whom they need to work. Finding others in key groups or communities with whom to hold a dialog may be what is needed.

• **Decision limits.** Different parties may come to opposite conclusions on the same question. Some process must be developed, or decisionmaker identified, that will resolve the deadlock and allow action to proceed in one direction or the other.

• **Resource limits.** An idea may be sound, but there may be insufficient resources in any of the relevant sectors to permit the idea to be enacted. In this case, processes can be formulated to identify where those resources might be available and who would have to be persuaded to free them up.

In each case, identifying the reasons why a proposal has not been implemented to date may be the first step in planning how to implement it in the future.
5. Conclusion

International engagement, cooperation, and collaboration are vital parts of the global effort to counter biological weapons proliferation and bioterrorism. Set within the context of a comprehensive, international, and multisectoral approach to countering biological risks, a focus specifically on international and interdisciplinary engagement highlights the many opportunities across the risk management spectrum to meet the challenge of minimizing the likelihood and the consequences of biological harm, whether from natural, accidental, or intentional causes. These opportunities for engagement involve government and a wide array of nongovernmental and professional community partners. It is imperative that these opportunities be exploited—now. The framework offered by the Global Forum on Biorisks and the functionality provided by the GFBR Web portal provide an effective means for doing so.
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David Heyman founded and directed the CSIS Homeland Security Program, where he led or contributed to numerous studies focused on shaping U.S. federal, state, local, and private sector homeland security policies, including studies on Islamic radicalization, aviation security, nuclear terrorism, pandemic flu planning, and bioterrorism preparedness. He has also served as an adjunct professor in security studies at Georgetown University and has lectured or consulted on national security matters with organizations and governments throughout Asia, Europe, and the Americas. Prior to joining CSIS, he was a senior adviser at the White House and to the U.S. secretary of energy, responsible for developing and shaping policy at the highest levels of government on a wide range of national security and international affairs matters. Previously, he held a number of positions in the private sector, including as the head of international operations for a software/systems engineering firm developing supply-chain management systems for Fortune 100 firms. He has provided commentary and analysis on CNN, BBC, NBC, FOX News, and NPR’s All Things Considered as well as in the Washington Post, New York Times, and USA Today. He has worked in Europe, Russia, and the Middle East.

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