

SECURITY IN THE BIOLOGICAL CENTURY

NEW KNOWLEDGE, TECHNOLOGY, and applications from biology promise to transform society, just as the industrial and information revolutions did in the nineteenth and twentieth centuries. Revolutionary discoveries in the life sciences have the potential to reshape the worlds of health, food production, energy, climate change, and economics, leading to fewer deadly diseases, new fuels, heartier food crops, longer life expectancy, and better quality of life.

The history of previous technological revolutions, however, provides a lesson that we ignore at our peril. As two of the world's foremost experts on biological weapons warn, "We know of no major technology with military utility that has not been vigorously exploited for hostile purposes."¹ A crucial test for responsible sovereignty will be to promote the benefits of the biotechnology revolution while ensuring that its potential harms—deliberate abuse by states, terrorists, or criminals or the accidental release of deadly pathogens—are prevented.

Biotechnology's benefits are needed to address myriad naturally occurring biological threats. Doctors, nurses, and public health officials do battle with bugs and germs that kill millions of people a year, most of them in the poorest regions of the world. Many of these frontline defenders of health fear that the bugs are winning. Mainline antibiotics have lost their potency, and new ones have been slow to take their place. New

drug-resistant forms of tuberculosis and staph infections pose challenges in the developed and developing worlds. On average more than two new deadly infectious diseases emerge every year; in the last thirty years, they have included HIV-AIDS, SARS, Ebola, West Nile virus, and avian flu. One expert warns that it is 100 percent certain that in the next decades the world will face a new, deadly influenza pandemic, which could be as lethal as the 1919 pandemic of Spanish influenza, which killed 50 to 150 million.² In August 2008 the U.K. government published a report listing such an influenza as the most dangerous threat facing its people.³

International cooperation is essential to address this growing array of biological threats. The challenge is twofold. The first is to build a strong global public health regime that effectively responds to disease outbreaks and builds local capacity to sustain the health and well-being of citizens. Effective public health systems also are an important part of a multilayered response to potential bioterrorism. Given that developments in biotechnology will make the threat of bioterrorism as diffuse as that of cybercrime, prevention will be difficult; defenses—excellent global and local public health systems—therefore will need to be robust.

Beyond defending against disease and bioterrorism, there is a second challenge: to promote the bright side of advances in biotechnology while preventing their potentially dark side from appearing. The security opportunity of the biological century is to forge arrangements that produce beneficial results *for poor and developed countries alike*, with biotech applications that improve health, food production, and energy security for *everyone*. At present, however, our existing international arrangements are inadequate for promoting opportunities or combating abuses. Scientists, biotechnology companies, and universities must be centrally involved to create a regime that will work and the means to enforce it.

THE BIOLOGICAL CENTURY: TODAY AND TOMORROW

At the International Genetic Engineered Machines competition in October 2007, a team of high school students from San Francisco used gene-splicing techniques to create a synthesome, or artificial organelle. An organelle is to a cell what an organ, like a stomach or heart, is to an animal—a structure that performs a specific function. To prevent the

synthesome from being eaten by a lysosome, an organelle responsible for disposing of unneeded molecules, the students had to create a DNA bar code that would fool the lysosome. Their creation has opened the door for possible future applications, such as programming yeast cells to make biofuels. Their accomplishment placed them in a group of six finalists, including students from the University of California at Berkeley who created “bacto-blood,” or *E. coli* bacteria engineered to produce hemoglobin and a chemical that enables cells to survive freeze-drying. Another finalist was a group of undergraduates from Slovenia, who doctored the DNA of mammalian cells to create a virus trap, which could prove beneficial in the fight against HIV-AIDS. The winners of the contest were students from Beijing University who created tiny assembly lines out of bacteria.⁴

The contest brings students from around the world to engineer biological devices. It is sponsored by the BioBricks Foundation, created by professors at MIT who have compiled a library of several thousand standardized DNA sequences (BioBricks), which can be used to design and create new genetic machines. According to the foundation’s website, scientists using BioBricks can “program living organisms in the same way a computer scientist can program a computer.”⁵

Several aspects of the competition are noteworthy. The participants are young, ages seventeen to twenty-two. They are doing cutting-edge manipulations that just several years ago would have been deemed impossible. They are working without large capital outlays, public or private. Finally, they come from all parts of the world. The biotech revolution is global.

The breakthroughs engineered by these young scientists are among the many reasons that the twenty-first century will be known as the biological century. In the last thirty years, scientists have cloned pigs, sheep, and human embryos; genetically engineered human insulin and vaccines; discovered specific genes that cause cancer; carried out trans-species organ transplants; and genetically modified foods to make them more nutritious and plants to make them more resistant to insects. To imagine biotechnology’s potential, one scientist predicts that within twenty to fifty years “genetically engineered carbon-eating trees” could reduce the amount of carbon dioxide in the environment by half.⁶ In 2008 anyone who so desired could buy his or her complete genetic blueprint for

\$350,000.⁷ The goal of several biotech companies is to provide that service for \$1,000, ushering in a world of medicine and disease prevention strategies designed for the individual. It also will bring us closer to what one scientist calls the domestication of biotechnology, whereby families will be as familiar with biological manipulation as they are today with personal computers.⁸

Before one shrugs this off as science fiction, consider that since the mid-1990s biotechnology has advanced faster than computer technology, which doubles in computational power every eighteen months.⁹ Christopher Chyba, an astrobiologist at Princeton, observes that the speed of DNA synthesis has increased more than 500 times in fifteen years: “The synthesis of the polio virus, completed in 2002, took the [State University of New York] team three years of work. A year later, a research group at the Institute for Biological Energy Alternatives in Maryland manufactured a virus of comparable genomic length in just two weeks.”¹⁰

A National Academy of Sciences committee tasked with reporting on globalization, biosecurity, and the future of the life sciences noted that several techniques, such as RNA interference and synthetic biology, came to fruition during the committee’s mandate. The committee’s report makes for sober reading:

Neither of these developments could have been foretold even a few years back, pointing to the futility of trying to predict with accuracy what will come in the next few years. This leads to the second conclusion, that our task, the task of surveying current technology trends in order to anticipate what new threats may face us down the road, will be never ending. Our report, published in early 2006, will in some respects be out of date by 2007.¹¹

Biotechnology’s discoveries also have a dark side—they have the potential to cause immense harm through accidental or intentional release of a manufactured pathogen or through what the National Academy of Sciences terms “enabling technologies,” such as acquisition of novel diversity, directed design, manipulation of biological systems, and enhanced packaging of biological materials, that can be used for weapons purposes.¹² The list of alarming scientific achievements includes

—synthetic re-creation of the virus that caused the 1919 Spanish influenza pandemic

—synthetic manufacture of the polio virus

—synthetic manipulation of the mousepox virus, making it much more lethal.

The work on the mousepox virus demands special reflection. The manipulated virus was fatal to rats that had been immunized against mousepox, raising the specter of what might be done with smallpox and humans. And it was an accidental discovery by researchers who were looking for ways to render rats sterile as a means of extermination.¹³ Imagine new findings in biotechnology being used to attack the fertility of ethnic or national groups—or the entire human species.

The dark side could be pursued by an individual scientist with a grudge, a terrorist group intent on mass death and disruption, or states that covet novel offensive biological weapons. It also could be reached inadvertently through shoddy safety systems and careless contamination.

THE NATURE OF BIOLOGICAL THREATS

Governments perceive biological threats to security differently, just as they do many of the issues covered in this book. In the Global South, the most salient biological threat is an onslaught of deadly infectious diseases, the biggest cause of death in poor countries. For the developed world there are the threats of the *potential* outbreak of deadly infectious diseases (for example, a recurrence of a deadly influenza pandemic or the spread of a newly emerging infectious disease such as SARS); the *potential* use of harmful biological agents by other states; and the *potential* for biological terrorism, especially tied to the dramatic discoveries in the life sciences described above.

Any arrangement to promote biological security should start by acknowledging that examples of bioterrorism have been few and their effects small.¹⁴ And while the potential harm of a pandemic of a deadly infectious disease in the developed world is hypothetical, the ravages of disease in the developing world are real and take their toll daily. Five people died in the 2001 anthrax attacks in the United States; five people die worldwide from infectious diseases every second.

We say that not to dismiss either the potential threat of pandemics to the developed world or the threat of bioterrorism, especially when tied to advances in biotechnology. Rather it is to underscore that if we need global cooperation to tackle biological threats to security effectively, then international approaches must also equitably tackle the primary threats to developing nations, whose priority is the ravages of disease.¹⁵

Deadly Infectious Diseases

Every year 15 million people die from infectious diseases such as HIV/AIDS, malaria, tuberculosis (TB), and cholera.¹⁶ Such diseases are both cause and consequence of poverty. Up to 1.7 million of the deaths are due to illnesses caused by contaminated water and poor sanitation.¹⁷ As one doctor insists, the greatest ethical problem facing the life sciences today is that life expectancy in the developed world is around eighty years, while in some poor countries it has fallen to about thirty years.¹⁸

The natural world of disease is not a static one. Between 1940 and 2004, 335 emerging infectious diseases, or diseases not previously recognized in humans, were reported.¹⁹ The peak emergence of those diseases was in the 1980s, but they have continued to develop at alarming numbers since. The majority come from non-human animal sources; they are abetted by high population density, antibiotic use, and a host of ecological and environmental conditions that promote the transfer of pathogens from wildlife to humans.²⁰ HIV/AIDS alone has infected more than 70 million people worldwide and killed more than 30 million.

Infectious diseases are related to a host of other threats that we examine in this book. Food insecurity and malnutrition make populations more susceptible to disease; disease and poor health, in turn, weaken agricultural productivity. HIV/AIDS, malaria, and TB have been shown to reduce economic growth in countries hard hit by these diseases. The International Labor Organization estimates that between 2006 and 2020, should HIV/AIDS remain at its already high levels in Africa, the disease will cost more than \$144 billion in economic growth.²¹ Other research has shown similar effects of malaria, which reduces Africa's GDP by 1.3 percent each year, on average.²² Poverty in turn contributes to the spread of infectious diseases because of poor public health and sanitation. As discussed later, poverty itself is a cause of civil war, and

civil war facilitates the spread of disease by destroying health systems, forcing populations to move, and overwhelming the carrying capacity of local communities.²³ In addition, the failure of governments to provide for the health of their populations contributes to their lack of legitimacy, which in turn makes them vulnerable to rebels and insurgents.

The extent of global travel means that the United States along with every other country is at risk from emerging infectious diseases and a global influenza pandemic. (In 2007 there were more than 830 million international air passengers and another 1.2 billion domestic air passengers. In 2006 the United States alone welcomed 52 million foreign visitors, while Americans took 60 million trips abroad that year.)²⁴ Although the public health systems in developed countries may be better equipped to respond to any potential outbreak than are those in less developed countries, there is no national defense against this transnational issue. Biological security anywhere, including in the United States, is only as good as global biological security.

Despite the need for international cooperation in fighting infectious diseases, issues of equity have created real barriers to joint action. The developing world resents that only 10 percent of the \$30 billion spent globally on health research and development is spent on the diseases of the developing world.²⁵ In 2007, the government of Indonesia refused to share strains of avian flu with the World Health Organization, charging that any vaccine that might be developed from the strains would be unlikely to reach Indonesia.²⁶ And the measure required to stanch avian flu—the indiscriminate elimination of poultry flocks—has disproportionately hurt the poorest farmers in Asia.²⁷

Bioterrorism

Given the wide diffusion of biological technologies and materials, the likelihood is greater that terrorist groups would be able to obtain the means to manufacture bioweapons than nuclear or chemical weapons. Moreover, there is evidence of intent: documents found in al Qaeda training camps in Afghanistan revealed rudimentary experiments with bioweapons.²⁸ Nonetheless, terrorist attacks using biological weapons have been few. Turning bioagents into weapons is difficult, and an attack of real magnitude remains a challenge. The lack of bioterrorism has led some to conclude that the threat has been exaggerated.²⁹ As one analyst

points out, an American is 235 times more likely to be hit by lightning than to die of anthrax poisoning.³⁰

But, as in the world of investing, past performance is no guarantee of future results, and it is precisely because of the revolutionary transformation of the life sciences that we should be concerned. The key is to create policies and institutions that help safeguard that transformation while building strong global public health defenses against natural and intentional disease outbreaks wherever and however they might occur.

Cultivation of Pathogens for State Programs

In the 1990s it was revealed that several states—the Soviet Union, Iraq, and South Africa—had created large-scale offensive biological programs.³¹ In the Soviet Union, scientific experiments led to large-scale production of weaponized anthrax; an accidental release of a plume of anthrax killed at least sixty-four people in the town of Sverdlovsk in 1979.³² Soviet scientists also experimented with the transfer and modification of genes in order to destroy the human immune system as well as with genetically engineered pathogens that could induce autoimmunity, which when tested on animals proved nearly 100 percent lethal.³³ In July 1995, the government of Saddam Hussein admitted to UN weapons inspectors that it had an extensive offensive biological weapons program; the inspectors in turn dismantled and destroyed Iraq's declared facilities and others that the regime had not declared.³⁴ In the 1980s, the South African apartheid regime attempted but failed to develop a vaccine that would render black women infertile.³⁵ To the question of whether advances in biotechnology could be used for the dark side, the answer is that they already have been.

States have a legal right under the Biological Weapons Convention to invest in biodefense, which by implication involves the development of agents that could have an offensive purpose. However, the criteria for defining offensive and defensive are not objective, and definitions depend largely on assessment of intent. The expansion of biodefense programs in response to the increasing threat from bioterrorism and the diffusion of biotechnology are arguably increasing the potential threat of diversion of both knowledge and materials. By the nature of their access and research, scientists inside state programs pose a considerable potential threat because they could circumvent controls on access to pathogens

and technology under the cover of national security. That seems to have been the case with the American scientist accused of carrying out the 2001 anthrax attacks, Bruce Ivins.

A critical question is whether we are likely to see in state biological weapons programs what happened with nuclear weapons in the 1990s, with rogue state weapons scientists using their knowledge and technology to create proliferation networks. In the 1990s the United States and United Kingdom feared that a leading scientist in South Africa's bioweapons program was selling his secrets to Libya. There are now more than 400 U.S. institutions with access to live bioweapons agents and 14,000 individuals approved to handle them. Will one of them or some other scientist elsewhere in the world turn out to be the A. Q. Khan of bioweapons?

Biotechnology

Global growth in this industry now generates annual revenues of more than \$60 billion. In thousands of laboratories around the world, scientists are using cutting-edge technologies to understand the causes of diseases in order to prevent and treat them. Similar activity is occurring in the areas of farming, plant and animal biology, and energy. Other scientific disciplines (nanotechnology, information technology, materials science) not normally associated with biotechnology are becoming integrated in ways that are generating new technological applications in the life sciences.

Advances in biotechnology greatly expand the reservoir of potentially lethal agents. The growing understanding of the mechanisms of both infectious diseases and the immune system creates the potential for genetically tailoring agents. The possibility increases of developing "stealth" viruses, which could be introduced secretly into the genomes of a given population and then triggered later by a signal and "designer" disease pathogens, which could be used to attack the genome of a given population on command.³⁶ As Claire Fraser and Malcolm Dando observe, such possibilities represent "an order-of-magnitude change in potential offensive capabilities."³⁷ Ever-expanding microbial genome databases now provide a parts list of dangerous genes from which to pick and choose the most lethal combinations. There is danger in the misuse of large-scale databases containing information on the genetics of specific populations,

just as there are potential risks in openly publishing complete sequences of dangerous pathogens.

The pace of change within biotechnology poses an almost unprecedented security threat, demanding a high level of responsiveness from international institutions. Today's capabilities in the life sciences and related technologies have already changed the nature of what is possible. The accelerating pace of discovery has fundamentally altered the threat spectrum. It may be futile to predict with any accuracy what will come over the next few years.

A considerable burden of responsibility falls on companies and individual scientists to ensure that they understand the harm that could be caused by the abuse of biotechnology in biowarfare and by terrorists. Irresponsible and careless behavior within the industry could have significant implications. Yet most scientists who are concerned about the potential dangers of biotechnology admit that there is no scientific consensus about the dark side, and there is plenty of opposition to any hint that regulation may be needed to address misuse of the science or its application.

At one remove that is understandable: for those who face the ravages of disease every day, the promise of biotechnology cannot be realized too soon, and it may seem misguided to express caution about potential scientific discoveries that could address those ravages. On the other hand, scientists often display a knee-jerk reaction against challenges to scientific inquiry and openness. In this case, however, they do so at great peril.

The likelihood of realizing biotechnology's promise will depend on popular confidence and trust in the technology. We start with an already immense amount of popular skepticism and doubt about where the life sciences are headed. Worldwide opinion surveys show much distrust in the safety of genetically modified food and seeds, and such distrust would be exacerbated by a devastating incident, either accidental or intentional, involving biotechnology.

RESPONSIBLE SOVEREIGNTY AND BIOLOGICAL THREATS

As with the other issues addressed in this book, possible solutions to the biological threats to security rest on a near-universal commitment of states to standards of responsible sovereignty, which provide a useful foundation for building an effective regime. Here we focus on three

important agreements: the Biological Weapons Convention, the International Health Regulations, and UN General Assembly Resolution 60/1. Together, these agreements define the current state of responsibility in the biological field. Responsible sovereignty includes rejecting the development of offensive biological weapons, preventing groups or individuals within state borders from accessing dangerous biological weapons, cooperating in the event of deadly disease outbreaks, building local and public health capacity throughout the world, and working to reduce disease and its effects in poor countries.

The Biological Weapons Convention

Evidence of repulsion against the use of biological weapons dates back thousands of years and across civilizations. In the twentieth century, in reaction to the horrors of the use of chemical and biological agents in World War I, states signed the 1925 Geneva Protocol, which prohibited the use of such agents on the battlefield. In 1975 states brought into force the Biological and Toxic Weapons Convention, which has been signed by 162 countries and ratified by 149. The convention puts forward several state obligations:

- to prohibit the development of biological agents for military offensive purposes
- to prohibit the transfer of such agents between states
- to prohibit any persons within the jurisdiction of the state from developing bioweapons
- to facilitate the transfer of knowledge, equipment, and materials for peaceful purposes.

Although the convention did not foresee a revolution in the life sciences or the fact that future weapons may be based on different scientific discoveries, its language implies that the convention applies to new developments and their application to bioweapons. Moreover, the convention does suggest that since governments have responsibility for prohibiting anyone in their jurisdictions from developing bioweapons, they must take responsibility for ensuring the security and safety of biotechnology.

Such an obligation can also be inferred from the International Convention on the Suppression of Terrorist Bombings (1998), which requires states “to make the creation, detonation, dissemination, and discharge of

biological agents or weaponry criminal offences under their domestic criminal codes.”

The International Health Regulations 2005

The principle of sovereignty as responsibility is well-established in the field of international health. Long before what we now call globalization, governments understood that outbreaks of devastating infectious diseases were a problem of international consequence, no matter where they occurred. In 1951 the member states of the World Health Organization adopted the International Sanitary Regulations, which focused on border controls to prevent the spread of five diseases: cholera, plague, smallpox, typhoid fever, and yellow fever. In 1969, the first International Health Regulations were adopted, creating a legal framework for reporting and responding to those diseases.

By the 1990s public health experts understood that the 1969 regulations were inadequate to ensure global health security. First, there was the challenge of emerging infectious diseases that were not covered by the regulations. Second, because border control was found to be an ineffective response to disease outbreaks, it would have to give way to thorough disease surveillance and response, with an emphasis on rapid expert intervention to diagnose and stanch outbreaks at their source. Third, changes in information technology meant that the World Health Organization should no longer rely simply on governments to report outbreaks; Internet networks could provide earlier indications of worrying symptoms than many ministries of health could.

In 2005 the International Health Regulations were thoroughly revised. The 2005 regulations require that states work to prevent and control outbreaks of infectious disease, protect their citizens against such outbreaks, and cooperate with the World Health Organization and other states against events (naturally occurring or caused by humans, accidentally or intentionally) that pose international public health risks.

The 2005 regulations are a universal agreement among states. States must report evidence of international public health threats to the World Health Organization, including laboratory results, the source and type of risk, number of cases and deaths, conditions affecting the spread of disease, and health measures employed. States also must develop a national response plan and coordinate their actions with hospitals, health person-

nel and organizations, and government health agencies at domestic points of entry (airports, water ports, and land crossings) in the event of an infectious breakout or instance of contamination.

States are expected to collaborate with each other in detecting and responding to health risks. That includes providing technical cooperation and logistical support in developing public health capacities as well as mobilizing financial resources to implement an adequate response to health hazards. States must aid each other in formulating domestic laws to ensure effective implementation of health regulations.

To understand how far and how fast responsible sovereignty has come in the world of public health, consider that when the World Health Organization began the quest to renegotiate the 1969 International Health Regulations in 1996, one legal expert questioned that strategy, arguing that “what is scientifically and medically necessary to combat emerging diseases may not be what states are willing to agree to undertake.”³⁸ The same expert rightly observed later that the subsequent 2005 regulations constitute “a major development in the use of international law for public health” that “imposes serious responsibilities that significantly affect sovereignty.”³⁹

UN General Assembly Resolution 60/1

The 2005 World Summit, a high-level plenary meeting of the UN General Assembly, reached decisions on development, security, human rights, and institutional reform of the United Nations. It also evaluated the progress made toward achieving the Millennium Development Goals, a set of targets for the year 2015 that states adopted in 2000, which include reducing child mortality by two-thirds, reducing the maternal mortality rate by three-fourths, achieving universal access to reproductive health care, and a host of measures to combat HIV/AIDS, malaria, and TB.

One outcome of the summit was General Assembly Resolution 60/1, which emphasizes the need for an international response to build the capacity of developing nations to help realize health-related millennium goals. All states are responsible for increasing investment and improving the infrastructure of health care systems in developing nations, including by ensuring that they have sufficient health care workers, management systems, and supplies to reach the Millennium Development Goals by

2015. States also must work toward improving investment strategies that promote the capacity of healthcare systems in developing nations. States are expected to contribute funding for academic and industrial research and for the development of vaccines, microbicides, diagnostic kits, and drug treatments to address major pandemics, tropical diseases, and other infectious health risks, such as avian flu and SARS. Finally, General Assembly Resolution 60/1 reinforces the 2005 International Health Regulations and calls on states to continue to ensure the implementation of obligations set forth in the regulations.

EVALUATING THE INTERNATIONAL ARCHITECTURE

Governments face a challenge that is both a multifaceted threat and a significant opportunity. In response, they have built important assets to help promote biological security, among them the World Health Organization, a competent first responder to disease outbreaks and strong coordinator of global and national health responses to pandemics; the International Health Regulations (2005), a universal agreement that places clear obligations on states to cooperate in responding to infectious disease outbreaks and to build strong global public health systems; and the Biological Weapons Convention, an agreement based on a long-standing repulsion against the use of diseases and pathogens as weapons of war. Nonetheless, the present international architecture is insufficient in scope and responsiveness and inadequate to tap the capacity of the private sector and individual scientists to address the dynamic nature of this challenge.

WHO

From 1990 to 2008, the World Health Organization transformed itself from an institution in crisis, foundering in its search for a role in meeting the health challenges of globalization, to an institution that has regained global respect and that is a key player in the fight for global public health. Its performance during that time shows that dynamic leadership is needed to anticipate challenges and aggressively position international institutions to perform in crisis.

WHO began as a technical agency with a narrow focus on disease control, and in the 1960s it achieved a major success in eradicating

smallpox.⁴⁰ Less remarked upon, however, is that during that time WHO also attempted to rid the world of malaria, a campaign that failed after showing positive results early on. In the 1970s, the organization rightly drew the conclusion that different diseases require different strategies and that achievements in medicine and immunization were not enough in the face of crumbling public health infrastructure. Toward the end of that decade, WHO and its director general, Halfdan Mahler, made primary health services—especially building public health infrastructure and delivering services to poor countries—central to WHO's mandate. Two WHO-led initiatives—an international code on baby formula and regulation of essential drugs—led to a clash with key wealthy member states, including the United States. In retrospect, however, it is clear that WHO was out in front on issues that were harbingers of global health challenges in the post-cold war era.

Poised to be a leader in global health at the end of the cold war, WHO instead retreated to issues of narrow medical competence. That sharp downward trajectory coincided with the disastrous choice of a new director general, Hiroshi Nakajima, in 1988. Nakajima led WHO into an era of intense bureaucratic politicking, low morale, and constant allegations of corruption and incompetence.

WHO's freefall could not have come at a worse time. In 1988, there were about 7 million cases of HIV/AIDS. The director of WHO's AIDS program, Dr. Jonathan Mann, resigned in 1990, citing undue infringement on his work by Nakajima and a lack of strategy and leadership in addressing what would turn out to be the worst global pandemic since the plague.⁴¹ When the United Nations created the Global Program on AIDS in 1993, it wrested control from WHO and made it a bit player in a larger multiagency program.⁴² By the 1990s the World Bank was arguably a greater player in global health than WHO.

AIDS was not the only emerging infectious disease challenge that WHO botched. In 1994 there was a reemergence of plague in India. Nakajima's handling of the outbreak was so obviously incompetent that it brought respect for WHO to an all-time low and threatened to discredit its work in infectious diseases, long a strength.⁴³ In 1998, the member states of WHO chose a dynamic new director general, Gro Harlem Brundtland, a three-time prime minister of Norway and a medical doctor by training.

Brundtland initiated important changes at WHO, but we want to focus on one issue in particular: her repositioning of WHO as the global leader and coordinator on issues involving deadly infectious diseases. First, under Brundtland, WHO advocated a change from international health to global health—health issues that transcend borders. WHO made revision of the International Health Regulations a priority and worked to fill the gaps between the old health regulations and the imperatives of public health in a globalized world. Under Brundtland, WHO created the Global Outbreak Alert and Response Network (GOARN) to coordinate the response to outbreaks of deadly diseases. Finally, WHO returned to its advocacy role, emphasizing primary public health and the need to strengthen local, national, and global capacity.

HARD CASE: SARS. Inept in confronting an outbreak of plague in 1994, WHO proved invaluable in stopping severe acute respiratory syndrome (SARS) in its tracks nine years later. SARS emerged somewhere in the southern Chinese province of Guangdong in late 2002, with outbreaks in several cities. On January 31 one victim caught a hyperinfective case of the disease and while being treated by three different hospitals infected an estimated 200 persons, most of them hospital workers. News of the outbreak reached WHO through electronic reporting systems, prompting GOARN to ask the Chinese government about the epidemic. China confirmed an outbreak of an infectious disease, which by that time had infected 300 persons and killed five in Guangdong. But Chinese authorities misattributed the outbreak to a commonly known bacterial agent, thereby unduly reducing alarm.

The disease spread outside of China on February 21, 2003, when a Chinese physician infected twelve people who were staying at the same hotel in Hong Kong. Within twenty-four hours, those twelve people traveled by air to Singapore, Vietnam, Canada, Ireland, and the United States, generating most of the 8,000 cases of the disease worldwide.

Global response was prompted by a February 28 report from Dr. Carlo Urbani, a WHO physician in Hanoi, identifying a patient with a high fever and atypical pneumonia. That triggered GOARN to send investigative and containment teams to Hanoi and Hong Kong, where reports of a mysterious, deadly infectious disease continued to find their way to the Internet. Dr. Urbani himself died of the disease.

According to a National Academy of Sciences evaluation of the response, WHO issued a global alert on March 12, “describing outbreaks of the yet-unnamed respiratory disease in Hong Kong and Vietnam, and instituted worldwide surveillance. A second alert on March 15 named the condition, listed its symptoms, and advised travelers to have a high level of suspicion of SARS and report to a health worker if they had SARS symptoms and had visited an area where SARS was known to be occurring. Two further alerts provided recommendations for airports to screen passengers and for travelers to avoid areas where SARS had been detected.”⁴⁴ The warnings to avoid travel to infected areas were “the most restrictive in the history of the organization.”⁴⁵

In March GOARN, using secure communications, created a virtual network among eleven laboratories in nine countries to hasten identification of the cause of the disease. The disease was identified a month later.

GOARN also succeeded in the difficult task of pressing China’s health authorities to cooperate with its efforts to stanch the pandemic. Key to its success was a warning that “if SARS was not brought under control in China, there would be no chance of controlling the global threat of SARS.”⁴⁶ Within days of GOARN’s first intercession, China agreed to cooperate. GOARN specialists, however, grew frustrated over China’s continued slow response to treating the disease. On April 16 WHO publicly criticized the Chinese authorities for “inadequate reporting” of cases. The Chinese reaction was swift. On April 20 a “nationwide war” on SARS was declared and several officials, including the minister of health, were fired for their inadequate response to the disease. For the next two months, Chinese health officials worked intensively to halt the spread of the disease, which they accomplished in late June.

On July 5, 2003, a little more than four months after GOARN responded to Dr. Urbani’s report from Vietnam, WHO declared that SARS had been broken. It had spread to thirty countries on six continents, infected more than 8,000 people and killed nearly 800 of its known victims. The epidemic’s toll on the economies of the hardest-hit countries was estimated to be \$40 billion.

The Institute of Medicine of the National Academies of Science in the United States deemed the international response to SARS a great success: “the quality, speed, and effectiveness of the public health response to

SARS brilliantly outshone past responses to international outbreaks of infectious disease, validating a decade's worth of progress in global public health networking."⁴⁷

A key part of this story was that Director General Brundtland pushed for WHO to exert autonomy and influence way beyond its authority and mandate. SARS was not covered under the existing International Health Regulations, but WHO demanded cooperation and openness nonetheless. Brundtland issued travel warnings and advisories without the legal authorization to do so and amidst some criticism from member states.

WHO's activism was tolerated, then championed, and ultimately enshrined in the new International Health Regulations negotiated in 2005, because governments all around the world came face to face with the health implications of a globalized, interconnected world. China's role in this story is crucial; when it realized that China's economic stake in an open international system was at risk and that its failures of response were bringing it unwanted global attention, it decided that its security and prosperity demanded a cooperative response.

SARS also showed the wisdom of creating the Global Outbreak Alert and Response Network. GOARN is a consortium of 140 technical partners in sixty countries, coordinated at WHO in Geneva, where it runs a situation room twenty-four hours a day, seven days a week, to monitor deadly infectious disease outbreaks around the world. With its network approach and reliance on fast communication, GOARN spotted SARS before any report from the Chinese government appeared; within twenty-four hours it had put together an international team under WHO auspices to investigate. While SARS was GOARN's most public work, it responded to seventy outbreaks of deadly infectious diseases between 2000 and 2005.

Nonetheless, the National Academy of Sciences study cautions that the success in addressing SARS also contains several warnings. National capacities were overstretched: in Toronto, for example, where two different outbreaks of SARS swamped public health officials, authorities asked for help from the United States. In the United States, the Centers for Disease Control was at the forefront of the response but quickly found itself overextended, with too few experts and scientists.

Moreover, as deadly as SARS was, it is not in the same league as an influenza pandemic. The transmission rate for SARS was slower than

that for influenza. An official from GOARN admits that SARS put it under maximum stress and that it does not have the capacity to address a large-scale influenza pandemic. In response to concerns about such a pandemic, WHO took the global lead in coordinating efforts to prepare for it by creating a special coordinator with a dedicated staff devoted solely to surveillance and response to avian flu.

The Biological Weapons Convention

The Biological Weapons Convention (BWC) has a limited mandate: to cover state-run biological weapons programs. Unlike nuclear and chemical conventions, the BWC lacks a verification mechanism to prove states' compliance; that means that it has no effective capacity to deter cheating by raising the possibility of discovery. In that regard the inability of the regime to prevent the Soviet Union and Iraq from developing sophisticated bioweapons capabilities over a sustained period is a significant failure.

Yet even if a verification mechanism existed, it is not clear how effective it would be in detecting noncompliance. The inherent difficulty of distinguishing illegitimate offensive bioweapons programs from legitimate defensive research adds to the dilemma, as does the practical problem of conducting inspections that actually yield substantive evidence. Even with such a process in place, parties to the treaty would still have little faith that verification could actually catch the cheaters. To reiterate a key theme of this chapter, the ability to detect offensive bioweapons programs will only get more difficult as experimentation in biotechnology becomes more widespread—down to the level of individual businesses and scientists and eventually households. Moreover, in a world of business competition over cutting-edge applications in the life sciences, neither states nor industry will have an interest in compromising confidential and proprietary business information.

Efforts to strengthen the BWC have for the most part failed. A 2001 draft protocol was rejected by the United States, which claimed that the verification procedures proposed would be ineffectual. Major opposition from industry led the United States to argue that confidential business information could be compromised; the United States also contended that potential proliferators could use the protocol to undermine international export control regimes such as the Australia Group, a group of

41 governments that has created stringent rules restricting the export and shipment of potential bioweapons agents and technology. Iran, for one, argued that as a party to the BWC, it should be allowed free trade in all biological materials.

While some of the proposed monitoring techniques might be useful, many experts agreed with the U.S. government that there were significant deficiencies in the verification regime. The inspectors would be too few in number, they would lack essential skills, and they would not be deployed to sites long enough to generate reliable findings.

The United States emphasized instead that BWC members should take measures to strengthen their own domestic legislation and develop codes of conduct for enhancing biosecurity. However, one problem with this individualistic approach was that there was no articulation of an acceptable international standard for biosecurity. In the absence of agreement on a standard, national legislation could be weak and inadequate. While national legislation could be the first step, without a high standard and extensive global participation in creating domestic biosecurity legislation, the likely outcome would be a patchwork of rules and regulations with clear and significant gaps that determined proliferators or terrorists could seek to exploit.

Gaps in the Architecture

The safety and security of biotechnology is an area in which a traditional type of arms control agreement has only limited utility; it can be but one thin layer in a multilayered solution to the challenge. Several problems remain: lack of universal biosafety and biosecurity standards, data deficits, the role of nonstate actors, and the question of who should attend to the fast pace of technological advances and their corresponding threats.

BIOSAFETY (WORKING WITH PATHOGENS). The World Health Organization defines biosafety as practices implemented to prevent unintentional exposure to pathogens or their accidental release. In many cases facilities and research centers are aware of the need for such measures but they are not necessarily obligated to abide by regulations. For example, government-funded organizations in the United States must follow the biosafety guidelines of the Centers for Disease Control and the National Institutes of Health, but adherence is optional for other institu-

tions. National biosafety regulations could be effective, but allowing governments to set their own standards in this area would not necessarily lead to an overall strengthening of the regime.

BIOSECURITY (PRECLUDING UNAUTHORIZED ACCESS TO AGENTS, TECHNOLOGY, AND KNOWLEDGE). While signatories to the BWC are prohibited from making biological weapons, individuals generally are not restricted from possessing biothreat agents. Not all countries have enacted legislation criminalizing the development, production, and use of biological weapons by individuals. The 1996 BWC Review Conference “strongly urged” states to pass criminal legislation barring offensive biological weapons research. Yet, as of 2001, only twenty-seven of forty-five states that provided any information to the United Nations said that they had done anything in that regard, while ninety-eight states failed to submit any data whatsoever. Again, if left to individual countries, the outcome may not be acceptable.

At the industry and university level, laboratories may be familiar with biosafety issues, but they are generally unaccustomed to the concept of biosecurity—for example, the need for enhanced on-site security measures, access and transfer regulations for pathogens, or even monitoring of the stocks of pathogens or toxins that they possess. Often such measures are perceived by scientists to be ineffective, intrusive, or too costly or as an obstruction to research, resulting in skepticism of their value. Self-regulation of biosecurity by facilities, including R&D facilities, is therefore unlikely to be adequate. Formal government oversight arrangements, including legislation, probably are necessary, yet such regulations must be developed in consultation with the scientists who are expected to implement them if they are to have any chance of being adopted and followed.

Only a small number of countries have enacted legislation that specifically addresses biosecurity, and again, as with biosafety, it is not clear that leaving it to individual countries to set their own standards is appropriate. In the absence of agreed-on universal standards, they could merely enact weak legislation. Although self-regulation by individual states may further biosecurity in some countries, it does not by itself provide a disincentive for states that are noncompliant.

DATA DEFICIT. Large numbers of laboratories around the world possess dangerous pathogens or toxins or conduct work on them, but there are no data on exactly how many such laboratories exist. Moreover, no compre-

hensive records exist on bioscience experts who have worked with lethal pathogens, nor is any sophisticated global structure in place to track and identify dangerous germs or critical equipment; consequently, there is no information on the scale and quantity of global transfers.

Voluntary measures have been proposed through the Biological Weapons Convention to close some of the data deficits, but they have proved singularly ineffective. At the 1986 BWC Review Conference, member states agreed to provide annual data on issues relating to biological research, high biosecurity laboratories, and suspicious disease outbreaks. In 1991, BWC members further agreed to provide more detailed data to the UN to promote transparency about their compliance with the BWC. During the first ten years when such data exchanges were to occur, not once did a majority of BWC member states participate—not even to check the “nothing to declare” box on the reporting form.⁴⁸

NONSTATE ACTORS. Traditional arms-control measures such as the BWC have concentrated almost exclusively on state programs. While state programs remain important, the activities of nonstate actors demand further attention. Today, a strategy is needed that focuses on denying knowledge and material to terrorists as well as interdicting their networks before they attack. Clearly not enough is being done to track potentially dangerous bioscience programs within the private sector. The system for detecting wrongful conduct and investigating suspicious activity at a national and international level is woefully inadequate.

KEEPING TABS ON THE EVOLUTION OF THE THREAT. As biotechnology advances, so do its possible applications to offensive bioweapons. Today it might be possible to, among other things, enhance the antibiotic resistance of biological agents, modify their antigenic properties, or transfer pathogenic properties between them. That could make them harder to detect, diagnose, and treat, increasing their military utility and thus increasing the temptation to pursue offensive programs. Should development of a new generation of offensive biological weapons programs occur, what might happen in a decade or two as the genomics revolution consolidates and spreads around the world?

An international regime must be supple enough to evolve with developments in technology. Given the widespread development and use of technology, the regime will require the active engagement of scientists, universities, and businesses to have any chance of detecting and acting on

violations, yet to rely on voluntary participation alone, as argued above, would be folly. Hence, a biotechnology security regime requires clarity and strength from the top down and bottom up in order to create the breadth and strength of response needed to succeed.

STRENGTHENING THE INTERNATIONAL RESPONSE TO BIOLOGICAL THREATS

The biological threats to security are diverse. They include old and new infectious diseases, potential outbreaks of new disease, use of diseases as weapons by states or terrorists, and the intentional or accidental release of new pathogens or agents produced by revolutionary developments in the life sciences. Despite the diversity of threats, efforts to defend against any or all of them must have several common features: strong global, national, and local public health systems; willingness of states to cooperate with other states and international organizations in the face of public health emergencies of international concern; and a strong World Health Organization to promote cooperation.

As with the other threats that we examine in this book, prevention is a primary goal. In the case of naturally occurring disease, WHO has shown that it is possible to take actions and put in place strategies that can help minimize the deadliness of the next influenza pandemic. But what of the threat from bioterrorism? It may be that the biotech revolution will render complete prevention impossible. What *can* be done, however, is to make it more difficult for groups or individuals to use the life sciences for nefarious purposes. And the universal adoption of strong safety procedures and the creation of a culture of safety can minimize the risk of accidental release of a devastating pathogen.

Two challenges are clear. The first—the need for a strong defense based on global public health systems and strong international cooperation—is not controversial. The dogged work of WHO in forging the 2005 International Health Regulations, its role in addressing avian flu, and the performance of the Global Outbreak Alert and Response Network against SARS have led to remarkable agreement on how to build public health security. What is needed now is the full implementation of the 2005 regulations and the creation of the necessary capacity to ensure that they succeed.

The second challenge—the creation of a new international regime to promote the safety and security of the life sciences and biotechnology—is contentious. As mentioned, the biotech industry is global, diverse, decentralized, competitive, and growing. Scientists and industry bridle at restraints—the former for fear of losing freedom of scientific inquiry and the latter for fear of being put at a market disadvantage. At the same time, the general public itself distrusts some of the key products of the biotech revolution. And many governments have not modified their assessment of the threat of bioweapons to meet the exponential pace of technological change.

A new regime for biotechnology safety and security will need to look and to be different from any existing international regime. Effective regulation, not heavy regulation, is required. The regime must engage industry, scientists, and the public. It is possible to sketch some of its features: universal standards for biosafety and biosecurity; national legislation to regulate domestic industry, universally applied; codes of conduct for scientists and industry; collection of information about what kinds of research are being done, by whom; awareness of scientific advancements and the dangers that they might produce; and a focal point for sharing information.

The first step toward building this regime is to create the scientific consensus, international trust, and knowledge necessary to forge a common perception of the problem and spur the collective action necessary to deal with it.

Capacity Building for Full Implementation of the International Health Regulations 2005

What the WHO calls public health security depends on a robust defense against disease that rests on strong surveillance, international and local preparedness, and international and local response. As WHO insists, such a defense must include “governments, industry, public and private financiers, academia, international organizations, and civil society.”⁴⁹ The International Health Regulations 2005 lay out in detail the key responsibilities of states:

—strengthen national disease surveillance, prevention, control, and response systems

- strengthen public health security in travel and transport
- strengthen WHO global alert and response systems
- strengthen the management of specific disease risks.⁵⁰

Implementation of the regulations requires developed countries to assist poorer countries in building national health systems; that in turn imposes the obligation on governments to cooperate globally with other states and with WHO in addressing public health emergencies of international concern.

The vital missing link is local capacity in much of the developing world. There is a widespread desire among governments, international organizations, and nongovernmental organizations to fight disease in the developing world and an unprecedented amount of private resources, such as funds from the Bill and Melinda Gates Foundation, to realize that goal. But as Laurie Garrett points out, the key issues for many of the disparate health projects of the last several years are scalability and sustainability—and the key to both are local talent in the form of trained health care professionals, facilities that the poor can access, and dependable flows of resources to sustain programs.⁵¹ What remains unknown is whether basic public health in the developing world can be strengthened through a sectoral approach that just targets health care or whether it requires broad systemic reform of governance, a topic examined in chapter 9.

In 2008 WHO called for governments and nongovernmental organizations to shift their emphasis to primary health care and to governance reforms to bolster national public health systems.⁵² As a first step in that direction, WHO should use implementation of the International Health Regulations to provide a strategic framework for donors to integrate infectious disease programs into general public health systems and to help developing countries adopt best practices from other nations to build effective and sustainable capacity.

Steps toward Implementation of a Universal Regime

The U.S. position on bioweapons control since the 2001 rejection of the BWC Protocol has been to move away from legally binding multilateral measures toward voluntary national actions. However, for a number of other countries the ultimate goal remains to develop a multilaterally negotiated, legally binding verification regime.

Members of the European Union, along with Latin American and Caribbean leaders, issued a political declaration in May 2002 in which they underlined their “conviction [that] the latter Convention [BWC] is best enhanced by the adoption of a legally binding instrument to oversee the prohibition of the development, production and stockpiling of Biological and Toxic Weapons and their destruction.”⁵³ In the lead-up to the 2006 BWC Review Conference, however, many states had started to look beyond the protocol, recognizing that there was more to an effective BWC than the open-ended and divisive debate over whether and how verification should be pursued.

The United States needs to reengage and reassert its leadership role in this area to promote a range of multilateral actions on biosecurity that need not undermine the BWC and that could even strengthen the prospects for establishment of a multilateral, legally binding verification regime in the long term, which is the ultimate goal of many states.

Several incremental steps can be taken to increase the costs for terrorists who try to obtain the capability to make a bioweapon and the probability that illicit activity will be detected. If fully implemented, such steps could form the basis for a global regime.

First, the United States could begin a dialogue with the G-16 and other countries of responsibility in the field of biotechnology to negotiate standards and facilitate uniform national action to improve biosecurity and biosafety. As a first step, lists need to be compiled that categorize pathogens, toxins, and new technologies that could be used for bioweapons and rank them by urgency. Such lists would change over time, and there would need to be a mechanism to ensure regular reassessment not just of pathogens but also of the trajectory of future research on “next-generation agents” and to identify techniques and technologies that might apply directly to biowarfare. Second, common models could be developed for access, transfer, and chain-of-custody regulations for select pathogens and toxins. The proposed dialogue would have to enlist scientists and the biotech industry as partners in formulating both standards and practices.

On the basis of the negotiated standards, the G-16 could work toward mandatory implementation of standards through national legislation and regulation. The only way to ensure that the agreed-on standards are being applied is for countries to establish a national regulatory mechanism to

provide oversight of facilities working with dangerous pathogens and engaged in research involving genetically modified organisms. Again, the participation of scientists and the biotech industry is crucial, and it would play a role in detecting and interdicting illicit conduct. While regulatory oversight is necessary, it needs to be complemented by measures, such as codes of conduct, best practice protocols, and dedicated training, to improve self-regulation within the life sciences and the biotech industry.

The goal of regulation is to protect legitimate scientific and business inquiry, research, and operations and to make it easier for authorities to detect illicit activity. That would require government registration of legitimate facilities, as well as audit declarations of activities from academic, research, industry, and government organizations. Again, the purpose of such reporting is not to restrict legitimate activity but to close some data gaps so that governments can better target illegitimate activities.

In the longer term, agreement among the G-16 and countries of responsibility, bolstered by national legislation and regulation, could be a step toward implementation of a universal international regime. The G-16 would need to work toward encouraging wider adoption by other states. Some countries have not even enacted legislation criminalizing the development, production, and use of biological weapons by individuals. The final step to ensure implementation would be to create an international body to coordinate and promote national legislation and its implementation, update standards, and provide a formal mechanism for sharing information on suspicious activity.

This approach is not a complete answer, but its emphasis on registering legitimate activity and detecting illicit activity makes it more difficult for groups or individuals to use advances in biotechnology for nefarious purposes. Global adoption of mandatory practices would help close some of the gaps that bioterrorists may try to exploit and increase the costs of achieving an offensive capability.

An “Intergovernmental Panel on Safety of Biotechnology”

Cooperation does not happen without trust and knowledge, and two initial steps can be taken to promote both. The first is to take a page from the battle against global warming and create an “Intergovernmental Panel on Safety of Biotechnology,” an independent scientific group, akin to the Intergovernmental Panel on Climate Change (IPCC), to analyze

objectively and assess the risks inherent in biotechnology's discoveries in health, food, agriculture, energy, and security. The IPCC, winner of the 2007 Nobel Peace Prize, was founded for two reasons: to bring the best scientific judgment about climate change to a debate that was otherwise highly politicized and to involve scientists from around the world, especially from developing countries, in a global scientific process of assessment and evaluation. Scientists from all over the world have the opportunity to submit peer-reviewed research to the IPCC for consideration, thus establishing a forum for systematic debate and the formulation of scientific consensus. The resulting assessments of the IPCC have been instrumental in creating trust among scientists from different parts of the globe and in creating knowledge about climate change that people and governments can trust.

Disagreements about the safety of biotechnology and appropriate measures to address its risks resemble the debates on climate change twenty years ago. In the past year, for example, the Prince of Wales dismissed all genetically manipulated food as an unmitigated environmental disaster, while the chief scientist of Great Britain declared such food to be a key tool for addressing world hunger. In Africa in the past several years, cultural suspicions about biotechnology have led a head of state to refuse donations of genetically modified food even as his country teetered on the brink of famine and a regional governor to refuse to carry out polio vaccinations, leading to a global outbreak of the disease.

In the field of bioterrorism, similar differences exist. A National Academy of Sciences panel could agree on key risks of biotechnology, especially various experiments of concern, yet its findings and judgment have not entered into the mainstream scientific debate.

The IPCC has created policy networks among scientists who work on climate research and among scientists, government officials, and advocates from nongovernmental organizations. To replicate its success, a similar institution on biotechnology would need to emulate the IPCC's scientific openness and dialogue and, more important, its essential commitment to scientific rigor, peer review, and objectivity.

“DNA for Peace” Program

While the creation of an Intergovernmental Panel on Safety of Biotechnology can go a long way toward producing the trust and knowledge to

support international cooperation in making biotechnology safe and secure, a second initiative could also work toward that goal: creation of a “DNA for Peace” program to help developing countries build their own expertise and capacity in biotechnology in exchange for implementing high standards of safety and security in their new life sciences industry.

It is all too easy to dismiss the potential contribution of the biotech revolution in improving the lives of the world’s poor. Some seek to trivialize the potential impact of the billions of dollars spent on new research by pointing out that much of what contributes to the health woes of the poor can be addressed by simple technologies, applied with sustained commitment.

But it is wrong to claim that a choice has to be made between spending resources on high-tech solutions and spending them on sustained application of simple technologies. We have advocated a strong international commitment to building local and national public health systems and surveillance and treatment of infectious diseases, all of which can improve the health of billions of people. And advances in biotechnology can play a role there too. The Gates Foundation commissioned a panel of top doctors and scientists from around the world to imagine a dream list of products that could have a huge impact on the health of the world’s poor.⁵⁴ These are just a few of the products that they listed:

- vaccines that do not require refrigeration
- needle-free delivery systems for vaccines
- creation of new vaccines
- a genetic strategy to deplete or incapacitate disease-transmitting insect populations
- creation of a full range of optimal bioavailable nutrients in a single staple plant species
- new drugs and delivery systems that minimize the likelihood of development of drug-resistant microorganisms.⁵⁵

The “DNA for Peace” initiative is the brainchild of the Canadian McLaughlin-Rotman Centre for Global Health, which has warned that global efforts to combat bioterrorism are on a collision course with legitimate biotechnology pursuits.⁵⁶ They argue that what is needed is a network of scientists who will promote biotechnology research to fight disease, hunger, and poverty in the developing world and to keep vigil against the misuse of biotechnology. They contend that the key is to

develop the capacity of poorer countries to participate in the biotech revolution and bolster their ability to use its remarkable advances to address the health problems that are most relevant to them. Investing in and fostering biotech development around the world will create a better environment in which to fight bioterrorism by building the network of experts needed to spot attempts to misuse the science.

CONCLUSION

Like nuclear energy in the twentieth century, the development of biotechnology in the twenty-first brings with it the potential for existential danger to the human species. Like computer technology in the twentieth century, biotechnology and its applications will be diffuse and domesticated. There will be broad potential for both benefits and harm. Promoting the former while preventing the latter will pose unprecedented challenges for development, security, and responsible sovereignty. Neither heavy government regulation nor self-regulation by industry and science alone will do. A new international regime will have to seek the active participation of science and industry to develop national legislation and regulations and appropriate international standards. Science and industry will need to help enforce compliance in order to sharpen the line between bright side and dark side activities. International cooperation for information sharing, monitoring of compliance, and updating threat assessments will be required.

A first step must be to create a common foundation for progress. As in the case of climate change twenty years ago, there is insufficient global and scientific consensus to move forward. That then is the urgent task, and it should be pursued immediately. The threat of biotechnology's dark side is only growing greater; should it be realized before that consensus is reached, the policy reaction will likely stifle the technology's positive potential.

In the meantime, there is the challenge of defense—against the ravages of disease and against the potential harm of bioterrorism. Both require a robust global health system, with strong disease surveillance and response. Both require national health systems that provide citizens in countries around the globe with adequate health care. A global initiative

to build such systems would provide a win-win result for development and security.

In large parts of the world, however, such an initiative can succeed only in conjunction with concerted efforts to end ongoing civil wars and rebuild failed states, both of which devastate public health and local health capacities. We turn to that challenge in the next chapter.