Center for American Progress

# Biosecurity

## A Comprehensive Action Plan

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Progressive Ideas for a Strong, Just, and Free America

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# Executive Summary

Biological weapons and infectious diseases share several fundamental characteristics that the United States can leverage to counter both of these threats more effectively. Both a bioweapons attack and a natural pandemic, such as avian flu, can be detected in similar ways, and the effectiveness of any response to an outbreak of infectious disease, whether natural or caused deliberately by terrorists, hinges on the strength of the U.S. public health and medical systems — the network of federal, state, local, and private-sector entities responsible for the health of the nation's population. Natural pandemic outbreaks and bioterrorist attacks would place different stresses on these systems at the outset, yet the basic response and containment mechanisms would be essentially the same.

The Biological Incident Annex — the portion of the U.S. government's National Response Plan (NRP) that addresses biological threats — recognizes the commonalities between natural and deliberate outbreaks. But having an emergency plan on paper is no guarantee that it will work in practice, as the federal government's faulty response to Hurricane Katrina demonstrates. The Biological Incident Annex is premised on the assumption that state, local, and tribal entities can, as a practical matter, assume primary responsibility for detecting and responding to major outbreaks of infectious disease. Unfortunately, the reality is that they cannot.

Only fifteen states and/or cities currently have the capability to administer stockpiled vaccines and other drugs on a large scale. More than 50% of Americans today live in states that do not have plans to deal with a large number of casualties in the event of a bioterrorist attack, and 20% live in states where hospitals lack medical equipment that would be required in a major emergency. Worse yet, only two states have plans to encourage medical personnel to report for work during an epidemic, and nearly half of the states do not use national standards to report infectious diseases to the federal Centers for Disease Control and Prevention (CDC).[1]

At the local level, too, our biosecurity is weak. A recent survey found that practicing physicians would misdiagnose anthrax, botulism, plague, and smallpox — all potential bioterrorist threats — an average of 47% of the time.[2] Another recent report predicts that the United States will face a 20% shortfall of nurses by 2020 to support our national health system — and that's without factoring in the possibility of a pandemic.[3]

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[1] Trust for America's Health, "Ready or Not?" (2005), available at http://healthyamericans.org/reports/bioterror05/bioterror05Report.pdf.

[2] Sara E. Cosgrove, Trish M. Perl, Xiaoyan Song, and Stephen D. Sisson, "Ability of Physicians to Diagnose and Manage Illness Due to Category A Bioterrorism," *Archives of Internal Medicine*, vol. 165, no. 17 (Sept. 26, 2005), pp. 2002-2006.

[3] Peter I. Buerhaus, Douglas O. Staiger, and David I. Auerbach, "Implications of an Aging Registered Nurse Workforce," *Journal of the American Medical Association*, vol. 283, no. 2 (June 14, 2000), pp. 2948-2954.

This woeful lack of preparedness is not for lack of trying, or for lack of funding. Since 9/11, the United States has spent more than $30 billion to counter the twin threats of biological weapons and natural emerging infections, such as pandemic influenza. The bulk of this money has been devoted to developing and stockpiling vaccines against known diseases, such as smallpox and anthrax, with the remainder going to improve disease surveillance systems and other public health infrastructure.

Overseas, too, the CDC has employees working in 46 countries and is expanding its network of Global Disease Detection and Response Centers. The U.S. is also cooperating with the World Health Organization, the United Nations agency that performed so well in tracking and responding to recent outbreaks of SARS and other emerging infections. By June 2007, WHO will implement a major revision of the International Health Regulations requiring member nations to notify the agency within 24 hours of any public health threat that could affect more than one country.

Yet all of these worthy efforts do not add up to an effective biosecurity system for all Americans. The primary reason is a failure to connect the dots between plans on paper and the capabilities needed to implement them. Correcting the gaps in the nation's preparedness for pandemic diseases and bioterrorism will require the United States to exercise bold leadership across a range of public policy arenas. We must improve our early warning systems for the detection of disease outbreaks and support advanced biomedical research to encourage the development of safe, cost-effective drugs capable of treating a broad spectrum of infectious diseases.

At the same time, we must revitalize global efforts to prevent the spread of biological weapons and promote strong international standards to ensure that legitimate scientific research is not misused to create novel pathogens for biological warfare or terrorism. The United States must also strengthen the capacities of international public health agencies, such as WHO, to identify and contain diseases before they evolve into global threats.

At home, the United States must address critical deficiencies in the nation's public health infrastructure. Preventive measures must extend to all Americans, not only for reasons of fairness but to safeguard public health and national security. An emergency vaccination campaign to contain an outbreak of a contagious disease, for example, will succeed only if it covers a large majority of the affected population, creating sufficient "herd immunity" to prevent rapid person-to-person contagion. The millions of Americans who are uninsured or underserved by the health care system are particularly vulnerable to infection, creating a potential reservoir of contagious disease that could spread to the rest of the population.

To implement an integrated biosecurity strategy, the U.S. government should:

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| **Strengthen global efforts to prevent terrorists and extremist regimes from acquiring the materials, equipment, and know-how needed to produce biological weapons.** | A layered, comprehensive strategy is critical to countering the spectrum of biological threats. The United States should actively promote "harmonized" international guidelines for securing dangerous pathogens in research laboratories and culture collections and for the oversight of sensitive research in the life sciences that could threaten public health or national security. The United States should also work to strengthen the international treaty banning biological arms and to strengthen export controls on "dual-use" technologies that have legitimate peaceful applications but could be diverted for biowarfare purposes. (See *Preventing Bio-Catastrophes: The Need for a Global Approach.*) |
| **Remedy critical deficiencies in the nation's public health infrastructure using an "all-hazards" approach.** | Stockpiles of drugs and vaccines will not save lives unless the public health system can rapidly detect and identify a disease agent and respond in a timely manner with medical and other interventions. The United States must strengthen disease surveillance and response systems at both the national and international levels. A so called "all-hazards" response strategy would give priority to combating natural infectious disease threats, which are inevitable and likely to increase in the coming years, while enhancing preparedness for deliberate biological attacks, whose probability remains uncertain. (See *Containing Outbreaks of Infectious Disease: An Integrated Public Health Strategy.*) |
| **Implement a new research and development strategy for anti-infective drugs and vaccines.** | The United States must create new incentives for private-sector and university investment in the development of broad-spectrum antimicrobial drugs. It is also critical to develop new systems that shorten the time lag between identifying a new biological threat agent and creating safe and effective medical countermeasures. (See *Defending Against Biological Threats: An Integrated Research Strategy.*) |

# Biological Threats Facing the United States

The United States today faces two types of potentially catastrophic biological threats: natural infectious diseases, such as avian flu and other newly emerging infections, and biological weapons in the hands of states and terrorist organizations. Understanding in detail these two types of threats is critical to formulating an effective biosecurity strategy.

## Natural Infectious Disease: Endemic and Emerging Infections

Throughout human history, infectious disease has posed the greatest threat to human lives and livelihoods, dwarfing the number of deaths and injuries caused by warfare. Major pandemics, such as the Black Death (bubonic plague) of the 14th century and the Spanish Flu of 1918-19, killed tens of millions of people and had major social repercussions. Today, infectious diseases such as cholera, yellow fever, tuberculosis, HIV/AIDS, and malaria remain a grim fact of life for millions of people in the developing world, where they cause great suffering and economic hardship.

In the United States and other advanced industrialized countries, effective disease surveillance and the widespread use of antibiotics and vaccines during the 1960s and '70s eliminated the major infectious scourges, such as polio and measles. Over the past few decades, however, infectious disease has staged a comeback. Established infections such as tuberculosis have re-emerged in drug-resistant forms and spread geographically. At the same time, the world has experienced a host of previously unknown "emerging" infections, including Legionnaire's disease, Lyme disease, HIV/AIDS, the Sin Nombre variant of hantavirus, hepatitis C, mad cow disease, Nipah viral fever, SARS, and new strains of influenza. (See Box, page 2.)

The majority of modern emerging diseases have originated in Euorpe, North America, and Japan, contrary to the popular perception that new diseases emerge primarily in the developing world.[4] Yet the globalization of commerce, travel, and immigration have enabled emerging infections

[4] A new global map of emerging infectious diseases, prepared by Peter Daszak of the Consortium for Conservation Medicine at the Wildlife Trust in New York City, covers the period from 1940 to 2004 and indicates roughly 500 locations around the world where specific diseases first emerged. This map suggests that the majority of emerging infections originated in Europe, North America, and Japan. People tend to assume that most infectious diseases emerge in the tropics because AIDS, SARS, Ebola, and other high-profile diseases originated there. But the new map suggests that food-borne infections and drug-resistant microbes in northern industrialized countries, caused by factors such as agricultural practices, the overuse of antibiotics, and international travel, actually pose a more significant public health threat. See Jocelyn Kaiser, "More Infectious Diseases Emerge in North," *Science*, vol. 307, no. 5713 (February 25, 2005), p. 1190.

**Where Do Emerging Infections Come From?**

Several factors have contributed to the emergence of deadly infectious diseases over the past few decades:

- The inappropriate use of antibiotic drugs has fostered the evolution of resistant forms of tuberculosis and other bacterial diseases, even as the development of new generations of antibiotics has lagged.
- Ecosystem disturbances, such as global warming and the clearing of rainforests for economic development or human settlements, have altered the geographical distribution of disease vectors such as rodents and mosquitoes, increasing their contact with humans.
- Rapid population growth and rural-urban migration have given rise to "megacities" in the developing world with poor public health infrastructure, enabling diseases that once remained isolated in rural areas to spread to large urban populations.
- The collapse of public health systems in Russia and other parts of the former Communist world have fostered the spread of diseases such as AIDS and multi-drug-resistant tuberculosis.

such as SARS and avian influenza in the developing world to crisscross the planet along international trade and transit routes. This situation has created new opportunities for the introduction of dangerous pathogens into the United States and accelerated the rate at which epidemics can spread. Because most U.S. cities are within a 36-hour commercial flight from any part of the globe, a time interval that is less than the incubation period of many diseases, infected individuals may not be visibly ill when they cross a U.S. border and may thus escape detection.[5]

Case in point: The source of the 1999 outbreak of West Nile encephalitis — a viral infection never before seen in the Western Hemisphere — was probably either travelers from the Middle East who were incubating the disease when they arrived in New York City or infected chickens imported into New York City.[6] Whatever the exact source, the disease is now permanently established in the United States.

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[5] The risk of disease importations is greatest in major hubs of global commerce such as New York, Los Angeles, and Miami.

[6] Jennifer Brower and Peter Chalk, *The Global Threat of New and Reemerging Infectious Diseases: Reconciling U.S. National Security and Public Health Policy* (Washington, DC: RAND, 2003), p. 15, available at: http://www.rand.org/pubs/monograph_reports/MR1602.ch2.pdf

The U.S. public health system is currently incapable of mounting a timely, effective response to major infectious disease threats, despite incremental improvements since 9/11. Ironically, the system is in part a victim of its own success. Some 40 years ago, public hospitals and clinical laboratories provided an effective early-warning network for detecting and containing the major epidemic threats of the time, such as polio and measles. But the sharp decline of these high-profile diseases in the United States, brought about by the widespread use of antibiotics and vaccination, led to a sense of complacency.

Leaders in Congress and the executive branch mistakenly came to view infectious disease as a problem of the developing world and not as a threat to the U.S. homeland. As a result, financial support for the nation's health departments dried up, making the current public health infrastructure ill-equipped to address the twin 21st century threats of emerging infectious diseases and bioterrorism. The rising cost and privatization of health care also contributed to the problem by eliminating incentives for private hospitals to maintain the surge capacity needed to cope with major epidemics.

**Historical Examples of Biological Warfare**

- In the fifth century B.C., Scythian archers contaminated their arrows by dipping them in decomposing bodies or blood mixed with manure.
- In the 14th century A.D., Tartar forces besieging the city of Kaffa catapulted plague-infected corpses into the walled city to spread the disease.
- In the 18th century, in the aftermath of the French and Indian War, the British forces under the command of Sir Jeffrey Amherst gave smallpox-contaminated blankets to rebellious Indian tribes.
- During World War I, saboteurs employed by the German Army covertly infected Allied horses with glanders and anthrax to impede their use in military logistics.
- During World War II, the Imperial Japanese Army carried out biological attacks with plague bacteria against 11 Chinese cities.[1]

[1] E-Medicine.com, "History of Biological Warfare," http://www.emedicinehealth.com/biological_warfare/article_em.htm

## Biological Weapons: The State-Level Threat

Since antiquity, militaries have used infectious disease as a weapon. (See Box above.) Although no state has used a biological weapon in battle since the end of World War II, both the United States and the Soviet Union developed and stockpiled biological weapons during the Cold War. Prior to the 1991 Persian Gulf war, Saddam Hussein's Iraq produced and weaponized large quantities of biological warfare agents, including concentrated slurries of anthrax bacteria, botulinum toxin, and aflatoxin.

Efforts to control biological arms came in the wake of the horrors of WWI. In 1925, the League of Nations negotiated the Geneva Protocol, which banned the use in war of both chemical and bacteriological weapons but permitted their continued development, production, and stockpiling. It was not until November 1969 that the United States, under President Richard M. Nixon, unilaterally renounced and pledged to dismantle its offensive biowarfare program, while retaining strictly defensive activities.

The rationale for doing so was strategically sound. On the one hand, biological weapons had limited military utility on the battlefield because of their delayed effects and inherent unpredictability caused by the vagaries of the wind and weather. On the other hand, sophisticated biological weapons had the potential to inflict mass casualties when used on a large scale against cities. By serving as a "poor man's atomic bomb," such weapons could enable weaker powers to pose a strategic threat to the United States.

It was therefore in the interest of the U.S. and other developed countries to delegitimate biological weapons before they spread widely. After the unilateral U.S. renunciation in 1969, a United Nations disarmament forum negotiated the 1972 Biological Weapons Convention (BWC), a multilateral treaty banning the development, possession, stockpiling, and transfer of "microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes." The BWC, which entered into force in 1975, also categorically prohibits the development and production of specialized munitions and delivery systems for such agents and toxins. As of June 2006, 155 countries (including the United States) have signed and ratified the treaty, and an additional 16 countries have signed but not yet ratified.[7] As a result, the BWC has come to embody the international norm against the development and possession of biological weapons.

Yet according to an unclassified estimate, seven countries (China, Egypt, Iran, Israel, North Korea, Russia, and Syria) are alleged to have offensive biowarfare programs at various levels of sophistication, ranging from research and development to an active stockpile.[8] Of these countries, four are parties to the BWC (China, Iran, North Korea, and Russia). Such illicit programs pose a serious threat to international security. A possessor state might employ biological weapons either overtly or covertly, deadly pathogens might leak accidentally from a clandestine production facility, as occurred in 1979 in the Soviet city of Sverdlovsk, or a terrorist group might steal deadly agents from a state program. (See Box, page 5.)

[7] "The Biological and Toxin Weapons Convention Website," Department of Peace Studies, University of Bradford, *available at*: http://www.opbw.org/.

[8] Joseph Cirincione, Jon B. Wolfsthal, and Miriam Rajkumar, *Deadly Arsenals: Nuclear, Biological, and Chemical Threats*, 2nd ed. (Washington, DC: Carnegie Endowment for International Peace, 2005), p. 82.

**The Anthrax Outbreak at Sverdlovsk**

In April and May 1979, an unusual outbreak of anthrax occurred in the Soviet city of Sverdlovsk (now Yekaterinburg), about 850 miles east of Moscow. U.S. intelligence agencies attributed the epidemic to the inhalation of anthrax spores released accidentally from a military microbiology facility in Sverdlovsk, but Soviet health officials insisted that the cause of the outbreak had been the ingestion of contaminated meat. The cover-up persisted until May 1992, when Russian President Boris Yeltsin was quoted as saying that "the KGB admitted that our military developments were the cause."

Dr. Ken Alibek (born Kanatjan Alibekov), the former deputy director of Biopreparat, the civilian branch of the Soviet biowarfare program, later confirmed in his memoirs that the Sverdlovsk outbreak had resulted from an accident at a military facility called Compound 19, which manufactured spores of a particularly virulent strain of the anthrax bacterium. The spores were dried and then milled into a fine, highly infectious powder.

On the day of the accident, a technician at the drying plant removed a clogged air filter for maintenance without informing the incoming shift manager, who gave the order to resume production. According to Alibek, "A fine dust containing anthrax spores and chemical additives swept through the exhaust pipes into the night air. Several hours passed before a worker noticed that the filter was missing. The shift supervisor shut the machines down at once and ordered a new filter installed."[1] By then, however, a plume of anthrax spores had been released over the city. Over the next few days, people who had inhaled the spores fell severely ill, and many of them died. The last case of anthrax was reported on May 19, by which time the outbreak had claimed at least 68 lives — the worst single epidemic of inhalational anthrax in the 20th century.

[1] Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999), p. 74.

Another dimension of the threat posed by state-sponsored biowarfare programs is the pool of specialized expertise and technology they create. Until at least 1992, the former Soviet Union and then Russia possessed the world's largest and most sophisticated BW program. This massive effort included four military microbiological institutes run by the Ministry of Defense and more than 50 research and production facilities operated by a state pharmaceutical company called Biopreparat, which operated under civilian cover but was secretly engaged in offensive BW activities. Although the Biopreparat facilities were either dismantled or converted to peaceful research in the early 1990s, the Ministry of Defense's research centers remain off-limits to Westerners and remain a focus of lingering suspicion. In addition, the Soviet biowarfare program left behind a dangerous legacy, including collections of dangerous pathogens that could be at risk of theft or diversion to other states or terrorist organizations.

## The Threat of Bioterrorism

In parallel with the pursuit of biological warfare capabilities by states, a number of subnational groups have attempted to acquire and use such weapons for attacks against civilians. A terrorist group with access to dangerous pathogens could probably build a crude biological weapon that is relatively limited in its effects, as happened in Oregon just over two decades ago.

In the 1980s, the Rajneeshee cult led by the Bhagwan Shree Rashneesh (originally of Poona, India) founded a large ashram near The Dalles, Oregon. The cult soon came into conflict with local Wasco County officials over land-use issues. A few months before the November 1984 election for county commissioner, the Rajneeshees devised a scheme to make the citizens of the county sick with food poisoning on election day so that they would not vote, enabling the candidate favored by the cult to win.

To carry out the attack, members of the cult obtained a sample of the bacterium *Salmonella typhimurium*, a common cause of food poisoning, from the ashram's licensed clinical laboratory. The laboratory had legally obtained the bacterium as a control for meeting state quality-assurance requirements.[9] In a trial run of the food-poisoning scheme, which was carried out in August and September 1984, members of the Rajneeshee cult cultivated the *Salmonella* bacteria in an incubator. They then carried out a covert attack, using vials of the bacterial suspension to contaminate the coffee creamer and dressing in salad bars at several local restaurants in The Dalles.

Following the contamination, more than 750 local residents fell ill with food poisoning. Although some of the cases were severe and required hospitalization, there were no fatalities. The CDC's Epidemic Intelligence Service investigated the outbreak and concluded that it was of natural origin. The truth only emerged a year later, in September 1985, when the Bhagwan accused other cult members of responsibility for the outbreak.

A more recent and deadly incident of bioterrorism in the United States was the mailing of letters contaminated with anthrax bacterial spores immediately after the 9/11 terrorist attacks. In this case, an unknown perpetrator sent five letters containing a total of about 10 grams of dry powdered anthrax spores through the U.S. mail. The strain of the anthrax bacterium used in the attack and the highly refined nature of the material suggested that it had either been stolen from a state-level biowarfare or biodefense facility or had been produced by individuals with specialized technical know-how.

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[9] The historical details are drawn from W. Seth Carus, "The Rajneeshees (1984)," in Jonathan B. Tucker, ed., *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons* (Cambridge, MA: MIT Press, 2000), pp. 115-137.

The tainted letters infected a total of 22 people with anthrax, 11 with the cutaneous form of the disease and 11 with the far deadlier inhalational form, of whom five ultimately died. Despite the limited scale of the anthrax attack, its pervasive ripple effects highlighted the remarkable power of biological weapons as an instrument of terror and disruption. The tainted letters provoked public anxiety from New York to California, forced more than 30,000 people in D.C. alone to take prophylactic antibiotics, caused the U.S. Postal Service to spend billions of dollars to decontaminate mail-sorting facilities and to irradiate government mail, and shut down the Hart Senate Office Building for several months.

In the foreseeable future, however, even a well-financed, technologically adept terrorist group would have to overcome major technical hurdles to carry out a mass-casualty biological attack. Contrary to popular belief, acquiring or producing a supply of a biological agent, such as the bacterium that causes anthrax, is not the same as an operational weapon. To infect a large number of people, the agent must first be "weaponized" by converting it into a concentrated slurry or a dry powder, stabilized with special chemicals, and then placed in  a suitable delivery system, such as an aerosol sprayer or a munition.

Because different skill sets are required for the acquisition, production, weaponization, and delivery of pathogens and toxins, even technologically sophisticated and wealthy terrorist organizations have had difficulty developing and using biological weapons effectively. In the early 1990s, for instance, the Japanese doomsday cult Aum Shinrikyo attempted to produce deadly pathogens as part of a scheme to seize control of the Japanese government. A young university-trained microbiologist named Seichi Endo led the cult's effort to produce anthrax bacteria, botulinum toxin, and possibly other biological warfare agents. On at least nine occasions between 1990 and 1993, Aum spread covertly what it believed were lethal bacteria in or around Tokyo and at a nearby U.S. military base, with the intent of causing chaos and loss of life.

Fortunately, the cult failed to make botulinum toxin and inadvertently produced a harmless vaccine strain of the anthrax bacterium. After the failure of its attempts at bioterrorism, however, the cult went on to produce a chemical warfare agent, sarin nerve gas, which it released on the Tokyo subway in 1995, killing 12 people and injuring nearly 1,000.[10]

[10] David E. Kaplan, "Aum Shinrikyo (1995)," in Tucker, ed., *Toxic Terror*, pp. 207-226.

Nearly all past efforts to carry out biological terrorism have either been unsuccessful or limited in their effect, suggesting that the technical hurdles to acquiring a mass-casualty capability are significant. At the same time, though, technological advances are gradually eroding these barriers, which means the threat of bioterrorism is likely to grow incrementally in the coming decades. In particular, globalization has led to the dispersal of advanced biotechnological research and production capabilities to many countries around the world. The equipment and materials needed to manufacture vaccines and other legitimate biological products — nutrient broths for growing bacteria, fermentation tanks, centrifugal separators, spray driers, and automated DNA synthesizers — can be misused to produce biowarfare agents.

In sum, as the biotechnology industry continues to expand worldwide, dual-use expertise and technology will become increasingly available to outlaw states and terrorists, potentially enabling a subnational group to carry out a small-scale but highly disruptive biological attack. A wealthy terrorist organization might also recruit scientists and engineers formerly employed by a state-level biowarfare program, such as that of Iraq, South Africa, or the former Soviet Union.

# Preventing Bio-Catastrophes:
## The Need for a Global Approach

U.S. government efforts to prevent bioterrorism have focused primarily on tightening domestic controls on the possession, use and transfer of so-called "select agents," or microbial agents and toxins, that could be used as weapons, among them the bacteria that cause anthrax, plague, and tularemia. Legislation enacted in the aftermath of 9/11 and the anthrax letter attacks requires all laboratories that possess select agents to register with the U.S. government and implement security enhancements, and any scientist seeking to work with select agents must undergo an FBI security check that involves screening against terrorism databases.[11] The Patriot Act also forbids citizens of countries on the State Department's list of state sponsors of terrorism from working with select agents.

Although these efforts are necessary elements of a layered prevention strategy, they are not sufficient. The United States must devote greater political, diplomatic, and financial attention to international efforts to prevent the misuse of biotechnology because terrorists and states with the will to develop biological weapons will shop for pathogens and production equipment wherever controls are weak. In addition, the United States must work to strengthen the international treaties that prohibit the possession and use of biological weapons and monitor and enforce compliance.

### Preventing the Misuse of Life Sciences

The life sciences are in the midst of a technological revolution that has already yielded enormous benefits for society. Since the invention of recombinant-DNA technology in early 1970s, scientists have had the ability to modify and transfer useful genes from one species to another. The recent decoding of the entire human genome has further transformed biology, as have dramatic improvements in the technologies used to sequence, synthesize, and manipulate genes in the laboratory. These advances promise to revolutionize the practice of medicine, agriculture, and other industries.

Despite the benefits of these powerful technologies, however, they could also be misused to create biological weapons. For example, the ability to synthesize strands of DNA from off-the-shelf chemical ingredients and assemble them into viral genomes has made it possible to recreate infectious pathogens in the laboratory. To date, scientists have synthesized poliovirus and the "Spanish flu" virus (the 1918 pandemic strain of influenza), and it

[11] The legislation in question is the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107-188), signed on June 12, 2002. The Select Agent regulations are in 42 CFR 73 (October 2005).

may only be a matter of time before the synthesis of more complex pathogens, such as the smallpox virus, becomes technically feasible.

Genetic engineering technology might also be used to enhance a pathogen's virulence or its ability to cause illness and death. In early 2001, a team of Australian scientists reported that splicing the gene for an immune-system protein into mousepox virus unexpectedly rendered the virus highly lethal in mice, even when the animals were genetically resistant to natural mousepox or had been vaccinated against it.[12] Although this finding was of scientific interest, it indirectly suggested a way to make the smallpox virus (a cousin of the mousepox virus) even more lethal to humans, possibly providing a "road map" for would-be bioterrorists.

There is broad agreement that research posing a potential threat to public health or national security should be designated "dual-use" and subjected to special oversight procedures or constraints on publication.[13] At the same time, the rapid pace of innovation in the life sciences depends in large measure on the free and open exchange of ideas among researchers in many countries. It is therefore essential to find a reasonable balance between preventing bioterrorism and maintaining the openness that is vital to scientific progress.

In 2004, the U.S. government established an advisory committee called the National Science Advisory Board for Biosecurity (NSABB) to help define this balance. The NSABB consists of 25 biologists, physicians, and security professionals from outside of government. Operating under the auspices of the National Institutes of Health (NIH), the board assesses the national security implications of dual-use research in the life sciences and develops additional guidelines for the Institutional Biosafety Committees (IBCs) that currently oversee recombinant-DNA research.

The NSABB held its first meeting in the summer of 2005. Since then it has created working groups to refine the definition of dual-use research, develop policies for the security review of such research projects prior to funding or publication, draft a professional code of conduct for the life sciences, and foster international cooperation in developing common approaches to the problem of dual-use research.[14]

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[12] R. J. Jackson, A. J. Ramsay, C. Christensen, S. Beaton, D. F. R. Hall, and I. A. Ranshaw, "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox," *Journal of Virology*, Vol. 75 (2001), pp. 1205-1210

[13] John D. Steinbruner and Elisa D. Harris, "Controlling Dangerous Pathogens," *Issues in Science and Technology*, vol. XIX, no. 3 (Spring 2003), pp. 47-54, online at: http://www.issues.org/19.3/steinbruner.htm. See also, John Steinbruner, Elisa D. Harris, Nancy Gallagher, and Stacy Okutani, "Controlling Dangerous Pathogens: A Prototype Protective Oversight System," December 2005, available online at <http://www.cissm.umd.edu/documents/pathogensmonograph_dec05.pdf>

[14] For more information on the NSABB, see http://www.biosecurityboard.gov

The establishment of the NSABB was a positive step, yet the board has major limitations that constrain its ability to strike an appropriate balance between national security and scientific progress. Most importantly, its recommendations are merely advisory and not binding on U.S. government agencies. Instead, the primary role of the NSABB is to develop guidelines for self-governance by the scientific community. Unlike physicists during the Cold War, however, biologists lack much awareness of the dual-use implications of their work, so it is an open question whether voluntary oversight mechanisms will be sufficient to safeguard national security. The NSABB also lacks the authority to oversee classified government research on biodefense topics, despite the fact that such research is a major area of dual-use concern.

**The Globalization of Life Sciences Research**

Another weakness of the current U.S. biosecurity regime is that it does not devote sufficient attention to the globalization of cutting-edge research in the life sciences. The United States and other advanced industrial countries no longer have a monopoly in this area. Developing nations with advanced biotechnology capabilities include China, Cuba, India, Malaysia, Singapore, South Africa, and South Korea, and many other countries aspire to follow their lead. Although the United States, the United Kingdom, Germany, and Singapore have introduced strict regulations on "select agents" of bioterrorism concern, most other countries have not. Because terrorists and states may shop for pathogens and dual-use production technologies where controls are weak, the uneven patchwork of national regulations leaves major gaps in biosecurity.

The United States and other members of the United Nations have sought to address the international dimension of biosecurity by enacting Security Council Resolution 1540 of April 2004, which imposes a legal obligation on all UN member states to adopt domestic measures to prevent terrorists from acquiring biological weapons and related technology. The potential of this measure will remain untapped, however, until the United States and other leading countries agree on a set of specific biosecurity measures required under Resolution 1540 and offer realistic incentives and inducements for all countries to fulfill their obligations.

Another critical dimension of biosecurity is the scientific and technical legacy of the biological weapons programs of the former Soviet Union and, more recently, South Africa and Iraq. Although these countries have officially renounced biological weapons, they retain the expertise of scientists, engineers, and technicians who were formerly involved in offensive research and development. The risk persists that these experts, many of whom are unemployed or underpaid, could be tempted to sell their

services to terrorists or extremist regimes. According to a 2003 survey of former weapons scientists in Russia, 21% would consider working in North Korea, Iran, or Syria for a year or more.[15]

The U.S. government is addressing the risk of this potentially lethal "brain drain" through a series of initiatives. The U.S. Department of Defense's Cooperative Threat Reduction program (better known as "Nunn-Lugar," after the two senators who sponsored the original legislation, Sam Nunn of Georgia and Richard Lugar of Indiana) involves dismantling former bioweapons production facilities and securing collections of dangerous pathogens. In addition, the Departments of Energy, State, and Health and Human Services sponsor programs to prevent brain drain by employing former Soviet bioweapons scientists in peaceful research projects.[16] The United States and several other countries also support International Science and Technology Centers in Moscow and Kiev that provide research grants to former BW scientists, along with training and workshops to integrate them into the international scientific community.[17]

These programs to prevent brain drain have kept former bioweapons scientists employed in peaceful research at home, significantly reducing the risk that they will be recruited by states or terrorist groups seeking biological weapons. Because most former Soviet weapons scientists receive short-term research contracts, however, the resulting economic uncertainty could lead some to consider selling their expertise to the highest bidder.

**RECOMMENDATIONS:**

Countries with advanced capabilities in biotechnology, including the United States, should launch a global effort under United Nations auspices to prevent the misuse of biological research and technology without imposing undue constraints on legitimate research and production. To this end, the United States should work with other governments, domestic and international scientific groups, and the biotechnology industry to ensure the effective oversight of scientific research that could inadvertently increase the risk of biowarfare and bioterrorism. Developing internationally harmonized rules for this purpose will demand an unprecedented level of cooperation among governments, the private sector, and academic institutions around the globe.[18]

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[15] Deborah Yarsike Ball and Theodore P. Gerber, "Russian Scientists and Rogue States: Does Western Assistance Reduce the Proliferation Threat?," *International Security*, vol. 29, no. 4 (Spring 2005), pp. 50-77.

[16] Center for Arms Control and Nonproliferation, "Biological Weapons Threat Reduction," *Issue Brief*, March 31, 2005.

[17] Government of Canada, Department of Foreign Affairs and International Trade, *Global Partnership Program: Securing the Future* (Ottawa, November 2005), p. 36.

[18] U.S. National Academy of Sciences, National Research Council, *Biotechnology Research in an Age of Terrrorism* (Washington, DC: National Academy Press, 2004).

Specifically, the United States should:

**Support the negotiation of "harmonized" guidelines for the physical protection, control, and accounting of collections of dangerous pathogens (including those synthesized in the laboratory) to prevent them from falling into the hands of terrorists.**

These guidelines should address the threats of theft or diversion by both outsiders and trusted insiders, and should include:

• An agreed list of "select agents" (or a set of clear, uniform criteria for designating them) that serves as the basis for regulation;

• Rules for registering and licensing facilities that work with select agents;

• Minimum standards and procedures for controlling access to pathogens, including physical security measures;

• Accounting mechanisms to track pathogens that are stored, used in experiments, transferred, or exported;

• Procedures for checking the trustworthiness of scientists and technicians who wish to work with select agents.[19]

To create incentives for participation by developing countries, which are more concerned about natural infections than bioterrorism, the United States and other wealthy countries should provide research grants for the development of medical therapies against endemic infectious diseases, with the condition that the recipient countries implement basic biosecurity measures.

**Condition NIH research funding for so called "experiments of concern" on compliance with select-agent rules and a pre-funding security review by an Institutional Biosafety Committee.**

A 2004 report by an expert committee organized by the National Research Council identified seven "experiments of concern" that warrant a pre-funding security review, such as demonstrating how to render a vaccine ineffective or conferring resistance to therapeutically useful antibiotic or antiviral drugs.[20] In the event that a proposed legitimate research project raises national security concerns, NIH should either deny funding or condition it on publication restrictions or other appropriate measures.

**Pursue the negotiation of harmonized international guidelines for assessing the national security implications of sensitive research in the life sciences.**

The U.S. government should work with other countries, scientific organizations, and relevant professional societies to develop a uniform approach to conducting pre-funding security reviews of dual-use research proposals and, in rare cases, to limiting the publication of unexpectedly sensitive results.

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[19] Jonathan B. Tucker, "A Strategy for International Harmonization of Biosecurity Standards Under SCR 1540," McGeorge School of Law web site, December 2004, http://www.mcgeorge.edu/resolution_1540/

[20] U.S. National Academy of Sciences, National Research Council, *Biotechnology Research in an Age of Terrrorism*, p. 5.

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| **Require graduate students in the life sciences to take a course or module on the risks of misuse of research results, and to sign a professional code of conduct.** | Although newly minted physicians are required to take the Hippocratic oath to "do no harm" before they can practice medicine, researchers in the life sciences are not obligated to adopt a professional code of conduct. In order to raise awareness of dual-use concerns associated with biological research, graduate students should be required to take a course or module that addresses issues of biological warfare and professional responsibility, including the obligation to "blow the whistle" on colleagues suspected of engaging in illicit or unethical activities. |
| **Increase funding for biological "brain drain" programs in the former Soviet Union and take steps to make these programs more sustainable.** | The United States and other sponsors should strive to create economically viable enterprises that can employ former weapons scientists in commercial research and development, although the political and financial obstacles facing such efforts remain considerable. |
| **Give biosecurity grants and technical assistance to developing countries that require assistance.** | The United States should provide grants and security technologies, such as access-control systems and inventory software, to poor countries to help them safeguard collections of highly dangerous pathogens that have been retained for legitimate biomedical research or epidemiological purposes. |

## Strengthening Biological Disarmament Measures

Unlike the international treaties that control the spread of nuclear and chemical weapons, the Biological Weapons Convention (BWC) lacks formal mechanisms to verify that the member states are complying with its prohibitions. Over the past 20 years, there have been two major attempts to remedy this shortcoming. The first was the agreement by BWC member states in 1986 and 1991 to "confidence-building measures" (CBMs), under which they would exchange data each year on several topics relevant to the treaty, including high-containment laboratories, biodefense programs, and unusual outbreaks of disease. Because the CBMs are voluntary, however, only a minority of states have submitted them on a regular basis.

The second attempt to strengthen the BWC involved formal verification procedures. In September 1994, the United States and other parties established a new forum called the Ad Hoc Group to develop a set of legally binding measures, including declarations of legitimate commercial facilities that could potentially be diverted to produce biological weapons, routine on-site inspections to check these declarations, and provisions for "challenge" inspections of facilities suspected of a treaty violation and for investigations of alleged use. In March 2001, after more than six years of negotiations, the Ad Hoc Group completed a draft of the BWC Protocol, and it appeared that the talks were finally entering the home stretch.

In July 2001, however, the new administration of U.S. President George W. Bush abruptly rejected the draft BWC Protocol and withdrew from the negotiations. U.S. officials claimed that on-site inspections would not deter countries that were determined to acquire biological weapons because the difficulty of distinguishing between peaceful and weapons-related development and production would make it easy to conceal violations.

The Bush administration also expressed concern that the international inspectors might spy on legitimate U.S. biodefense research activities and steal commercial trade secrets. Since then, the United States has blocked proposals to revive the BWC Protocol or to negotiate other legally binding multilateral agreements to strengthen the treaty. Instead, the Bush administration has endorsed a number of non-binding voluntary measures, to be taken on a national basis.

Verifying that the parties to an arms control treaty are complying with its obligations is always challenging because countries that intend to cheat will work hard to cover their tracks. Moreover, verification measures are not simply imposed on states that join a disarmament treaty but must be negotiated voluntarily and adopted by consensus. For this reason, any system of on-site verification involves a delicate balance between making the inspections sufficiently intrusive to provide confidence in the compliance of other countries, and the desire of each state to protect sensitive military facilities and confidential business information unrelated to treaty compliance. Given this balancing act, there is no such thing as "perfect" verification.

Due to the technical characteristics of biological weapons, the difficulties associated with checking BWC compliance are particularly great. The BWC does not ban "research" involving dangerous pathogens, for example, because it is vital for human health and welfare, even though some basic knowledge in the life sciences might be misused to develop biological weapons. Moreover, since the equipment and supplies used to make biowarfare agents have a variety of legitimate uses, it can be difficult to determine whether a biotechnological facility such as a vaccine plant is being utilized strictly for peaceful purposes or is being secretly diverted for illicit production.[21]

Despite the formidable technical and political challenges associated with verifying the ban on biological weapons, it is not true that such efforts are useless, as the Bush administration contends. The mere chance of getting

[21] This "dual-use" dilemma is considerably greater for biological weapons than for chemical or nuclear weapons. Whereas manufacturing the chemical nerve agent sarin requires a large industrial plant and access to precursor chemicals whose physical traces are difficult to remove, biological agents, such as anthrax spores, may be produced in small, ostensibly civilian facilities, using fermenters that can be sterilized after a production run.

caught in a violation would be sufficient to deter many countries from pursuing biological arms. Iraq, for instance, halted its biological weapons program in the face of persistent UN inspections. Moreover, by forcing countries that intend to cheat on their treaty obligations to incur significant added costs and risks, a verification regime — however imperfect — can deter or impede prohibited activities and increase the probability of detection.

It would be much easier for the United States to garner international support for efforts to isolate or sanction violators of the BWC so as to bring them back into compliance if the evidence of their guilt came from an independent verification regime carried out by international civil servants who do not act on behalf of any individual government. This advantage of verification has become particularly salient since the U.S. failure in 2003 to find weapons of mass destruction in Iraq, which undermined the international credibility of American intelligence assessments.

The Bush administration has exaggerated the risk that on-site inspections of government and industry facilities would jeopardize biodefense and trade secrets. During the BWC Protocol negotiations, the British government performed several mock inspections of military installations and pharmaceutical plants. These exercises demonstrated that "managed-access" techniques, such as shrouding sensitive items of equipment, can protect legitimate secrets while still enabling inspectors to check BWC compliance with a reasonable degree of confidence.[22] Nevertheless, given the deeply entrenched political opposition from the United States and a few other countries, the BWC Protocol is unlikely to be revived, at least for the foreseeable future.

**Beyond the BWC Protocol**

As an alternative to the now-defunct verification protocol, the United States and other parties to the BWC should support a number of other measures, both inside and outside the treaty framework, to bolster the international norm against the acquisition and use of biological weapons. One such approach would be to strengthen two existing mechanisms for investigating unusual outbreaks of infectious disease: the epidemiological investigations conducted by the World Health Organization and an existing but little-known procedure by which the UN Secretary General can investigate alleged violations of the 1925 Geneva Protocol banning the use of biological or chemical weapons.

The World Health Organization would probably be the first international body to evaluate an unusual outbreak of disease, whether it is natural or caused by

[22] "Working Paper by Great Britain: Investigations: Managed Access," Ad Hoc Group of the States Parties, Ninth Session, Geneva, BWC/AD HOC GROUP/WP.247, December 16, 1997, available online at: http://www.opbw.org/ahg/docs/09th%20session/wp247.pdf

the covert use of a biological weapon. It is critical, however, for WHO to remain politically neutral or it will no longer be able to carry out its core public health missions. For this reason, WHO should conduct a strictly technical investigation of a disease outbreak and leave it to individual UN member states to refer suspicious evidence of biological weapons use to the Security Council, which would then decide whether or not to pursue the matter.

A complementary option would be to strengthen the existing United Nations procedure whereby the Secretary General assembles a team of experts from various member countries (selected from a roster) and dispatches them to the site of a reported biological or chemical attack or an unusual outbreak of disease to conduct an objective, forensic scientific inquiry and determine whether a suspicious event was caused by natural factors or resulted from the use of a biological or chemical weapon. This option has the merit of past experience. Between April 1981 and July 1992, the UN investigated four cases of alleged chemical or toxin weapons use:

- by the Soviet Union and its allies in Southeast Asia and Afghanistan;
- by Iraq and Iran during the Iran-Iraq War;
- by the Mozambican National Resistance in Mozambique;
- by Armenian forces in Azerbaijan.

Although the four cases all dealt with the alleged use of a chemical or toxin weapon, investigations of biological weapons use or suspicious outbreaks of disease would involve similar procedures. The historical record shows that small groups of three to five experts can conduct field investigations rapidly, effectively, and cheaply if they arrive shortly after an alleged attack and the team is granted unrestricted access to the affected sites and people.[23]

The main weakness of the UN Secretary General mechanism is the fact that no country is legally obligated to cooperate with an investigation team. During the early 1980s, for example, the governments of Laos, Vietnam, and Afghanistan denied UN experts access to the sites of alleged toxin warfare ("yellow rain") attacks, with the result that the UN investigation could not be conducted properly and the findings were inconclusive.

[23] Jonathan B. Tucker and Raymond A. Zilinskas, "Assessing U.S. Proposals to Strengthen the Biological Weapons Convention," *Arms Control Today*, April 2002, available online at: http://www.armscontrol.org/act/2002_04/tuczilapril02.asp

A second problem is that because the most recent UN field investigation was in 1992, the roster of experts is seriously out of date. Moreover, a shortage of funds would probably prevent the Secretary General from launching an alleged-use investigation unless the complainant nation was prepared to cover the costs. The UN Department of Disarmament Affairs (DDA), the sole branch of the Secretariat with the relevant expertise, lacks any discretionary funds for carrying out field investigations. Although DDA staff could approach UN member states and request special contributions for this purpose, it is far from certain that the money would be forthcoming. The ad hoc nature of the investigation mechanism also raises questions about its credibility and undermines its deterrence value.

## Recommendations

The next opportunity to strengthen the BWC will come at the Sixth Review Conference of the treaty, which will convene in Geneva, Switzerland, in late 2006. During and after this conference, the United States should work with other states parties to the BWC to:

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| **Reaffirm the understanding that the prohibitions in the BWC apply to pathogenic microorganisms synthesized in the laboratory.** | The United States should encourage the Sixth Review Conference to reaffirm the understanding that Article I of the BWC, which bans all uses of microbial pathogens and toxins for hostile purposes (the "general purpose criterion"), covers partially or totally synthetic microorganisms. |
| **Strengthen the annual confidence-building-measure data declarations under the BWC.** | The United States should propose that the annual confidence-building-measure declarations be made mandatory, as only a minority of BWC members have filed them on a voluntary basis. In addition, all countries should be encouraged to publish their data declarations on the Internet, as the United States did in 2004 but not since then. |
| **Establish a small Scientific Advisory Committee for the BWC.** | As the British Royal Society has recommended, the BWC Review Conference should establish a small Scientific Advisory Committee to monitor developments in science and technology relevant to the BWC and suggest ways of countering these emerging threats. |

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| **Create a permanent Implementation Assistance Unit (IAU) for the BWC.** | An IAU would strengthen compliance with the BWC by helping member states to draft domestic legislation outlawing the development, possession, and use of biological weapons, and to file their annual CBM declarations. The IAU would also organize the five-year review conferences of the BWC and annual intersessional meetings. Consisting of 20 permanent staff, an IAU could operate effectively with an annual budget of about $5 million, of which the United States would contribute about 25%. |
| **Update the existing mechanism for conducting field investigations under the auspices of the UN Secretary General.** | The United States should urge the Security Council to pass a resolution requiring all UN member states to cooperate with a field investigation launched by the Secretary General without right of refusal. In addition, the member states should be assessed enough money to create a small fund within the Department of Disarmament Affairs to support the conduct of field investigations. The estimated cost of maintaining a strengthened field-investigation capability would be about $500,000 per year, and each investigation would cost about $200,000 per week.[24] |
| **Seek a UN Security Council resolution requiring that any credible allegation of the use of biological weapons be placed automatically on the council's agenda.** | Because an item placed on the agenda of the Security Council can only be removed by a vote of the council itself, this provision would reduce the ability of a small number of countries to block discussion of an allegation of biological weapons use. Although a permanent member of the Security Council could veto a proposed investigation of the incident, the council would still have to consider the issue, raising the profile of the allegation and increasing the chances that appropriate investigative measures will be taken. |
| **Seek a UN Security Council Resolution branding specific acts involving biological weapons as international crimes, comparable to aircraft hijacking or torture.** | This measure would criminalize the development, production, and stockpiling of biological weapons. It would also require that countries adopt domestic legislation granting their national courts criminal jurisdiction over any individuals present on their territory (regardless of nationality or official position) who order, direct, or knowingly render substantial assistance to the acquisition or use of biological weapons anywhere in the world.[25] The accused party could either be extradited to the country of nationality or sent to the International Criminal Court in The Hague. |

[24] Trevor Findlay, "A Standing United Nations Verification Body: Necessary and Feasible," *Compliance Chronicles*, No. 1 (December 2005), p. 19.

[25] Harvard-Sussex Program on CBW Armament and Arms Limitation, "A Draft Convention to Prohibit Biological and Chemical Weapons Under International Criminal Law," *CBW Conventions Bulletin*, No. 42 (December 1998), pp. 1-5.

The strategy outlined above to prevent the illicit acquisition and use of biological weapons, materials, and technology would reduce the threat of bioterrorism but not eliminate it altogether. In the event prevention fails, the United States must be prepared to manage the consequences of disease outbreaks, whether natural or deliberate in origin. To that end, the nation must develop a web of preparedness measures that are flexible enough to address any contingency, from an anthrax attack to an outbreak of pandemic influenza.

Such an "all-hazards" approach would offer political as well as security benefits. Because natural outbreaks are inevitable but bioterrorist attacks are not, preparedness measures that cover all infectious threats would not only be far more cost-effective but politically more sustainable, particularly if a major bioterrorist event does not occur for many years, if ever. The all-hazards approach demands a responsive public health infrastructure that is capable of detecting and containing disease outbreaks in a timely manner.

The Biological Incident Annex — the portion of the U.S. government's National Response Plan (NRP) that addresses biological threats — echoes much of this strategy, at least on paper. It correctly identifies natural and intentional disease outbreaks as two sides of the same coin. It recognizes that timely detection and a surge capacity for medical treatment are critical to limiting the effects of an outbreak and that mounting a response will require federal government agencies to cooperate seamlessly with one another and with state, local, and tribal authorities. It designates the Department of Health and Human Services (HHS) as the lead agency responsible for coordinating the public health response, and the Department of Homeland Security (DHS) as the lead agency responsible for nonmedical support and response.[26]

Responsibility for detecting outbreaks of infectious disease is shared among the more than 3,000 local, county, city, and tribal health departments; 59 state and territorial health departments; and officials from several federal agencies, including HHS, DHS, the Veterans Administration, and the U.S. Public Health Service.[27] (Health departments for some of the larger metropolitan areas, such as New York City, are larger than many state health departments.) Under the NRP, "State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks." The federal government is expected to play a support role, including the

[26] See National Response Plan, Biological Incident Annex (December 2003).

[27] U.S. Congress, Government Accountability Office (GAO), *Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure*, June 2005, p.7, available at: http://www.gao.gov/new.items/d05308.pdf

stockpiling of vaccines and other medical countermeasures, and fledgling efforts to coordinate national disease surveillance.

Nevertheless, having an emergency plan on paper is no guarantee that it will work in practice, as the federal government's faulty response to Hurricane Katrina demonstrates. The Biological Incident Annex is premised on the assumption that state, local, and tribal entities can, as a practical matter, assume primary responsibility for detecting and responding to major outbreaks of infectious disease. Unfortunately, the reality is that they cannot. Only seven states and four cities currently have the capability to administer stockpiled vaccines on a large scale, let alone deal with the other aspects of detecting and containing an outbreak in a timely manner.

## Timely Detection of Outbreaks

Epidemiological surveillance, or efforts to detect outbreaks of infectious disease, has long been a vital component of the nation's public health system. Traditional surveillance systems rely on physicians to report certain infectious diseases immediately after diagnosis. These reports are then submitted to local or regional health departments, which in turn report unusual patterns of disease activity up the chain to state health departments and to the CDC. Local public health agencies conduct follow-up investigations and mobilize the appropriate responses, with back-up support from state and federal agencies.

In recent years, epidemiological surveillance has evolved from informal reporting by phone and fax to a more standardized and largely electronic system, but it still relies on the willingness of physicians to submit case data to city and state health departments in a timely manner. There is also a need for improved communications links between hospitals and public health departments to facilitate disease reporting.

For many natural infections such as SARS and influenza, the slow onset of an epidemic usually provides enough time for traditional surveillance systems to detect an outbreak and respond with mitigating measures. In the event of a bioterrorist attack, however, a large number of people might be exposed simultaneously to an infectious agent. Under these conditions, traditional epidemiological surveillance would be too slow to detect the outbreak in a timely manner.

This concern has led to an increased interest in so called "syndromic" surveillance, or the computerized monitoring of a variety of data streams that provide information about the health of a population, including pharmacy prescriptions, EMS calls, school absences, and hospital diagnoses. Although syndromic surveillance systems have certain limitations depending on the types of data streams they utilize, this technology is playing a more prominent role in national preparedness for both emerging infections and bioterrorism.[28]

The timely detection of an outbreak of a contagious disease would be vital to minimizing its impact on public health — a few days could mean the difference between successful containment and a spreading epidemic. In the case of a bioterrorist incident involving smallpox, for example, a delay of five days in correctly diagnosing the disease could result in a 30% increase in the number of people affected.[29]

Today the U.S. public health system is somewhat better equipped to detect biological threats than it was before 9/11, largely as a result of incremental progress in upgrading state public health laboratories and emergency communications systems. But two major gaps remain.

First, doctors and nurses working in emergency rooms, health clinics, and medical centers around the United States are the first line of defense against outbreaks of infectious disease, yet many health professionals lack experience in correctly diagnosing rare infectious diseases. A recent survey conducted by researchers at Johns Hopkins University found that practicing physicians would misdiagnose anthrax, botulism, plague, and smallpox — all potential bioterrorist threats — an average of 47% of the time.[30]

For natural epidemics of avian influenza or severe acute respiratory syndrome (SARS), the prospects for misdiagnosis are high because the early symptoms of these diseases resemble those of more common ailments such as seasonal flu. Differential diagnosis also requires specialized expertise or laboratory tests that take days to complete. As a result, infectious threats may only become manifest when public health authorities study broader patterns of disease incidence in large populations. Yet the United States currently lacks a standardized, national mechanism for detecting suspicious outbreaks in "near-real time."

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[28] David C. Roberts, "Surveillance Systems: Present Practice, Future Goals," *Sigma* (Mitretek Systems), vol. 5, no. 2A (February 2006), pp. 12-20.

[29] Martin I. Meltzer, Inger Damon, James W. LeDuc, and J. Donald Millar, "Modeling Potential Responses to Smallpox as a Bioterrorist Weapon," *Emerging Infectious Diseases*, vol. 7, no. 6 (November-December 2001), available at: http://www.cdc.gov/ncidod/eid/vol7no6/meltzer.htm.

[30] Sara E. Cosgrove, Trish M. Perl, Xiaoyan Song, and Stephen D. Sisson, "Ability of Physicians to Diagnose and Manage Illness Due to Category A Bioterrorism," *Archives of Internal Medicine*, vol. 165, no. 17 (Sept. 26, 2005), pp. 2002-2006.

Second, the United States has not yet developed a fully integrated network of local, state, federal, and private-sector health surveillance systems that permits the sharing of diagnoses and the identification of suspicious patterns of disease incidence. At the national level, the CDC is responsible for coordinating the collection, analysis, and distribution of data on infectious diseases. The agency acquires most of its information from state and local public health departments, which are required to report epidemiological data to the CDC as a condition of receiving grants. Nevertheless, nearly half of U.S. states do not use modern information technologies or standard national formats to report and share data on infectious disease.[31] This critical deficiency makes it less likely that CDC officials will detect outbreaks rapidly and communicate their findings to multiple jurisdictions.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required the executive branch to strengthen national disease surveillance mechanisms. In response, the federal government launched an effort to develop a standardized, national mechanism for tracking infectious disease threats known as the Public Health Information Network (PHIN). Directed by the CDC, PHIN seeks to integrate dozens of local, state, and federal surveillance systems into a single, unified network. PHIN has eight major components: three mechanisms for detecting outbreaks and five for communicating and distributing data. (See Box, page 25.)

[31] Trust for America's Health, *Ready or Not?* (2005), p.22.

**Major Components of the Public Health Information Network**

**Detection-Related Components**

*BioSense***.** A syndromic surveillance system that uses data from hospitals and other health care systems in major U.S. cities to provide surveillance alerts in real-time.

*The National Disease Surveillance System (NDSS)***.** Encourages interoperable disease surveillance systems among federal, state, and local public health officials by promoting uniform data standards.

*National Environmental Public Health Tracking Network (NEPHTN)***.** Promotes coordination and cooperation on disease surveillance between the Environmental Protection Agency (EPA) and the CDC.

**Communications-Related Components**

*Epidemic Information Exchange (Epi-X).* Facilitates sharing of public health information among public health officials via a secure, Internet-based communications system.

*Health Alerting.* Broadcasts e-mail alerts on disease outbreaks to state and local health officials.

*LRN Results Manager.* Utilized by cities participating in the BioWatch program to transmit data electronically to the CDC.

*Outbreak Management System.* Assists federal, state, and local public health agencies in monitoring cases during the course of an outbreak investigation.

*PHIN Messaging System.* Enables encrypted communications and data exchanges.

More than two dozen states and two major cities (Los Angeles and New York) have taken steps to upgrade their disease surveillance networks in order to participate in PHIN.[32] Even so, major gaps in the system remain. Two of the three surveillance components of PHIN — the National Disease Surveillance System and the National Environmental Public Health Tracking Network — are still years away from being fully operational.[33]

The surveillance component of PHIN that is fully operational, known as BioSense, is a "web-based application which enables healthcare facilities and state and local public health organizations to see data from their own communities."[34] Unfortunately, BioSense provides health data of limited utility, according to state and local public health officials interviewed by the

[32] "Progress in Improving State and Local Disease Surveillance – United States, 2000-2005" *Morbidity and Mortality Weekly Report*, vol. 54, no. 33 (August 26, 2005), pp. 822-825, available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5433a3.htm

[33] U.S. Congress, Government Accountability Office, *Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure*, pp. 22-25.

[34] Richard F. Besser, Testimony before the House Subcommittee on the Prevention of Nuclear and Biological Attack, "Creating a Nation-wide Integrated Biosurveillance Network," May 11, 2006, p. 2.

congressional Government Accountability Office (GAO).[35] In the case of a smallpox attack, for example, hundreds of cases might need to occur before the indicators monitored by BioSense recognized the outbreak, by which time the epidemic could have already spun out of control.

GAO also found that most of the other components of PHIN are either burdensome to use or redundant with other capabilities.[36] Moreover, 23 states do not employ national disease reporting standards, impeding the timely sharing of information that is critical to identifying and containing an outbreak.[37]

DHS is also involved in surveillance of infectious diseases through its BioWatch program, which consists of hundreds of air-sampling systems deployed around the nation (mostly at air-pollution monitoring stations) in an attempt to detect and identify the presence of pathogens of bioterrorism concern.[38] Although BioWatch samplers would probably detect the airborne release of a biological threat agent over a large area, they would probably not be effective for more limited attacks involving the contamination of water or food sources.

In addition, when an air sampler picks up an unusual microbe, the local health department is responsible for performing the preliminary testing. If the initial test is positive, the local department notifies the CDC and the testing moves up the organizational ladder to the state and federal levels. Unfortunately, BioWatch is not accurate enough to provide a cost-effective way of strengthening the nation's surveillance capability. In several cases, air-samplers have detected trace levels of a dangerous pathogen from an environmental source rather than from a deliberate release. These false alarms are costly to investigate and impose an additional burden on local health departments, stretching their limited resources and leaving them less prepared to deal with actual threats.

DHS also plans to award a contract in mid-2006 to develop the National Biosurveillance Integration System (NBIS) to provide early warning of a biological weapons attack, although the system could also detect pandemic flu and other natural epidemics.[39] Launched in FY 2005, NBIS is the U.S. government's leading initiative to develop "an integrated and comprehensive bio-surveillance system" that links local, tribal, state, federal, and private-

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[35] U.S. Congress, Government Accountability Office (GAO), *Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure,* June 2005, p. 24, available at: http://www.gao.gov/new.items/d05308.pdf

[36] Ibid., p.22-26

[37] Ibid.

[38] Associated Press, "Nationwide Monitoring System Planned For Detecting Bioterror Attack," January 22, 2003.

[39] Mary Mosquera, "DHS to develop biosurveillance system for pandemic," GCN, May 12, 2006, available at: http://www.gcn.com/online/vol1_no1/40725-1.html

sector surveillance efforts covering food, agriculture, public health, and the environment.[40] Since NBIS is currently operating as a modest pilot program, it is too early to judge how effective the new system will be. To succeed, however, NBIS will require sustained, high-level leadership and the effective cooperation of nearly a dozen department and agencies.

Another critical dimension to a national public health surveillance system is the monitoring of people entering the country, especially through airports. Most major international airports in the United States — including Washington's Dulles International Airport and New York City's John F. Kennedy International Airport — lack the personnel and facilities to screen and isolate large numbers of travelers infected with a communicable disease.[41]

Honolulu International Airport has taken the lead in developing a contingency plan for a major pandemic, including designating facilities for the screening and isolation of sick patients. For infectious diseases with a long incubation period, quarantine (the holding of individuals who are not ill but may have been exposed to a contagious disease) is generally ineffective at halting disease spread because of logistical and other problems. Nevertheless, once screening has identified infected individuals, it may be necessary to quarantine their close contacts.[42]

**Surveillance of Zoonotic Infections**

The specter of avian influenza has called attention to the threat of so called "zoonotic" diseases, or infections that can jump the species barrier from animals to humans. Wild or domesticated animal populations are reservoirs for several infectious diseases that infect humans, including anthrax (cattle, sheep, goats), plague (rodents), rabies (dogs, raccoons), West Nile virus (birds), and Ebola hemorrhagic fever (bats). Avian influenza is carried and transmitted by migratory birds, which can pass the virus to domestic ducks and chickens, and these fowl can in turn infect their owners.

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[40] Kimothy Smith, Testimony before the House Subcommittee on Prevention of Nuclear and Biological Attack, "Creating a Nation-wide Integrated Biosurveillance Network," May 11, 2006, p. 2.

[41] John Ritter, "Airports not ready for large-scale bird flu quarantine," *USA Today*, March 10, 2006, available at: http://www.usatoday.com/travel/flights/2006-03-09-airports-bird-flu_x.htm

[42] John Ritter, "Honolulu, on front line to spot and corral virus, has aggressive plan," USA Today, March 9, 2006, available at: http://www.usatoday.com/travel/flights/2006-03-09-honolulu-airport-birdflu_x.htm. On the limitations of quarantine, see Joseph Barbera, Anthony Macintyre, Larry Gostin, Tom Inglesby, Tara O'Toole, Craig DeAtley, Kevin Tonat, and Marci Layton, "Large-Scale Quarantine Following Biological Terrorism in the United States," JAMA, vol. 286, no. 21 (Dec. 5, 2001), pp. 2711-2717

Because animals are often more susceptible to zoonotic diseases than humans, they can serve as "sentinels" to provide early warning of an impending human epidemic.[43] For example, the 1999 human outbreak of West Nile encephalitis in New York City was preceded a few months earlier by a major die-off of crows, although the connection between these two events was not recognized at the time.[44]

Despite the threat to human health and the agricultural economy posed by zoonotic diseases, the United States lacks an integrated zoonotic disease surveillance system capable of monitoring both animal and human populations.[45] The reason for this disconnect is that the expert communities that address the health of people, domesticated animals, and wildlife are organizationally, geographically, and jurisdictionally distinct — even though zoonotic diseases do not respect these artificial boundaries.[46]

Agencies involved in protecting human health rarely communicate with state and local veterinary agencies, which focus on the health of domestic pets, horses, livestock, and other economically important species. Veterinary agencies, for their part, rarely communicate with the parks departments and animal control officers responsible for monitoring the health of wild animals. In particular, efforts to monitor non-endangered species such as crows and rats tend to receive little priority and funding. Finally, although zoos are responsible for the health of the exotic animals in their care, only a small minority of zoos in the United States employ full-time veterinary pathologists capable of diagnosing infectious diseases.

**Global Disease Surveillance Systems**

U.S. infectious-disease surveillance systems, while embryonic, are still ahead of similar efforts in most other countries — particularly in the developing world. The United States can help to minimize the chances that foreign epidemics will reach our shores by working with international partners to detect and contain disease outbreaks close to the point of origin. The CDC,

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[43] Peter Rabinowitz, Zimra Gordon, Daniel Chudnov, Matthew Wilcox, Lynda Odofin, Ann Liu, and Joshua Dein, "Animals as Sentinels of Bioterrorism," *Emerging Infectious Diseases*, vol. 12, no. 4 (April 2006), pp. 647-652.

[44] Laura H. Kahn, "Confronting Zoonoses, Linking Human and Veterinary Medicine," *Emerging Infectious Diseases*, vol. 12, no. 4 (April 2006), pp. 556-561.

[45] For a summary of major animal and plant disease surveillance systems in the United States, see John Clifford, Testimony before the House Subcommittee on the Prevention of Nuclear and Biological Attack, "Creating a Nation-wide, Integrated Biosurveillance Network," May 11, 2006.

[46] Jonathan B. Tucker, "Improving Infectious Disease Surveillance to Combat Bioterrorism and Natural Emerging Infections," Testimony before the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the U.S. Senate Committee on Appropriations, October 3, 2001.

in particular, has employees working in 46 countries and is improving its preparedness for global threats such as avian influenza by expanding its Global Disease Detection and Response Centers in China, Egypt, Guatemala, Kenya, and Thailand.[47]

The international entity with primary responsibility for detecting and containing outbreaks of infectious disease is the World Health Organization. In 2000, WHO launched the Global Outbreak Alert and Response Network (GOARN), which compiles global disease surveillance information from a wide range of official and unofficial sources. GOARN also includes a response network of more than 140 partner organizations around the world that move rapidly to contain disease outbreaks in their respective regions, providing the world's first line of defense. If greatly expanded and upgraded, GOARN could significantly reduce the risk that deadly epidemics originating overseas will affect the United States.

Just as the CDC relies on local and state public health departments for epidemiological data, WHO relies on individual countries for information about outbreaks of infectious disease. In 2005, the member states of WHO took an important step to improve the national reporting of outbreaks by negotiating a major revision of the International Health Regulations (IHR). First adopted in 1951, the IHR define the legal rights and obligations of the participating states with respect to infectious diseases that can cross borders and affect more than one country. The new regulations, which will go into effect in June 2007, should bring about sweeping changes in the way countries report and respond to major epidemics.[48]

The revised IHR contain three major innovations. First, instead of the current requirement to report only three specific communicable diseases (plague, cholera, and yellow fever), the participating countries will have to notify WHO within 24 hours of *any* event that has the potential to become a Public Health Emergency of International Concern (PHEIC). Second, the term PHEIC has been broadly defined to cover accidental or deliberate releases of biological, chemical, or radiological agents that could harm more than one country.

Third, WHO may draw on informal sources of information when identifying and investigating a possible PHEIC, in addition to official governmental sources. The revised IHR also provide that within five years after the regulations go into effect, all of the participating countries must establish the national surveillance capabilities needed to identify and report disease outbreaks of international concern.

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[47] Erin Moriarty, "CDC to increase role, labs overseas," *Atlanta Business Chronicle*, April 16, 2006.

[48] Jonathan B. Tucker, "Updating the International Health Regulations," *Biosecurity and Bioterrorism*, vol. 3, no. 4 (December 2005), pp. 338-347.

Although WHO plays a key coordinating role in combating major outbreaks of infectious diseases, the organization suffers from serious budgetary, operational, and political constraints. WHO's ability to implement the revised IHR is constrained by its relatively paltry budget of less than $1 billion a year.[49] To help countries upgrade their disease-surveillance capabilities under the revised International Health Regulations, WHO will be called upon to provide extensive assistance to member states, further straining the agency's limited financial resources.

## Recommendations

The United States should undertake a high-priority effort to modernize its national system for surveillance and response to outbreaks of infectious disease and work with other countries to upgrade WHO's capacities for detecting and responding to outbreaks of infectious disease throughout the world. To achieve these objectives, the U.S. government should:

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| **Undertake a "needs and new technology assessment" to ensure a modernized, integrated, and standardized disease-surveillance system for the entire nation.**[50] | This study would be led by the CDC, with participation by other stakeholding federal agencies and distinguished scientists from outside government. |
| **Make significant improvements to the PHIN system at an annual cost of $100 million a year.**[51] | In addition to personnel and communications upgrades, the 23 states that do not use national disease tracking standards must be mandated to adopt them and given federal assistance in doing so. |
| **Modernize the U.S. network of public health laboratories for the rapid diagnosis of infectious diseases.** | Upgrading the network of diagnostic laboratories would significantly improve the nation's ability to detect and respond to the full range of infectious threats. These improvements could be made at an annual cost of $100 million a year, plus a one-time additional outlay of $100 million to cover the cost of new equipment.[52] |

[49] World Health Organization, 56th World Health Assembly, "Proposed programme budget for 2004-2005," A56/51, May 17, 2003.
[50] Trust for America's Health, "Ready or Not?" (2005), p. 69.
[51] Ibid.
[52] Ibid.

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| **Require airports, sea ports, and other ports of entry to develop contingency plans for screening and isolation in the event of a major pandemic.** | Major airports at high risk of importing avian flu and other contagious disease should designate gates and other facilities for isolating sick travelers. In addition, the United States should implement a CDC proposal to require airlines to include passenger home addresses and emergency contact information on flight manifests to aid in the tracking of disease outbreaks. |
| **Institute a national system of electronic health records.** | Computerizing medical records would benefit routine health care and greatly facilitate the management of a large-scale outbreak of infectious disease. |
| **Support continuing medical education programs to train health professionals in the diagnosis of uncommon infectious diseases.** | Such programs have already proven their effectiveness: The physician in Boca Raton, Florida, who correctly diagnosed the first victim of the anthrax letter attacks in October 2001 had recently completed a continuing medical education course on bioterrorism. Even so, the Bush administration's FY 2007 budget did not request any new funding for Health Professions Training Activities and proposed a 40% cut in Bioterrorism Training and Curriculum Development. At a minimum, Congress should support these two programs at their FY 2006 funding levels of $100 million and $21 million, respectively. |
| **Develop an integrated U.S. zoonotic surveillance network based on a CDC pilot project for monitoring the spread of West Nile virus.** | In 2001, the CDC funded a pilot project for monitoring the spread of West Nile virus by testing blood and tissue specimens from zoo animals, as well as dead birds and other wildlife found on zoo property. This project could serve as a basis for a veterinary surveillance network in which unusual patterns of zoonotic disease in livestock, zoo animals, or wild animals are reported promptly to state and local public health departments. This system should include an improved communications infrastructure between veterinary health agencies such as USDA's Plant and Animal Health Inspection Service (APHIS) and its counterparts at the state level, the CDC, and public health departments. |
| **Support more epidemiological research on the complex relationships between human and animal health.** | The West Nile outbreak was a catalyst for greater cooperation among veterinarians, physicians, ecologists, and wildlife biologists in studying zoonotic infections. Such interdisciplinary research should be promoted with targeted research grants from the CDC and APHIS, building on discussions at the International Symposium on Emerging Zoonoses that CDC recently sponsored in cooperation with the World Organization for Animal Health (Office Internationale des Epizooties, or OIE) in Paris.[53] |

[53] Lawrence K. Altman, 'Tackling the Animal-to-Human Link in Illness," New York Times, March 25, 2006.

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| **Launch an international partnership to improve global zoonotic disease surveillance and develop a veterinary surge capacity.** | The United States should work with WHO, the OIE, and the World Bank to increase the number of experts in zoonotic infections, most of whom are veterinarians. Formal information exchanges between WHO and the OIE would permit more effective global monitoring of zoonotic infections in both animal and human populations. |
| **Support the global implementation of the revised International Health Regulations (IHR).** | The United States should join with other Western industrialized countries to make up shortfalls in the WHO budget associated with implementation of the revised IHR. |
| **Allocate least $100 million a year to the CDC for the support of GOARN field operations, including additional staff and equipment.** | This support would cover funding and personnel for additional diagnostic field laboratories throughout the world. A strengthened GOARN would facilitate the control of natural epidemics that must be detected early to prevent spread, such as SARS and avian influenza. Improved global disease surveillance would also help to deter the use of biological weapons by permitting the prompt detection of suspicious outbreaks and helping to identify the perpetrators. |

## Rapid Containment of Outbreaks

Diagnosing an infectious disease correctly is only the first step in fighting an outbreak. Once the agent has been diagnosed, the public health response must be swift and decisive to prevent further spread, treat the victims, and minimize fatalities. Today, however, the U.S. response to a major outbreak would face two major stumbling blocks: persistent inefficiencies and confusion among U.S. federal, state, and local disaster-response agencies; and the diminished state of the U.S. public health system, which has suffered from more than 30 years of neglect.

A major infectious disease incident, such as a terrorist attack with a contagious agent or a natural outbreak of avian influenza, might occur with little or no advance warning and emerge in several geographic locations simultaneously. The U.S. public health system would have to respond quickly before the epidemic became unmanageable, spawning panic and social disruption. Local, state, and federal agencies would have to mount a coordinated effort to diagnose, isolate, and treat people exposed to the disease and to vaccinate contacts, while minimizing economic disruption and safeguarding civil liberties.

The failure of all levels of government to mount an effective response to Hurricane Katrina in August 2005 is a stark reminder that having an emergency plan on paper is no guarantee that it will work in practice. In the case of Katrina, local, state, and federal officials knew days in advance that the disaster was imminent, and the broad outlines of the response were clearly identified in the National Response Plan: evacuate people from the affected geographic areas and provide vital services to the refugees (food, water, housing, and health care). Yet it took state and federal agencies more than four days to mount even a minimally effective response.

Efforts since 9/11 to improve U.S. preparedness for dealing with biological threats have fallen short in four main areas. First and foremost, the United States has devoted about half of all biodefense spending to the procurement and stockpiling of vaccines and other medicines, but not enough to improving the public health infrastructure, including the "surge" capacity needed to deliver vital medical services such as vaccination and antibiotics to thousands of victims.

Overall, the U.S. public health infrastructure is poorly equipped to meet the twin threats of emerging infectious diseases and bioterrorism. Decades of chronic funding shortfalls, inadequate staffing levels, and low salaries have hollowed out the public health work force. Only fifteen states or cities currently have the capacity to distribute and administer antibiotics and vaccines during a major disease outbreak. More than 50% of Americans live in states that do not have plans to deal with overflows of patients from hospitals, and 20% of Americans live in states where hospitals lack medical equipment for use in a major emergency.[54]

Just two states have plans to encourage medical personnel to report for work during an epidemic, and almost half of the states do not use national standards to report disease information, making it far more difficult to identify suspicious outbreaks.[55] These bottlenecks would seriously limit the ability of state and local governments to mount an effective response in the event of a biological incident. When the current generation of baby boomers retires, the public health workforce and available expertise will contract even further.[56] According to one study, the United States will face a 20% deficit of nurses needed during non-emergencies by 2020; the deficit would be even higher during a public health emergency.[57]

[54] See Trust for America's Health, *Ready or Not?* (2005), pp. 9-34.

[55] Ibid.

[56] Janet Heinrich, Director, Health Care-Public Health Issues, Government Accountability Office, Testimony before the House Subcommittee on Health, Committee on Energy and Commerce, "Health Workforce: Ensuring Adequate Supply and Distribution Remains Challenging," August 1, 2001, available at: http://www.gao.gov/new.itsems/d011042t.pdf

[57] Peter I. Buerhaus, Douglas O. Staiger, and David I. Auerbach, "Implications of an Aging Registered Nurse Workforce," *Journal of the American Medical Association*, vol. 283, no. 2 (June 14, 2000), pp. 2948-2954.

President Bush's plan for pandemic influenza preparedness illustrates the point: more than 90% of the $3.8 billion that Congress appropriated as the first installment of the administration's $7.1 billion budget request was for the acquisition of vaccines and antiviral drugs. Disease surveillance and other public health preparedness measures received only $350 million, despite major deficiencies in these areas, and there was no funding for hospital preparedness. Simply put, vaccines will not save lives if they cannot be delivered and administered fast enough to stop an epidemic. Moreover, states are expected to bear 75% of the cost burden for purchasing antiviral drugs, with only a 25% match from the federal government, amounting to an unfunded mandate of about $510 million.[58]

The second major deficiency of the U.S. preparedness effort is the fact that the hospital sector is not equipped to deal with large-scale health emergencies. Local, state, and tribal public health departments lack the capacity to care for the sick in the wake of a major biological incident, and there is no economically feasible way for them to do so. Thus, the nation's 5,000 hospitals, nearly all of which are in the private sector and hence outside the direct authority of government officials, will be expected to care for large numbers of seriously ill people. Yet few hospitals have spare beds even in quiet times, and there are insufficient economic incentives for them to invest in "surge capacity" that could be activated in an emergency.

The third weakness of the U.S. public health preparedness effort is that poor coordination among the responsible federal departments and agencies would hamper the response to a major outbreak of infectious disease. Today, emergency preparedness initiatives at the CDC and the Health Resources and Services Administration (HRSA) operate largely in a vacuum, separate from the plans developed by DHS and HHS. Moreover, the public health components of the National Response Plan have been subjected to little interagency review or public accountability.

Finally, public health preparedness measures will make a difference only if the public is willing to follow instructions from federal, state, and local officials during an outbreak. Studies of how people might behave during an epidemic suggest that the ordinary citizen is poorly informed about biological threats and often disinclined to obey official instructions. A September 2004 survey found that only two out of every five Americans would travel to a designated vaccination center in the event of a smallpox outbreak, and that only three out of every five respondents said they had confidence in official instructions.[59]

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[58] Laura Segal, Trust for America's Health, personal communication, April 11, 2006.

[59] Roz D. Lasker, "Redefining Readiness: Terrorism Planning Through the Eyes of the Public," Center for the Advancement of Collaborative Strategies in Health, New York Academy of Medicine, September 14, 2004.

Public confidence has likely declined even further since the inept federal and local response to Hurricane Katrina. These findings are disturbing because people who do not trust the government are only half as likely to comply with official instructions.[60]

## Recommendations

The United States must enhance the nation's ability to deliver vital medical services in a public health emergency, such as an outbreak of pandemic influenza or an incident of mass-casualty bioterrorism. To this end, the U.S. government should:

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| **Eliminate the assumption in the NRP that local, state, and tribal authorities have the capacity to respond effectively to major biological incidents.** | At the present time, state and local authorities lack the capacity to fulfill the role envisioned for them by the NRP. Until these authorities acquire that capacity, the NRP should assume that they would be rapidly overwhelmed in the event of a major biological incident and would require early support from federal agencies. |
| **Develop and coordinate federal, state, and local contingency plans for treating large numbers of casualties in a public health emergency.** | Because creating an emergency reserve of hundreds of private hospital beds is not economically feasible, communities should identify alternative facilities — schools, convention centers, armories, stadiums, and recreational facilities — that could potentially hold large numbers of patients and develop plans for taking over these facilities in a public health emergency. In the case of an epidemic of contagious disease, sick individuals may have to be isolated at home or elsewhere. |
| **Determine a logistical support role for the U.S. military, both active duty and the National Guard and Reserve, in responding to a major public health crisis.** | Given the legal constraints on the use of active duty forces in a law-enforcement capacity, as specified under the Posse Comitatus Act, the role of the military in disaster response should be analyzed in detail and the necessary legal authorities negotiated with Congress. |

[60] Ibid., p.2.

**Develop mechanisms to recruit, retain, and deploy emergency response personnel.**

State and local governments should develop incentive plans to encourage emergency response staff and other key personnel, such as health and security workers in the transportation sector, to report to work in the event of a major outbreak. Key personnel are more likely to show up for work if they have received all necessary vaccinations and the safety of their families has been provided for. State and local governments should develop mechanisms to make up for chronic shortfalls of trained medical personnel, such as maintaining lists of retired physicians and nurses who agree to serve in an emergency.[61] In addition, the federal government could offer scholarship and loan repayment incentives for students entering national security-related fields of public health through the Public Health Workforce Preparedness Act, at an annual cost of $130 million.

**Improve coordination under the National Response Plan.**

Federal, state, and local agencies should negotiate memoranda of understanding and other administrative agreements that specify their respective responsibilities in the event of a major infectious-disease incident. These agreements should cover areas ranging from interoperable radio frequencies to the administration of vaccines and drugs. Realistic field exercises are also essential because a plan that looks reasonable on paper may fall apart under the stress of an actual incident.

**Emphasize community-based planning for the response to biological emergencies.**

To persuade local citizens to follow instructions from public health officials in an infectious disease emergency, it is essential that they be informed in advance about contingency plans. Educational outreach can help citizens to understand the rationale for various policies, such as isolation, vaccination, and quarantine, and learn how to minimize their own health risks and those of others.

**Identify credible spokespersons at the federal, state, and local levels to communicate with the public during an infectious disease emergency.**

At the federal level, a single, highly credible medical official such as the U.S. surgeon general should be designated to serve as the primary spokesperson in the event of a bioterrorist incident, backed up with state and local public health officials as necessary. Having a familiar, trustworthy individual with medical credentials providing key information would reassure the public and make them more likely to follow government instructions and official preparedness plans.

[61] Trust for America's Health, "Ready or Not?" p.69.

# Defending Against Biological Threats:
## An Integrated Research Strategy

Despite a major investment in civilian biodefense research over the past five years, the United States remains at serious risk of being overwhelmed by future outbreaks of infectious disease because of a lack of suitable medical countermeasures. The Bush administration responded to 9/11 and the subsequent anthrax letter attacks by requesting a massive increase in funding for basic and applied research on diseases of bioterrorism concern, most of it administered by NIH. Spending for this purpose soared from $418 million in fiscal year 2001 to $3.7 billion the following year.

Since then, the overall budget for civilian biodefense has stabilized at about $5 billion a year, or 12 times higher than pre-9/11 levels.[62] Yet this huge investment has not been accompanied by a clear strategic vision of how to maximize the national security benefits of each R&D dollar, and HHS will not even have a draft plan ready until late 2006.[63]

There are three main problems with the current U.S. approach to civilian biodefense research. First, the research agenda has been driven primarily by past events and is not sufficiently forward-looking. Its primary focus is on drugs and vaccines against known bioterrorist threat agents, such as anthrax, smallpox, and tularemia. Although such medicines are no doubt important to have on hand, they will not prepare the country to respond to a contagious strain of avian influenza or a genetically modified biological threat agent.

Second, current U.S. policies do not create the right mix of market incentives for developing new antibiotics, antivirals, vaccines, and rapid diagnostic tools. As a result, the United States is at grave risk of being overwhelmed by a bioterrorist attack or a natural pandemic.

Third, certain types of biodefense research are counterproductive and may generate new dangers. For example, classified biodefense research undermines other countries' confidence that the United States is abiding by its BWC commitments and might therefore provoke offensive developments. The boom in biodefense spending has also resulted in a dramatic increase in the number of inexperienced researchers working with dangerous pathogens, increasing the risk of laboratory accidents and security breaches.

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[62] For an analysis of federal biodefense budgeting, see Ari Schuler, "Billions for Biodefense: Federal Agency Biodefense Budgeting, FY2005 – FY2006," *Biosecurity and Bioterrorism*, vol. 3, no. 2 (June 2005), pp. 94-101.

[63] Justin Gillis, "White House Admits Lag in Bioterror Effort," *Washington Post*, April 7, 2006, p. A11, available at: http://www.washpost.com/wp-dyn/content/article/2006/04/06/AR2006040601992.html

**The Drug Development and Approval Process**

Bringing a new drug to market involves several phases: research to identify a new compound with specific and potentially useful effects; development to improve the medicinal properties of the compound; and stringent safety and efficacy testing in animals and humans. Developing a new drug takes upwards of 10 years, costs between $400 million and $800 million, and is a high-risk endeavor: of every 5,000 compounds identified during the basic research phase, only one will receive FDA approval for marketing. About 40% of drugs in the clinical-trial pipeline fail because of lack of efficacy, often caused by poor absorption by the body.

**Drug Development Timeline**

| Basic research | "Lead" discovery | Preclinical development | Clinical trials & FDA approval |
|---|---|---|---|
| (Years) | (6 – 24 mos.) | (30 – 36 mos.) | (54 – 60 months) |

Although federally funded basic research has made dramatic strides, the applied research, testing, and manufacturing capabilities needed to translate new discoveries into safe and effective medical therapies have not kept pace.[11] Small biotechnology firms have often proven adept at translating basic research findings into innovative products, but they lack the financial resources of the pharmaceutical giants. Instead, the pharmaceutical industry has preferred to invest in R&D on drugs with a larger market and return on investment, such as treatments for chronic diseases (e.g., the anti-cholesterol drug Lipitor) or "lifestyle" drugs (e.g., Viagra, Levitra, Propecia, etc.).

[1] U.S. Food and Drug Administration, Innovation or Stagnation?

## Reforming the Drug Development Process

In the United States, on average, the drug-development cycle can cost up to $800 million and takes about 10 years to complete, including securing approval from the Food and Drug Administration (FDA).[64] Limitations on capital, competition among rival firms, high economic risks, and liability for adverse drug reactions have all hampered efforts to encourage the development of anti-infective drugs and vaccines.[65] According to Gail H. Cassell, a vice president at Eli Lilly and Company, "There is a 90 percent failure rate from the discovery of a [drug] target to the launch of a new antibiotic. This lack of success has likely dampened further spending in this area."[66] Because of the difficulty of developing anti-infective drugs and the relatively poor rate of financial return, pharmaceutical industry investment in anti-infective drug development has declined significantly in recent years. (See Box, above.)

[64] U.S. Food and Drug Administration, *Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products*, March 2004, http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

[65] Ronald T. Borchadt, "Integrating Drug Discovery and Development," *The Scientist*, Vol. 15, No. 5 (March 5, 2001), p. 43.

[66] Gail H. Cassell, "Countermeasures to Biological Threats: The Challenges of Drug Development," in Stacey L. Knobler, Adel A. F. Mahmoud, and Leslie A. Pray, eds., *Biological Threats and Terrorism: Assessing the Science and Response Capabilities* (Washington, DC: National Academy Press, 2002), pp. 115-116.

The Project BioShield Act, which President Bush signed into law in July 2004, authorized spending $5.6 billion over 10 years to buy and stockpile drugs and vaccines to combat anthrax, smallpox, and other agents of bioterror. Although this law was specifically designed to create economic incentives for the U.S. pharmaceutical industry to invest in developing drugs and vaccines against bioterrorist threat agents, it has failed to achieve its initial objectives because of bureaucratic inertia and management problems. Much of the money committed so far has been to procure 75 million doses of anthrax vaccine from VaxGen, Inc. of Brisbane, Calif., but this contract has run into serious delays and technical problems.[67]

The BioShield program as currently structured has also failed to overcome the disincentives associated with developing biodefense drugs. Not only is the potential market extremely small because the drugs would be used only in an emergency, but the development of such products is associated with high risks and legal liabilities. Second, because the chief purpose of Project BioShield is to spur the development of drugs against specific biowarfare agents, the legislation requires that the program only support the development of drugs with "insignificant commercial potential."

Regrettably, this provision of the law has tended to reinforce the ineffective "one bug, one drug" approach and impeded the development of broad-spectrum antimicrobials. Moreover, Project BioShield has tended to support the development of costly vaccines and monoclonal antibodies rather than less expensive small-molecule drugs. Whereas so called "biologics" often require manufacturing facilities that must be dedicated to a single product, manufacturing facilities for small-molecule drugs can be quickly modified to produce new products.[68]

Some critics of the Project BioShield legislation have argued that giving pharmaceutical companies financial incentives to develop broad-spectrum antimicrobials amounts to subsidizing R&D on drugs that can also be used for non-biodefense purposes. The reality, however, is that broad-spectrum antimicrobials (antibiotics and antivirals) could be critical to responding to natural emerging infections or bioterrorism, yet the market has failed to provide sufficient incentives for their development.

Correcting such a market failure is a textbook example of where government should intervene. The issue is not industrial subsidies per se, but rather how to ensure that the pharmaceutical industry uses federal resources most effectively to benefit the public good. Given the shoddy performance of

[67] Gillis, "White House Admits Lag in Bioterror Effort," p. A11.

[68] Lynn C. Klotz, "Supplying the Strategic National Stockpile: Manufacturing Incentives and Countermeasure Choices," March 7, 2006, Center for Arms Control and Nonproliferation, available on-line at: http://www.armscontrolcenter.org/archives/002252.php

companies such as VaxGen, which has failed to meet the contract timetable for production of the anthrax vaccine, measures to ensure adequate oversight and quality control are essential.

Another key issue is legal liability arising from adverse reactions to drugs and the need to compensate victims. In December 2005, the U.S. Congress passed the Public Readiness and Emergency Preparedness (PREP) Act, which provides additional liability protections for pharmaceutical companies seeking procurement opportunities under Project BioShield. The legal immunity created by the PREP Act can only be overcome by demonstrating that willful misconduct on the part of the manufacturer was responsible for a serious injury or death.

Although the PREP Act also contains a provision to compensate the victims of adverse biodefense drug reactions, Congress did not appropriate any funds to implement it. A compensation provision has been vital to the success of past vaccination programs, however, and the lack of one doomed the Bush administration's plan for widespread vaccination against smallpox.

Finally, although the regulatory process for gaining FDA approval of new drugs is in most respects justifiably stringent, given the public interest in ensuring drug safety and efficacy, some major bottlenecks in the current process should be addressed. At present, the FDA can grant biodefense products "fast track" approval status, and the agency has also instituted an "animal efficacy rule" to guide the testing of products for which clinical trials in humans would be unethical. In addition, the original BioShield law gave the HHS secretary the power to issue an "emergency use authorization" for the use of an unlicensed drug or vaccine during a public health emergency.[69]

According to CDC director Julie L. Gerberding, however, current bottlenecks to the availability of medical countermeasures against biological threats include the lack of suitable animal models to demonstrate efficacy, the length of time necessary to demonstrate the safety of any new product in adults and children, and the time and resources needed to ramp up production in an emergency.[70]

Recently, the Department of Defense launched a Transformational Medicines Technology Initiative, funded at $1.5 billion, which seeks to use systems biology to develop broad-spectrum antiviral drugs and new approaches to rapid

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[69] Jesse L. Goodman, "Meeting the Regulatory and Product Development Challenges for Vaccines and Other Biologics to Address Terrorism," in Knobler, Mahmoud, and Pray, eds., *Biological Threats and Terrorism*, pp. 105-110.

[70] Julie L. Gerberding, "Faster . . . but Fast Enough? Responding to the Epidemic of Severe Acute Respiratory Syndrome," *New England Journal of Medicine*, Vol. 348, No. 20 (May 15, 2003), p. 2031.

diagnostics and detection. It remains to be seen if this ambitious initiative will yield innovative approaches to rapid countermeasure development.

## Recommendations

Congress should develop a new mix of financial, legal, and regulatory incentives to ensure that the United States has the medical countermeasures it needs to detect, contain, and treat outbreaks of infectious disease, be they natural or deliberate. Establishing a capability for accelerated medical countermeasure development would strengthen the nation's preparedness to defend against both natural emerging infections and bioengineered threat agents in a cost-effective way.

**Formulate a comprehensive strategic plan to guide R&D on countermeasures against the full spectrum of biological threats.**

To develop this plan, the U.S. government should establish a task force that would perform a "bottom-up review" of the current system for developing medical countermeasures. This review would identify critical gaps in the existing infrastructure to counter infectious diseases, assess how R&D could narrow those gaps, make specific recommendations, and assess their budgetary implications. The task force would be chaired by the director of the National Institute of Allergy and Infectious Diseases (NIAID) and include officials from all interested U.S. government agencies, as well as an advisory committee of leading biomedical scientists from academia and industry.

**Support the creation of a nonprofit drug company that would focus exclusively on developing new antibiotics, diagnostics, and other means of combating infectious diseases.**

This company would be funded by private foundations, as well as direct contributions and R&D tax credits provided by the federal government. Although the company would file patents to protect its intellectual property, it would issue licenses free of charge to any private firm or government agency that commits to manufacturing and distributing anti-infective drugs and diagnostics for the benefit of public health.[71] The company might either be "virtual" and physically distributed among several participating firms, or it could consist of a dedicated facility funded by a major pharmaceutical company in conjunction with a public partner.

**Expedite the development of new technologies to streamline the pre-clinical testing and clinical trials of anti-infective drugs.**

The United States should promote the development of a streamlined system of animal and clinical trials so that the FDA can assess the safety and efficacy of a new drug or vaccine and decide whether or not to administer it on an emergency-use basis. At the same time, the drug-approval process should include rigorous oversight to address ethical questions that may arise when testing medical countermeasures in healthy people.

[71] Carl Nathan, "Antibiotics at the Crossroads," *Nature*, Vol. 431 (October 21, 2004), pp. 899-902.

**Appropriate money to compensate individuals harmed by biodefense drugs and vaccines.** The PREP Act of December 2005 gave pharmaceutical companies that develop biodefense drugs and vaccines liability protection in the event the drugs cause unexpected injuries. Congress must now fund the compensation program in the Act for those individuals who are harmed.

## Rationalizing Biodefense Spending

Although the Bush administration's major investment in biodefense may seem impressive, the overall picture is more complicated. The benefits of the massive increase in funding for biodefense research are uncertain because the country lacks the public health infrastructure needed to deliver drugs and vaccines in a timely manner.

Moreover, even if an adequate delivery capability existed, the U.S. civilian biodefense program has been driven by unrealistic threat assessments that have distorted biodefense priorities. There has been a strong tendency toward worst-case analysis, based on what is theoretically possible with emerging biotechnologies rather than on a realistic assessment of the capabilities, motivations, and patterns of behavior of existing terrorist groups and state-level programs.

The security benefits of civilian biodefense research have been further offset by a number of significant costs. One major downside of the biodefense boom is the excessive secrecy surrounding certain aspects of the research program. While some secrecy is obviously needed to prevent an adversary from circumventing U.S. defenses, too much secrecy risks weakening the global norm, embodied in the BWC, against the development and possession of biological weapons.

Since 9/11, for example, the Bush administration has placed a new emphasis on "laboratory threat characterization," which includes the development and study of known and putative biowarfare agents to guide the development of medical countermeasures.[72] The U.S. Department of Homeland Security's National Biodefense Analysis and Countermeasures Center (NBACC), currently being built at Fort Detrick, Md., will include a Biological Threat Characterization Program (BTCP) to examine how bioterrorists might use genetic engineering and other advanced techniques to convert viruses and

[72] James B. Petro and W. Seth Carus, "Biological Threat Characterization Research: A Critical Component of National Defense," *Biosecurity and Bioterrorism*, vol. 3, no. 4 (December 2005), pp. 295-308.

bacteria into more deadly and effective weapons.[73] Such defensive research includes creating and assessing genetically modified pathogens that an enemy might *in theory* develop.

This type of research does more harm than good. Given the vast genetic diversity of microorganisms, it is extremely unlikely that the United States could anticipate the specific organisms that an enemy might create. Instead, the genetically engineered pathogens would simply be potential offensive weapons in their own right.[74] Thus, even though the research is for defensive purposes, other countries may not take us at our word. Instead, they may view such experiments as possible cover for offensive activities — in part because many U.S. biodefense projects are shrouded in secrecy.[75]

For this reason, the BTCP risks softening global support for biological disarmament and provides an excuse for other countries to undertake provocative threat-assessment programs of their own — in some cases, as cover for a bioweapons program. Even countries that do not believe the United States is secretly engaged in offensive work may ramp up their own R&D activities as a hedge against technological surprise and the unpredictability of future adversaries — a "keeping up with the Joneses" effect.

Yet another negative consequence of the biodefense boom has been to spread dangerous pathogens and related know-how to hundreds of laboratories across the United States. About 16,500 scientists at 400 institutions are now authorized to study "select agents" of bioterrorism concern, such as the bacteria that cause anthrax and plague.[76] Many of these individuals lack previous experience with biohazardous research, with the predictable result of a sharp increase in the number of laboratory accidents, such as the infection with tularemia of four researchers at Boston University Medical School in 2004.[77] Incredibly, despite the carelessness reflected by this accident, the university received a major NIH grant to build a Biosafety Level 4 (BSL-4) laboratory for work with the most dangerous and incurable pathogens.

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[73] Milton Leitenberg, James Leonard, and Richard Spertzel, "Biodefense Crosses the Line," *Politics and the Life Sciences,* vol. 22, no. 2 (2004), pp. 1-2.

[74] David Keppel, "When Fears of Bioterrorism Grow" [Letter to the Editor], *New York Times*, October 21, 1999.

[75] Jonathan B. Tucker, "Biological Threat Assessment: Is the Cure Worse Than the Disease?" *Arms Control Today*, vol. 34, no. 8 (October 2004), pp. 13-19.

[76] Scott Shane, "Bioterror Fight May Spawn New Risks," *Baltimore Sun*, June 27, 2004; Mark Williams, "The Knowledge," *Technology Review*, March/April 2006, p. TK.

[77] Committee on Responsible Genetics, "Mistakes Happen: Accidents and Security Breaches at Biocontainment Laboratories" (2005), available online at: http://www.gene-watch.org/bubiodefense/pages/accidents.html

NIH has also provided funding to construct three other BSL-4 facilities to study deadly viral diseases with no known cure and dozens of new Biosafety Level 3 facilities for studying somewhat less dangerous infections.[78] Ironically, the proliferation of biodefense research to academic institutions throughout the country has increased the risk that dangerous pathogens could be diverted, stolen, or misused by a sociopathic scientist or an al-Qaeda sympathizer working within the newly expanded U.S. biodefense community. Although some procedures have been put in place to screen personnel working with select agents, such methods are far from foolproof. These safety and security risks must be weighed when considering the costs and benefits of building additional biodefense laboratories.

Finally, a letter signed by more than 700 leading scientists expressed the concern that NIH's new emphasis on studying rare diseases of bioterrorism concern, such as anthrax and tularemia, has siphoned funds away from research on infectious diseases of much greater public health import, such as influenza and tuberculosis.[79]

## Recommendations

The U.S. biodefense program should focus on developing a rapid and agile capability for swiftly detecting and characterizing new infectious diseases and genetically engineered threat agents and developing medical countermeasures against them. In order to avoid undermining the global norm against the acquisition and use of biological weapons, biodefense research should become more transparent and less provocative by defending against novel threat agents in ways that do not create additional risks.

| | |
|---|---|
| **Renounce "laboratory threat characterization" studies involving the creation and study of putative biological warfare agents.** | The Department of Homeland Security should support basic research on pathogenesis that informs the development of countermeasures such as broad-spectrum antibiotics and antivirals, without creating novel threat agents in the laboratory. |

[78] For a current list of such facilities, see the web site of the Sunshine Project, www.sunshine-project.org

[79] Sidney Altman, Bonnie L. Bassler, Jon Beckwith, et al., "An Open Letter to Elias Zerhouni," *Science*, vol. 307, no. 5714 (March 4, 2005), pp. 1409-1410.

**Conduct a needs-based assessment of biodefense research facilities, followed by the consolidation of research at a smaller number of secure facilities.**

The United States should improve the security of its biodefense program by conducting a net assessment of how many biocontainment laboratories (Biosafety Level 3 and 4) are truly required to meet national needs and imposing a moratorium on new construction until the study has been completed. Although consolidating work on bioterrorism threat agents in fewer facilities might reduce somewhat the chances of a scientific breakthrough, this drawback would be greatly outweighed by the benefits of enhanced biosafety and biosecurity.

# Glossary

**Biological Incident Annex.** The component of the National Response Plan that deals specifically with biological incidents.

**Biological and Toxin Weapons Convention (BWC).** A multilateral treaty banning the development, possession, stockpiling, and transfer of "microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes." The BWC also prohibits the development and production of specialized munitions and delivery systems for such agents and toxins. Since the treaty entered into force in 1975, 155 countries (including the United States) have signed and ratified it and a further 16 countries have signed but not yet ratified.

**BioSense Initiative.** A national epidemiological surveillance program designed to improve the capacity of the United States for early detection and quantification of disease outbreaks related to bioterrorism and naturally occurring infections. BioSense draws on health data from existing databases and delivers these data and analyses to local, state, and national public health officials and investigators. In addition to early detection, BioSense helps to determine the location and size of an outbreak and disseminates information needed for investigation and response.

**BioWatch Initiative.** A program involving the deployment of air-sampling systems around the United States (mostly at air-pollution monitoring stations) to detect the presence of pathogens of bioterrorism concern. When the system picks up an unusual microbe in the air, the local health department is responsible for performing the preliminary testing. If the initial test is positive, the local department notifies the CDC and the testing moves up the organizational ladder to the state and federal levels.

**Confidence-building mechanism (CBM)**. A mechanism whereby parties to the Biological and Toxin Weapons Convention (BWC) voluntarily exchange data each year on several topics relevant to the treaty, including high-containment laboratories, biodefense programs, and unusual outbreaks of disease.

**Cooperative Threat Reduction (CTR).** A program, run by the U.S. Department of Defense, that assists the states of the former Soviet Union in controlling and protecting their nuclear weapons, weapons-usable materials, and delivery systems; destroying the former Soviet stockpile of chemical weapons; and dismantling former biological weapons production facilities. The program is also known as "Nunn-Lugar" after Senators Sam Nunn (D-GA) and Richard Lugar (R-IN), who sponsored the original legislation.

**DNA.** The molecule of heredity; it encodes genetic information in various permutations of four units (nucleotide bases), often represented by the letters A, T, C, and G.

**Dual-use.** Research, technology, and equipment that could be used either for peaceful or military purposes, e.g., to advance a biological weapons program.

**Emerging infections.** Previously unknown infectious diseases (such as SARS) or established infections that have re-emerged in drug-resistant forms and spread geographically (such as multi-drug-resistant tuberculosis).

**Epidemic.** An outbreak of infectious disease that, upon investigation, proves to include excessive cases based on the specific case definition and the background numbers of cases expected at that particular place and time.

**Geneva Protocol (1925).** An international treaty banning the use in armed conflict (but not the development or possession) of chemical and biological weapons.

**Global Outbreak Alert and Response Network (GOARN).** A global system under the auspices of the World Health Organization (WHO) that compiles disease surveillance information from a wide range of official and unofficial sources and includes a response network of more than 140 partner organizations around the world that can move rapidly to contain disease outbreaks in their respective regions, providing the world's first line of defense against emerging infections.

**Institutional Biosafety Committees (IBCs).** Committees established under the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules to provide local institutional review and oversight of potentially risky types of research utilizing recombinant DNA.

**International Health Regulations (IHR).** First adopted in 1951, this document defines the international legal rights and obligations of the signatory states with respect to infectious diseases that can cross borders and affect more than one country. The IHR were revised extensively in 2005.

**Laboratory threat characterization.** An approach to assessing the threat of biological weapons that includes the development and study of validated and putative biowarfare agents so as to guide the development of medical countermeasures.

**Life sciences.** Basic scientific research in biology, biomedicine, and related fields.

**National Biosurveillance Integration System (NBIS).** An initiative directed primarily at early detection of a biological weapons attack that could also detect natural outbreaks of pandemic flu and other emerging infections. Begun in fiscal year 2005, NBIS is the U.S. government's leading initiative to "develop an integrated and comprehensive bio-surveillance system" that links local, tribal, state, federal and private sector human, animal and plant health surveillance efforts. NBIS is currently operating as a modest pilot program.

**National Institutes of Health (NIH).** The primary U.S. government agency for conducting, supporting, and providing public funding for biomedical research.

**National Response Plan (NRP).** The U.S. government plan detailing federal roles and responsibilities for major disasters, terrorist attacks, and other significant threats to homeland security.

**National Science Advisory Board for Biosecurity (NSABB).** A committee consisting of 25 biologists, physicians, and security professionals from outside government that operates under the auspices of the National Institutes of Health (NIH), the NSABB has been tasked with assessing the national security implications of "dual-use" research in the life sciences and developing security-related guidelines for the Institutional Biosafety Committees (IBCs) that currently oversee recombinant-DNA research.

**NIH Guidelines.** A document created in 1976 under the auspices of the National Institutes of Health (NIH) that outlines practices and procedures for the safe conduct of research employing recombinant-DNA technology or involving human gene transfer or genetically modified plants and animals.

**Outbreak.** A cluster of cases of an infectious disease that occur within a short period of time.

**Pandemic.** An epidemic that is widespread across a country, a continent, or the entire globe.

**Project BioShield Act.** Legislation, signed into law in July 2004, that authorized spending $5.6 billion over 10 years to buy and stockpile drugs and vaccines to combat anthrax, smallpox, and other agents of bioterror.

**Public health.** Medical and health issues that affect populations and communities.

**Public Health Emergency of International Concern (PHEIC).** A biological incident — including the accidental or deliberate release of a biological, chemical, or radiological agent — that could harm more than one country. Under the revised International Health Regulations that will go into effect in June 2007, participating countries must report a potential PHEIC to the World Health Organization within 24 hours of learning about it.

**Public health system.** The network of federal, state, and local entities responsible for monitoring the health of a nation's population and implementing public policies designed to address community health problems.

**Public Health Information Network (PHIN).** An initiative, directed by the U.S. Centers for Disease Control and Prevention (CDC), that seeks to integrate the myriad local, state, and federal disease surveillance systems into a single, unified national network.

**Select agent.** A microbial agent and toxin that could be used for biological warfare or terrorism, such as the bacteria that cause anthrax, plague, and tularemia, or the viruses that cause smallpox or hemorrhagic fevers. Under U.S. law, select agents are subject to regulations that restrict access and use.

**Recombinant-DNA technology.** A set of techniques that make it possible to combine genes (DNA sequences) from two or more different species.

**Security Council Resolution 1540.** A resolution, enacted by the United Nations Security Council in April 2004, that imposes a legal obligation on all UN member states to adopt domestic measures to prevent terrorists from acquiring weapons of mass destruction (including biological weapons) and related materials and technology.

**Synthetic biology.** The use of advanced DNA synthesis techniques to design and fabricate biological components and systems that do not exist in the natural world, or to redesign and fabricate existing biological systems, in pursuit of practical applications.

**U.S. Public Health Service.** A uniformed service led by the U.S. Surgeon General to implement federal public health policies.

**World Health Organization (WHO).** A United Nations functional agency established in 1948 that specializes in issues of international health. Headquartered in Geneva, Switzerland, the WHO has 192 member countries.

**World Organization for Animal Health (Office Internationale des Epizooties, or OIE).** An international organization founded in 1924 that facilitates global cooperation to prevent the spread of animal disease and develops standards for international trade in animals and animal products. Headquartered in Paris, the OIE has 167 member countries.

**Zoonotic disease.** An infectious disease that can jump the species barrier from animals to humans.

**Zoonotic surveillance.** The monitoring of zoonotic diseases.

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