Chapter Five

# U.S. CAPABILITIES TO COUNTER INFECTIOUS DISEASES

In 1992, the Institute of Medicine (IOM) challenged the United States to respond to the threat of infectious diseases by improving public health and medical capacity. Partly in response to the IOM, in 1994 the CDC drafted a strategy that included improvements in surveillance, applied research, prevention and control, and infrastructure.[1] Recognizing the ongoing risks of increasing global interdependencies, in 1995 the National Science and Technology Council's CISET further recommended that the United States play a stronger role in global efforts to control infectious disease.[2] The CISET report served as the basis for a 1996 Presidential Decision Directive calling for the formation of an emerging infectious disease task force to oversee efforts to develop a global surveillance and response network, enhance research and training, and strengthen cooperation with international partners.[3] The continued emergence of new strains of infectious diseases, changes in healthcare delivery, and new technologies and scientific findings prompted additional action by the

[1]CDC, "Preventing Emerging Infectious Diseases," p. 3; CDC, "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States," Atlanta: CDC, 1994.

[2]National Science and Technology Council, *Infectious Disease,* September 1995, available at http://clinton4.nara.gov/textonly/WH/EOP/OSTP/CISET/html/toc.html as "Global Microbial Threats in the 1990s," accessed August 17, 2001.

[3]See The White House, Office of Science and Technology Policy, "Addressing the Threat of Emerging Infectious Diseases," PDD/NSTC-7, June 12, 1996, available at http://www.state.gov/www/global/oes/health/task_force/whthtreat.html, accessed June 28, 2001.

CDC, which revised its strategic plan in 1998.[4] Despite these initiatives, however, in 2002 the public health infrastructure across the United States remains variable and in many cases inadequate.

This chapter analyzes U.S. capabilities to counter infectious disease and discusses the challenges posed by this system for maintaining or increasing America's relative success with respect to fighting contagion. The first section assesses efforts by the federal government, particularly the CDC, to bolster state and local capabilities to detect and investigate disease outbreaks and examines legal restrictions to federal action. The second section considers various federal interagency initiatives aimed at addressing foodborne disease, antibiotic resistance, bioterrorism, research, and global surveillance. The final section examines the holes in these systems and the risks inherent in failing to deal with these gaps.

## RESOURCES FOR FIGHTING INFECTIOUS DISEASE

In the United States, resources and responsibilities for monitoring, preventing, and controlling infectious disease are distributed throughout the public health system. Hospitals, clinical laboratories, pharmaceutical companies, healthcare providers, universities, and research groups form part of a larger system that works to reduce the impact of pathogens. The CDC acts as the lead U.S. federal agency, providing information, recommendations, and technical assistance in support of state and local public health departments.[5] Although lacking specific authority for public health functions—which remain a state responsibility in the American federal system—this agency assumes the primary burden of surveillance for and initial response to outbreaks.[6] This being said, the actual mobilization of federal resources in response to an outbreak is necessarily contingent on state capabilities to detect problems and request assistance. More-

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[4]CDC, "Preventing Emerging Infectious Diseases."

[5]Foreman, *Plagues, Products, and Politics,* p. 25.

[6]IOM, "Public Health Systems and Emerging Infections: Assessing the Capabilities of the Public and Private Sectors, Workshop Summary," Washington, D.C.: National Academy Press, 2000, p. 31.

over, the disease mitigation resources that are often contributed at the local level are considerable and should not be ignored.[7]

State and local public health capabilities are coordinated and largely provided for through the CDC, which has recently enhanced its efforts to build capacity in the areas of disease surveillance, investigation, and prevention and control of infectious diseases.[8]

## Surveillance and Detection

Surveillance is a core public health function, representing the first link in a chain of activities aimed at countering infectious viral and bacterial agents.[9] Disease surveillance in the United States hinges on a staged process of reporting from clinicians and laboratories to local or state health departments to the CDC. Although the CDC represents the pinnacle of this system, statutory authority for disease surveillance mechanisms and the determination of associated monitoring agendas belongs to states and their respective environmental and public health departments.[10]

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[7]Foreman, *Plagues, Products, and Politics,* p. 44. Foreman cites officials of the CDC's Epidemiology Program Office to the effect that the CDC may initiate investigations in the case of multistate outbreaks.

[8]In FY 2002, the CDC invested $332 million to fight diseases, a portion of which is specifically earmarked for assistance to states and localities. It should be noted, however, that for FY 2002 HIV/AIDS, STD, and TB prevention are budgeted separately for over $1 billion. The same is true for immunization, bioterrorism, and surveillance, which are slated for nearly $600 million, $182 million, and $27 million, respectively. All of the recommended funding represents increases from the previous year's budget with the exception of surveillance, according to the U.S. Department of Health and Human Services, "FY 2002 President's Budget for HHS," p. 33, available at http://www.hhs.gov/budget/pdf/h.PDF, accessed August 30, 2001; also see ASM Clinical Microbiology Issues Update, "ASM Submits Testimony to Congress," April 2001, available at http://www.asmusa.org/pasrc/clinicalmicro-april2001.htm, accessed June 22, 2002.

[9]The CDC defines public health surveillance as "the ongoing, systematic collection, analysis, interpretation, and dissemination of health data, including information on clinical diagnoses, laboratory-based diagnoses, specific syndromes, health-related behaviors, and use of products related to health." GAO, "Global Health: Framework for Infectious Disease Surveillance," GAO/NSIAD-00-205R, July 20, 2000, pp. 5–6; CDC, "Preventing Emerging Infectious Diseases," p. 17.

[10]At the state level, epidemiologists analyze test results and laboratory reports, initiate epidemiological investigations, and design, institute, and evaluate prevention and

An epidemic may be detected by routine surveillance or by the recognition of an unusual cluster of cases, often by an alert clinician. Sometimes this involves the reporting of cases and symptoms not under formal surveillance. This occurred with the hantavirus outbreak in the Southwest in 1993 (see Chapter Four), when two deaths from sudden respiratory failure prompted a U.S. Indian Health Service physician to alert the New Mexico state health department, which in turn called in the CDC.[11] Similarly, the investigation that revealed the presence of West Nile virus in the Western Hemisphere was instigated by a hospital infectious disease specialist who reported unusual cases of suspected encephalitis or meningitis to the New York City Department of Health.[12]

The bulk of routine surveillance reporting from states to the CDC is conducted under the auspices of the National Notifiable Disease Surveillance System (NNDSS, see the Appendix).[13] State disease reporting to CDC, however, is voluntary. Reflecting this, only 60 percent of the 19 notifiable diseases on the national list were reported in more than 90 percent of U.S. states and territories in January 1999.[14] In an effort to enhance the effectiveness of the overall U.S. disease monitoring regime, the CDC is currently in the process of developing the National Electronic Disease Surveillance System (NEDSS), the goal of which is to coordinate, and thus improve, local, state, and national surveillance systems (see the Appendix).[15] In addition, the

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control measures. GAO, "Emerging Infectious Diseases: National Surveillance System Could Be Strengthened," GAO/T-HEHS-99-62, February 25, 1999, p. 4.

[11]Stephen S. Morse, "Controlling Infectious Diseases," Federation of American Scientists, available at http://www.fas.org/promed/papers/morse.htm, accessed July 11, 2001.

[12]GAO, "West Nile Virus Outbreak: Lessons for Public Health Preparedness," GAO/HEHS-00-180, September 2000, p. 10.

[13]Incidence of diseases deemed notifiable by the CDC and a given state are reported to the CDC on a weekly basis and published in the *Morbidity and Mortality Weekly Report* (MMWR). The National Electronic Telecommunications System for Surveillance was established in 1985 to facilitate weekly computer-based reporting of surveillance data from state health departments to the CDC.

[14]Sandra Roush et al., "Mandatory Reporting of Diseases and Conditions by Health Care Professionals and Laboratories," *JAMA,* Vol. 282, No. 2, July 14, 1999, pp. 165–168.

[15]CDC, "Supporting Public Health Surveillance through the National Electronic Disease Surveillance System (NEDSS)" available at http://www.cdc.gov/od/hissb/docs/NEDSS%20Intro.pdf, accessed July 6, 2001.

CDC is working to augment epidemiology and laboratory capacity,[16] develop a network for population-based surveillance and research,[17] and establish four provider-based sentinel networks designed to monitor conditions not covered by routine health department surveillance.[18]

Because other surveillance methods often do not provide anything near real-time reporting, and since this is critical for the timely recognition and treatment of infectious outbreaks, there is growing interest in early warnings through syndromic surveillance. This particular type of monitoring relies on reports about syndromes or symptoms that may indicate an epidemic sooner than reports of specific diagnoses.[19] As an example, New York City has established a sentinel network of 11 hospitals that report daily to the New York City Department of Health on the number of hospital admissions via the emergency department.[20]

The Department of Defense (DoD) is developing several other syndromic surveillance systems. The Early Warning Outbreak Recognition System (EWORS), instituted jointly by the U.S. Navy, the Indonesian Ministry of Health, and the WHO, collects daily clinical data from five sentinel sites around Indonesia. Another initiative, the

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[16]The CDC created the Epidemiology and Laboratory Capacity (ELC) program, and ELC cooperative agreements have been concluded in all 50 states. Funding is also provided to ELC programs in six large local health departments and the territory of Puerto Rico. The average grant award in FY 2000 was $311,000, a portion of which was used to hire 60 epidemiologists and 43 microbiologists.

[17]The Emerging Infection Program (EIP) aims to assess both the public health impact of emerging infections and the measures used to prevent and control them.

[18]Ann Marie Kimball, "Overview and Surveillance of Emerging Infections," available at http://cer.hs.washington.edu/em_inf/emerging/emerg.html, accessed September 3, 2001. Kimball observes that syndromic surveillance is less specific than traditional disease surveillance, and points to the danger that it may supersede laboratory-based surveillance.

[19]Ibid.

[20]Amy E. Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response,* Stimson Center Report N. 35, available at www.stimson.org/cbw/pubs.cfm?cd=12, p. 256. According to Smithson and Levy, public health officials are considering monitoring other kinds of information that may indicate an outbreak, such as school absenteeism, sick calls to health clinics for certain city employees such as firefighters and police, calls to healthcare hotlines, and sales of drugs to treat flu-like systems.

Global Emerging Infections Surveillance and Response System (GEIS), administers a syndromic surveillance system in the Washington, D.C., area, which records and compares to trends, the outpatient diagnoses in eight syndrome categories from area military medical treatment facilities.[21] Additional information on this system can be found in the Appendix.

## Investigation

Once a potential epidemic has been detected, an investigation is necessary to confirm the outbreak, identify the source of infection, and determine its mode of transmission. Investigations may include epidemiological, laboratory, and environmental assessments.[22] The CDC assists state and local health officials, epidemiologists, and laboratory personnel with outbreak investigations by providing technical advice, reference and diagnostic services, and, upon state request, a member of the Epidemic Intelligence Service (EIS) to support field investigations.[23] State and local outbreak investigators may additionally take advantage of Epi-Info and Epi-Map, two public-domain software packages designed by the CDC as standard investigative tools.[24] The CDC also assists state and local public health laboratories through consultation, training, technology transfer, and reference and diagnostic services. The CDC's National Center for Infectious Disease plays an important role in this regard, providing

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[21]Col. Patrick Kelley, "Bioterrorism: Alert and Response," available at http://cer.hs.washington.edu/em_inf/bio/bio.html, accessed August 31, 2001. Following the attacks on the World Trade Center and Pentagon on September 11, the GEIS system was expanded to worldwide operations.

[22]IOM, "Public Health Systems and Emerging Infections," p. 34. For an interesting and widely acclaimed study on shoe-leather epidemiology, see Arthur Reingold, "Outbreak Investigations—A Perspective," *Emerging Infectious Diseases,* Vol. 4, No. 1, January–March 1998, available at http://www.cdc.gov/ncidod/EID/vol4no1/reingold.htm.

[23]In FY 2000, EIS officers participated in 74 Epidemiologic Assistances (EPI-AIDs), of which 63 were domestic. CDC, "Requests for Epidemiologic Assistance (EPI-AIDs)," available at http://www.cdc.gov/programs/partners9.htm, accessed August 15, 2001.

[24]CDC, "About Epi-Info," available at http://www.cdc.gov/epiinfo/aboutepi.htm, accessed July 12, 2001.

public health laboratories with a reliable supply of microbiological references and working reagents not commercially available.[25]

Currently, there is no comprehensive national laboratory system to support these facilities, with most laboratories cooperating according to local arrangements based on diagnostic capabilities.[26] There are roughly 150,000 physician office and health clinic laboratories, 17,000 independent and hospital laboratories, and 2,000 public health laboratories in the United States.[27] Most of these laboratories also rely on out-of-state or private testing rather than analyses performed by designated state public health facilities.[28] According to Dr. Patty Quinlisk, the CDC provides resources to revamp the public health system's state laboratories, and most if not all laboratories are in the midst of improving their capacity for rapid diagnoses, identification, and coordination.[29]

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[25]CDC, "National Center for Infectious Disease (HCR)," available at http://www.cdc.gov/maso/ncidfs.htm, accessed August 3, 2001.

[26]Michael R. Skeel, "Toward a National Laboratory System for Public Health," *Emerging Infectious Diseases,* Vol. 7, No. 3, Supplement, June 2001, p. 531. It should be noted, however, that the Division of Laboratory Systems within the CDC's Public Health Practice Program Office is supporting efforts to establish a National Laboratory System, drawing on funding from bioterrorism, food safety, and emerging infectious diseases initiatives. See Division of Laboratory Systems, available at http://www.phppo.cdc.gov/mlp/nls.asp, accessed August 13, 2001.

[27]CDC, "Towards a National Laboratory System," November 2000, p. 3, available at http://www.phppo.cdc.gov/mlp/pdf/nls/nls.1101.pdf, accessed August 3, 2001. With respect to state, local, and territorial public health laboratories, this report adds, "[W]e do not have an accurate estimate of either the number of laboratories in each category or the types and volumes of the important public health testing that they perform."

[28]GAO, "Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance," GAO/HEHS-99-26, February 1999, p. 7.

[29]Author interview with Patty Quinlisk, October 4, 2001. State laboratories may be categorized as belonging to one of three biosafety levels (BSL 2–4). Most clinical laboratories are categorized as BSL-2, while most state public health department labs operate at BSL-3. There are only four BSL-4 laboratories in the United States and no BSL-4 veterinary labs. There are fewer than 20 veterinary laboratories with BSL-3 capabilities. The four labs are located at the CDC in Atlanta, Georgia; the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) at Fort Detrick, Frederick, Maryland; the NIH Maximum Containment Lab, Bethesda, Maryland; and the Southwest Foundation for Biomedical Research, San Antonio, Texas, according to the American Society for Microbiology, "List of Currently Known BSL-4 Facilities Worldwide," available at http://www.asmusa.org/memonly/asmnews/nov99/figs/t1f1.htm, accessed July 12, 2001.

A number of measures have also been initiated to deal with the specific threat of bioterrorism. One of the most important is a CDC-run program that aims to build capacity for identifying and containing critical biological agents that could be used as weapons. The CDC has also collaborated with the American Society for Microbiology to devise simple screening algorithms for five high-priority bioterrorism agents, and more protocols are under development.[30] In 1999, the CDC trained some 700 laboratory and public health personnel on protocols for detecting, handling, and shipping critical biological agents, and 43 states received CDC funding to improve diagnostic and reference testing capabilities for selected agents.[31] An important feature of these various initiatives is the CDC's Rapid Response and Advanced Technology (RRAT) Laboratory. This lab operates 24 hours a day and is designed to provide diagnostic confirmatory and consultation support for bioterrorism response teams as well as to expedite molecular characterization of critical biological agents in federal BSL-4 facilities.[32] During FY 2000, enhanced diagnostic capabilities for the analysis of tularemia, plague, and anthrax were instituted under the rubric of RRAT.[33]

Additionally, the CDC has been actively engaged in supporting the development of more effective bioterrorist diagnostic capabilities at the state and local levels. An important component of this effort, which has been undertaken in conjunction with the Association of Public Health Laboratories (APHL), is the National Laboratory Training Network. This particular initiative trains public health workers on protocols for screening potential bioterrorism agents, including *B. anthracis*, *Brucella abortus*, *Francisella tularensis* and *Yersinia pestis*. The long-term objective is to provide a national sys-

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[30]James W. Snyder and William Check, *Bioterrorism Threats to Our Future: The Role of the Clinical Microbiology Laboratory in Detection, Identification and Confirmation of Biological Agents*, Washington, D.C.: American Academy of Microbiology, 2001, p. 8.

[31]Gregory D. Koblentz, "Overview of Federal Programs to Enhance State and Local Preparedness for Terrorism with Weapons of Mass Destruction," Belfer Center for Science and International Affairs, Discussion Paper 2001-5, Executive Session on Domestic Preparedness Discussion Paper ESDP-2001-3, Cambridge, Mass.: John F. Kennedy School of Government, Harvard University, April 2001, pp. 19–20.

[32]Koblentz, "Overview of Federal Programs," p. 39.

[33]Comments made by Scott Lillibridge during the ICEID, Atlanta, July 16–19, 2001.

tem for effectively disseminating emergency information and testing guidelines.[34]

## Response (Prevention and Control)

The response to an infectious disease epidemic will depend on the disease and circumstances of the outbreak. Prevention and control efforts often involve simple means to interrupt the transmission process of an infectious agent. These measures may take a variety of forms, such as vaccination, rodent or insect (vector) control, food recall, isolation, and quarantine. Because behavior is an important factor in the transmission of most infectious agents, education and information campaigns are also a feature of most disease-response initiatives.

One of the foremost tools in preventing infectious diseases is immunization, which during the last century has eradicated smallpox, eliminated polio from the Americas, and brought measles, rubella, diphtheria, tetanus, *Haemophilus influenzae* type b, and other diseases under control.[35] The National Immunization Program assists health departments in planning, developing, and implementing regular immunization programs and supports the establishment of vaccine supply contracts for the distribution of vaccines to states and localities.[36] The CDC may also provide vaccines or available treatments if there are shortages, usually by supplying state or local health agencies.[37] In addition, CDC's Vaccines for Children program, initiated in 1994, provides free vaccines to public and private providers in all states and territories, with the aim of ensuring immunization of eligible children.[38]

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[34]CDC, 2001 Program Review, "National Laboratory Network," press kit, available at www.cdc.gov/od/oc/media/presskit/training.htm, pp. 21–22.

[35]"Ten Great Public Health Achievements, 1900–1999," *MMWR,* available at http://www.cdc.gov/od/nvpo/arttop10.htm, accessed October 15, 2001.

[36]CDC, "About NIP," available at www.cdc.gov/nip/about/, accessed August 15, 2001.

[37]Foreman, *Plagues, Products, and Politics,* p. 74.

[38]Through this program, VFC vaccines are available to children from birth through 18 years old who are eligible for Medicaid, have no health insurance, are Native American or Alaska Native, or have health insurance that does not cover immunizations, provided they go to a federally qualified health center. CDC, "National Immunization

The CDC supports a variety of new and existing community-based programs for generally preventing and controlling diseases, such as the HIV Prevention Community Planning project.[39] The CDC also develops, evaluates, and updates clinical and public health guidelines for a variety of diseases and conditions, most of which can be accessed by state and local health officials via the CDC's online Prevention Guidelines database.[40] Finally, the CDC provides scientific support to the Task Force on Community Preventive Services, an independent group charged with developing recommendations on population-based interventions to prevent disease, injury, and premature death.[41]

While most disease prevention-and-control efforts are generally accepted as necessary for the public good, model legislation financed by the CDC for responding to bioterrorist attacks has come under some fire. Known officially as the Model Emergency Health Powers Act, this statute invests state governors and health officials with broad powers to examine, quarantine, and vaccinate American citizens exposed to pathogenic agents during a major health emergency. Although no state has formally acceded to the plan, the American Legislative Exchange Council, a bipartisan group of state legislators, has warned that the plan would intrude on Americans' civil liberties and could be used for purposes that extend well beyond bioterrorism.[42] Experts reject these arguments, however, and insist that the model law is essential in providing state authorities with the neces-

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Program: Vaccines for Children," available at http://www.cdc.gov/nip/vfc/Parent/ParentHomePage.htm, accessed August 27, 2001.

[39]CDC, "Preventing Emerging Infectious Diseases," p. 42.

[40]CDC, "Prevention Guidelines," available at http://wonder.cdc.gov/wonder/prevguid/library/library.asp, accessed August 15, 2001.

[41]CDC, "Guide to Community Preventive Services," available at http://www.cdc.gov/programs/partners4.htm, accessed August 15, 2001.

[42]The model legislation, for instance, also gives state authorities the power to "control, restrict and regulate food, fuel, clothing and other commodities, alcoholic beverages, firearms, explosives, and combustibles." See Dave Ebhert, "Model State Bioterror Law Stirs Controversy," Vaccine Information Center, January 3, 2002, available at http://www.vaclib.org/legal/invol.htm. (For the full text of the model law, see http://www.publichealthlaw.net.)

sary statutory authority to act decisively in the event of a bioterrorist attack or emerging infectious disease outbreak.[43]

## OTHER FEDERAL PROGRAMS AND INTERAGENCY INITIATIVES

In addition to the state- and local-level counterdisease activities outlined above, various agencies within the federal government work with the CDC and local and international partners to address specific concerns related to infectious disease. This section examines these efforts with respect to foodborne illness, antimicrobial resistance, bioterrorism, research, and global surveillance.

### Foodborne Disease

Foodborne illness in the United States has recently received increasing attention. As regulatory agencies, the USDA's FSIS and the FDA play important roles in preventing and responding to outbreaks of foodborne diseases.[44]

In 1996, FSIS issued its rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems, which mandated the implementation of HACCP systems in meat and poultry facilities. This regulation requires hazard analysis to identify critical points in the food production process and the application of preventive and corrective measures aimed at eliminating hazards at those

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[43]See, for instance, Marsha Berry and Lawrence Gostin, "Model Emergency Health Powers Act in Response to Bioterrorism Written for the CDC and Governors: Act to Help Ensure Rapid and Orderly Response to Public Health Threats," Georgetown University Law Center, October 30, 2001, available at http://www.law.georgetown.edu/topics/releases/october.30.2001.html.

[44]FSIS is responsible for meat, poultry, and eggs, while the FDA is responsible for all other food products. Currently, FSIS and FDA do not have authority to order mandatory recalls of dangerous food products. The FDA may suggest that a recall is in order based on its findings. If the company does not comply, the FDA may seek a court order authorizing the federal government to seize and destroy the product. FSIS likewise may request that a food product be recalled; to date, no such request has been refused. However, FSIS does have legal authority to seize and destroy meat and poultry products if they are thought to pose a serious hazard to public health. See FDA, "Food and Drug Administration Recall Policies," available at http://vm.cfsan.fda.gov/~lrd/recall2.html, and FSIS, "Food Recalls," available at http://www.fsis.usda.gov/OA/pubs/recallfocus.htm

points.[45] The HACCP rule represents a shift in FSIS's regulatory approach to include the production process as well as the finished product;[46] implementation of the HACCP system was completed in 2000.

The USDA has also worked in conjunction with the Department of Health and Human Services (HHS) in relation to food safety. In 1997, the two departments inaugurated a combined drive to enhance surveillance, risk assessment, research, inspection, and response to outbreaks.[47] This initiative expanded existing surveillance efforts, most notably FoodNet, and created the PulseNet program for molecular subtyping of foodborne bacteria. See the Appendix for further details.

## Antimicrobial Drug Resistance

In 1999, HHS joined other federal agencies to form the Interagency Task Force on Antimicrobial Resistance, cochaired by representatives from the CDC, FDA, and NIH. This body recommended specific, coordinated federal actions to address the emerging threat of antimicrobial drug resistance through surveillance, prevention and control, research, and product development.[48] Some of the initiatives based on the agenda that the task force coordinates focus on developing systems to monitor antimicrobial drug use, educating physicians and the public about proper use of antibiotics, expanding

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[45]FDA, "HAACP: A State-of-the-Art Approach to Food Safety," August 1999, available at http://vm.cfsan.fda.gov/~lrd/bghaccp.html, accessed July 26, 2001.

[46]USDA/FSIS, "Protecting the Public from Foodborne Illness: The Food Safety Inspection Service," April 2001, available at http://www.fsis.usda.gov/oa/background/fsisgeneral.htm, accessed July 24, 2001.

[47]FDA, USDA, U.S. Environmental Protection Agency, and CDC, "Food Safety from Farm to Table: A National Food Safety Initiative," report to the President, May 1997, available at http://www.cdc.gov/ncidod/foodsafe/report.htm, accessed August 3, 2001.

[48]Other members of the task force are HHS's Agency for Healthcare Research and Quality, the Health Care Financing Administration, the Health Resources and Services Administration, USDA, DoD, Department of Veterans Affairs, Environmental Protection Agency, and the U.S. Agency for International Development (USAID).

research of antimicrobial drug resistance, and facilitating development of new antimicrobial products.[49]

The food supply also has been recognized as a major source for the transmission of antimicrobial drug resistance from animals to humans.[50] To deal with this the National Antimicrobial Resistance Monitoring System (NARMS) for Enteric Bacteria has been set up to track susceptibility to 17 antimicrobial agents in humans and food animals and to yield information on trends that is used in developing regulations for the use of drugs in food and animal production.[51]

## Biodefense Resources for Countering Infectious Disease

The threat of bioterrorism has spawned a number of initiatives and programs with "dual use" capabilities applicable to countering infectious diseases. Responsibility for managing public health and emergency medical preparedness for bioterrorism belongs primarily to the CDC and HHS's Office of Emergency Preparedness (OEP), although it is unclear how the new Office of Homeland Security will affect this arrangement. Some biodefense programs, particularly the National Pharmaceutical Stockpile (NPS) and National Disaster Medical System (NDMS), as well as some DoD assets have clear utility for mitigating catastrophic infectious disease epidemics.[52]

As part of the 1999 HHS bioterrorism initiative, the CDC was designated to lead the effort to improve the nation's public health capacity to respond to bioterrorism. The CDC's Bioterrorism Preparedness and Response Program oversees grant programs designed to

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[49]HHS, "Antimicrobial Resistance: The Public Health Response," fact sheet, available at http://www.hhs.gov/news/press/2001pres/01fsdrugresistance.html, accessed June 28, 2001.

[50]Up to 35 percent of antibiotics produced in the United States are used in agriculture as feed supplements. Stuart Levy, American Society for Microbiology, "Antibiotic Resistance: Microbes on the Defense," in *Congressional Briefing: Infectious Diseases as We Enter the New Century: What Can We Do?* June 21, 1999, p. 5.

[51]CDC, "What Is NARMS?" available at http://www.cdc.gov/ncidod/dbmd/narms/what_is.htm, accessed August 16, 2001.

[52]"From 1997 to 2000, federal spending to prepare for [weapons of mass destruction] terrorism swelled from $130 million to $1.4 billion, a tenfold increase." Koblentz, "Overview of Federal Programs to Enhance State and Local Preparedness for Terrorism with Weapons of Mass Destruction," p. 3.

enhance state and local preparedness, epidemiology, and surveillance capabilities. Forty-two percent of the CDC's bioterrorism budget is devoted to enhancing state and local laboratory capabilities and communication.[53]

The CDC has delegated the management of the NPS to the Department of Veterans Affairs. This stockpile includes a range of pharmaceuticals and equipment for treating victims of a chemical or biological attack.[54] Eight immediate "push packages" are positioned in secure warehouses across the country, ready for deployment to the affected area within 12 hours of the federal decision to release NPS assets.[55] Technical Advisory Response Units, including pharmacists, public health experts, and emergency responders, will accompany the deployment of supplies to expedite transfer to local officials.[56] If additional medications are required, follow-up vendor-managed inventory supplies or packages, which are tailored to the situation, will arrive within 24 to 36 hours.[57]

The Federal Emergency Management Agency (FEMA) coordinates delivery of federal assistance to state and local governments in the event of a major emergency or disaster through the Federal Response Plan (FRP), a signed agreement among 27 federal departments and agencies.[58] The OEP in HHS is designated the lead agency for health

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[53]Ibid., p. 1.

[54]These supplies include antibiotics (including those for the treatment and prophylaxis of anthrax, plague, and tularemia), chemical antidotes, antitoxins, life-support medications, intravenous administration and airway maintenance supplies, and medical and surgical items that would be used to supplement and resupply state and local public health agencies in the event of a biological or chemical terrorism incident.

[55]James M. Hughes, M.D., Director, National Center for Infectious Diseases, CDC, HHS, testimony before the Subcommittee on National Security, Veterans Affairs and International Relations, Committee on Government Reform, U.S. House of Representatives, May 1, 2001, available at http://www.hhs.gov.asl/testify/t010501a.html, accessed July 9, 2001.

[56]Ibid.

[57]CDC, "NPS Synopsis," available at http://www.cdc.gov/nceh/nps/synopses.htm, accessed July 6, 2001. It should be noted, however, that based on only a few recent cases of anthrax, the President asked for additional stockpiles of antibiotics. It is not clear that estimated requirements were made on reliable analyses of needed pharmaceuticals.

[58]Federal Emergency Management Agency, "FRP . . . at a Glance," available at http://www.fema.gov/r-n-r/frp/frpglnc.htm, accessed July 10, 2001.

and medical services within the FRP. The OEP manages the NDMS, an asset-sharing partnership among federal, state, and local governments; private industry; and civilian volunteers to provide medical assistance nationwide within 12 hours for up to 100,000 victims.[59]

In 1997, OEP established four National Medical Response Teams (NMRTs) designed to respond to incidents involving weapons of mass destruction. NMRTs have disease detection, decontamination, and medical care capabilities. Three of these teams may be deployed nationwide, while the fourth is stationed in Washington, D.C. Each NMRT has a standard supply of pharmaceuticals designed to treat 5,000 people exposed to chemical weapons and hundreds of people exposed to a biological agent. An additional stockpile may be loaned to localities or predeployed for special events.[60]

DoD has also developed programs to deal with bioterrorism. Two important initiatives are the Chemical and Biological Rapid Response Team (CB-RRT) and the Chemical and Biological Incident Response Force (CBIRF). Both of these bodies are able to provide additional detection, mitigation, decontamination, treatment, and remediation capabilities within four hours of the recognition of a chemical or biological event.[61]

## Research

The search for diagnostic, therapeutic, and preventative measures to combat infectious disease depends on basic and applied biomedical research. As the nation's foremost institution in this area and with a budget of $23 billion, NIH is the major source of funding for U.S. research into infectious disease.[62] Within NIH, NIAID is the main

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[59]HHS, "Office of Emergency Preparedness," available at http://www.oep.dhhs.gov/, accessed July 6, 2001.

[60]Koblentz, "Overview of Federal Programs to Enhance State and Local Preparedness for Terrorism with Weapons of Mass Destruction," pp. 33–34. OEP also manages the Metropolitan Medical Response System program for support of municipal emergency response to weapons of mass destruction events.

[61]Koblentz, p. 31; U.S. Army Technical Escort Unit, Web page, available at http://teu.sbccom.army.mil/index.htm, accessed September 6, 2001.

[62]Approximately 84 percent of the NIH budget supports extramural research conducted by more than 50,000 researchers at some 2,000 universities, hospitals, and

body charged with supporting studies to better understand, treat, and prevent infectious disease. NIAID sponsors and conducts research related to ecological and environmental factors influencing disease emergence, microbial changes and adaptations, human susceptibility to new microbes, and new and improved control strategies.[63] Four major areas are emphasized in this effort: global health and infectious diseases; HIV/AIDS; immune-mediated diseases such as allergy and asthma; and vaccines.[64] Basic research is typically directed toward development of vaccines, diagnostics, and drugs. However, NIAID has also funded projects aimed at sequencing the genomes of more than 50 pathogens, at least a dozen of which have already been mapped (including the bacteria that cause TB, gonorrhea, and cholera and the individual chromosomes of the malaria parasite, *P. falciparum*).[65]

DoD is also engaged in a variety of research areas that have applications for infectious disease detection, diagnosis, treatment, and prevention and defense. The U.S. Army Medical Research and Materiel Command (USAMRMC) is DoD's executive agent for medical chemical and biological defense (and combat) as well as telemedicine and infectious disease research. USAMRMC's Infectious Disease Program focuses on several areas, all of which have applications to the civilian world. These include the following:

- "Development of vaccines against militarily important diseases
- Discovery and development of prophylactic and treatment drugs for parasitic infectious diseases
- Techniques for rapid identification of disease organisms and diagnosis of infections

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other research facilities. Eleven percent of the budget supports intramural research at NIH. HHS, "FY 2002 President's Budget for HHS," pp. 39–41.

[63]NIAID, "Infectious Diseases Research," available at http://www.niaid.nih.gov/eidr/mceid.htm, accessed July 5, 2001.

[64]Anthony S. Fauci, Director, NIAID, statement before the Subcommittee on Labor, Health, and Human Services and Education, U.S. House of Representatives, May 16, 2001, available at http://www.niaid.nih.gov/director/congress/2001/051601.htm, accessed August 28, 2001. See NIAID, "NIAID: Planning for the 21st Century," 2000, available at http://www.niaid.nih.gov/strategicplan2000/default.htm.

[65]Anthony S. Fauci, statement before the Subcommittee on Labor, Health and Human Services, and Education.

- Collection and analysis of epidemiological data that aid in the control of relevant infectious diseases
- Studies of control measures against infectious disease vectors."[66]

## Global Surveillance and Response

Several federal agencies in the United States have been engaged in efforts to prevent and control infectious disease on a global scale. Many of those efforts have been initiated in coordination with other partners. These include foreign ministries of health, the WHO, the Pan American Health Organization, the UN Children's Fund (UNICEF), the World Bank, and others.

As the primary dispenser of foreign aid, USAID plays a major role in international efforts to counter infectious disease. Most efforts are aimed at building public health capacity in developing countries. USAID also leads the U.S. government response to the international HIV/AIDS crisis, having dedicated $1.6 billion toward prevention and control of the epidemic since 1986. In 2001, USAID distributed HIV/AIDS assistance to nongovernmental organizations in nearly 50 countries.[67] Other programs include an initiative to address antimicrobial resistance, TB, and malaria and a plan for surveillance and response through provision of technical assistance, applied research, and development of indigenous capacity.[68]

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[66]This research has produced vaccines for hepatitis A and B, Japanese B encephalitis, Argentinian hemorrhagic fever, typhoid, adenovirus, and meningitis. U.S. Army Medical Research and Materiel Command, "RAD 1—Military Infectious Disease Research Program," available at http://mrmc-www.army.mil/, accessed October 15, 2001. An additional military initiative is the Unconventional Pathogen Countermeasures Program at the Defense Advanced Research Projects Agency (DARPA), which sponsors a number of projects that seek novel ways to detect and protect against pathogens. Another DoD program, DARPA's Advanced Diagnostics program, aims to develop "the capability to detect in the body—in real time and in the absence of recognizable signs and symptoms and when pathogen numbers are still low—the presence of infection by any pathogen."

[67]USAID, "USAID: Leading the Global Fight Against HIV/AIDS," available at http://www.usaid.gov/press/releases/2001/fs010420_4.html, accessed August 13, 2001.

[68]USAID, "Reducing the Threat of Infectious Diseases of Major Public Health Importance: USAID's Initiative to Prevent and Control Infectious Diseases," March 1998, p. 3, available at www.usaid.gov/pop_health/pdf/idfstrategy.pdf.

The CDC also plays a role in international health activities because all disease outbreaks have the potential to impact the United States. In fact, the CDC's support of international disease control and prevention is considered a key institutional objective. Much of this work is carried out through the CISET Emerging Infectious Disease Task Force.[69] Six priority areas for international cooperation have been identified: outbreak assistance, disease surveillance, applied research, dissemination of public health tools, support of global initiatives for disease control, and public health training and capacity building.[70]

The CDC is seen as a world leader in outbreak investigation. Epidemiologic Assistance (EPI-AIDs) is available to respond to foreign outbreaks (when requested); in FY 2000, EIS officers participated in 11 overseas investigations.[71] The CDC also collaborates with USAID, the WHO, and others on disease-specific surveillance and control efforts, particularly targeting HIV/AIDS, measles, TB, and malaria.[72]

Finally, DoD is playing an increasingly important role in global disease surveillance, particularly with regard to building epidemiological capacity of foreign laboratories. Apart from the GEIS initiative noted above, DoD has established an HIV/AIDS Prevention Program, which is run by the Naval Health Research Center as a component of

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[69]CDC, "Preventing Emerging Infectious Diseases," p. 47.

[70]From CDC's soon-to-be-released global strategy, Protecting Our Nation's Health in an Era of Globalization: CDC's Global Infectious Disease Strategy, forthcoming. See also Bruce Brown et al., "Setting Priorities for Global Infectious Disease Control," *U.S Medicine,* April 2001, available at http://www.usmedicine.com/column.cfm?columnID=44&issueID=25, accessed July 6, 2001.

[71]CDC, "Requests for Epidemiologic Assistance (EPI-AIDs)."

[72]The CDC has been designated as the lead agency within HHS to implement the Leadership and Investment for Fighting an Epidemic Initiative, addressing HIV/AIDS in India and Africa. To foster more local capacity, the CDC has established 25 Field Epidemiology Training Programs around the world. These training programs, modeled on the EIS, have graduated more than 1,200 participants since 1980. In addition, the CDC supports research centers in Botswana, Cote d'Ivoire, Guatemala, Kenya, and Thailand and houses more than 40 WHO Collaborating Centers in the United States, each addressing a specific global health problem. CDC and Agency for Toxic Substances Disease Registry (ATSDR), "Working with Partners to Improve Global Health: A Strategy for CDC and ATSDR," September 2000, p. 4, available at http://www.cdc.gov/ogh/pub/execsummary.pdf, and CDC, "International Training Programs for Applied Epidemiology and Global Health Leadership," available at http://www.cdc.gov/programs/global5.htm, accessed August 15, 2001.

the U.S. participation in the International Partnership Against HIV/AIDS in Africa. The program received $10 million in 2000 to establish training and prevention programs aimed at reducing the spread of HIV among military personnel in select African countries. The long-term aim is to integrate the prevention activities of USAID, CDC, and the Health Resources and Services Administration for application to African military communities.[73]

## ASSESSMENT OF U.S. CAPABILITIES TO COUNTER INFECTIOUS DISEASES

While the various initiatives described above have helped to provide the United States with one of the most advanced public health systems in the world, several critical weaknesses are currently serving to undermine the effectiveness of U.S. disease prevention and mitigation efforts. Principal areas of concern include the inadequacy of surveillance mechanisms; fiscal neglect; a lack of personnel, especially those with experience in recognizing and treating emerging infections; a shrinking capacity to produce needed vaccines and therapeutics; and a lack of coordination for many of these functions.

### Surveillance

Surveillance is key to the prevention of epidemics. However, adequate monitoring capabilities do not exist uniformly across the United States. As Davis and Lederberg note, "Although a tremendous amount of surveillance is accomplished [in the United States], much of it is disease-specific, resulting in disjointed programs and

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[73]Naval Health Research Center, "DoD HIV/AIDS Prevention Program," available at http://www.nhrc.navy.mil/programs/life/managementplan.html, accessed August 30, 2001. It should be noted that the International Services branch of the USDA's Animal and Plant Health Inspection Service (IS/APHIS), which seeks to safeguard U.S. agriculture from foreign pests and diseases, additionally plays a role in overseas disease monitoring. Operating in 27 countries, IS/APHIS works to ensure that foreign agricultural officials understand and adhere to U.S. agricultural health policies and import regulations. For further details, see APHIS, "International Services," available at http://www.aphis.usda.gov/is/, accessed August 17, 2001.

unsustainable systems supported by categorical funding."[74] Increased trade, travel, changes in agricultural practice, and other factors further exacerbate difficulties in surveillance, heightening problems associated with performing effective epidemiological investigations.[75]

A lack of adequate surveillance mechanisms not only compounds the problem of correctly identifying and assessing appropriate control-and-prevention tools. It also makes it more difficult to recognize new diseases, discriminate among geographically separated but epidemiologically linked outbreaks, detect factors responsible for illnesses, and identify a potential bioterrorist attack.

Indicative of this was a 1999 General Accounting Office (GAO) review of U.S. infectious-disease surveillance capabilities, which concluded that laboratory capabilities vary from state to state and are not comprehensive with most jurisdictions surveying only five of six important diseases and many ignoring hepatitis C and penicillin-resistant *S. pneumoniae*.[76] The unavoidable message of the GAO assessment was that the U.S. first line of defense against diseases is severely impeded and requires considerable investment in the development of significantly improved and coordinated surveillance capabilities.

## Fiscal Neglect

Surveillance is only one part of the larger public health infrastructure, and it has been recognized in many studies that America's overall system has worsened significantly over the last quarter century due to fiscal neglect.[77] According to the Health Care Financing

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[74]Jonathan R. Davis and Joshua Lederberg, eds., *Public Health Systems and Emerging Infections: Assessing the Capabilities of the Public and Private Sectors—Workshop Summary,* Washington, D.C.: National Academy Press, 2001, p. 6.

[75]Ibid. p. 1.

[76]As cited in Davis and Lederberg, p. 90. See also GAO, "Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance," 1999.

[77]For instance, U.S. Senate, "Bioterrorism: Public Health and Medical Preparedness," statement by Janet Heinrich, October 9, 2001, before the Senate Subcommittee on Public Health, GAO-02-141T; and Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Second Annual Report to the President and the Congress—II: Toward a National Strategy for Combating Terrorism,* Santa Monica, Calif.: RAND, December 15, 2000.

Administration (HCFA), only 3 percent of the $1.1 trillion the United States spent on healthcare was devoted to explicit public health activities. Slightly more than 50 percent of U.S. expenditures were dedicated to hospital care and physician services, while drugs and other nonmedical durables accounted for 11 percent of the budget.[78]

As a result of insufficient financial resources, laboratories crucial to the identification of diseases have become increasingly ill-equipped to deal with outbreaks when they occur. This has not only affected diagnostic capabilities at the state level (the current effectiveness of which varies greatly from one region to the next), it has also detracted from appropriate capacity federally.[79]

A lack of resources has also at least partly detracted from the development of a modern information-sharing system that is able to overcome historical difficulties in communicating across state lines; among federal, state, and local officials; and among emergency rooms, hospitals, and government departments. The anthrax attacks in fall 2001 exemplify the difficulties currently facing the United States in this regard. Although public health authorities in Washington, D.C., were aware of cases that had arisen in Florida, and the presence of anthrax spores in the Senate offices had been disclosed in a timely manner, physicians in the nation's capital were not alerted. As a result, at least two postal workers exposed to the agent were identified only after it was too late for effective treatment.[80] If more individuals had been affected or if there had been no advance

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[78]National Health Care Anti-Fraud Association, "Impact of Fraud: U.S. Healthcare Spending," fact sheets, available at http://www.nhcaa.org/factsheet_impact.htm, accessed December 15, 2001.

[79]GAO, "West Nile Virus Outbreak," pp. 26–32. Indicative of this is that there is just a single full-time employee dedicated to the CDC's reference laboratory for plague (the only one in the world). As a direct result of this paucity of experience and knowledge, two of the five people in the United States who contracted plague in 1996 died of the disease before it was even identified. See "Fatal Human Plague—Arizona and Colorado, 1996," *MMWR*, Vol. 46, No. 27, July 11, 1997, pp. 617–620.

[80]"Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Exposure Management and Antimicrobial Therapy, October 2001," *MMWR*, Vol. 50, No. 42, October 26, 2001, pp. 910–919, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5042a1.htm, accessed June 22, 2002; Elizabeth Becker and Robin Toner, "A Nation Challenged: The Victims, Postal Workers' Illness Set Off No Alarms," *New York Times*, October 24, 2001, p. B1.

warning, the overall seriousness of the crisis would likely have been far worse.

## Personnel

Insufficient staffing at all levels and in all sectors of the medical and public health communities is emerging as a significant threat in the United States, not least because an adequate number of educated and trained personnel is critical to maintaining necessary public health and medical capabilities. The GAO has cited a lack of laboratory personnel as one of the primary problems facing laboratories today, largely because it detracts from state and local laboratory capabilities to perform infectious disease surveillance.[81] Nurses are also in critically short supply, and this problem is expected to worsen. By 2020, based on current trends in supply and requirements, there is expected to be a 20 percent deficit in the overall nurse workforce, which will mean that other, less-trained individuals will have to take over nursing duties, potentially putting patients at severe risk.[82]

Shortages of nurses and other staff are already emerging as a significant problem. During the 1999–2000 flu season, demand exceeded hospital capabilities across the country, affecting the ability to provide definitive treatment to those suffering from the virus as well as those concurrently in need of other types of care.[83] Assessing the situation, Mary Beachley, president of the Maryland Nurses Association, stated, "If a major super bug hit, we'd be in trouble. Our response in the short-term would be okay, but long-term care with large numbers of critically ill patients [would] be a problem."[84]

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[81]Janet Heinrich, "Health Workforce: Ensuring Adequate Supply and Distribution Remains Challenging," Washington, D.C.: GAO, August 1, 2001.

[82]P. Buerhaus, D. Staiger, and D. Auerbach, "Implications of an Aging Registered Nurse Workforce," *JAMA,* Vol. 283, No. 22, June 14, 2000, pp. 2948–2954. A number of studies have found that healthcare quality is related to the nursing staff's education level and the number of registered nurses on staff.

[83]M. Schoch-Spana, "Hospitals Buckle During Normal Flu Season: Implications for Bioterrorism Response," *Biodefense Quarterly,* Vol. 1, No. 4, March 2000, available at http://www.hopkins-biodefense.org/pages/news/quarter1_4.html, accessed December 15, 2001.

[84]As quoted in Schoch-Spana.

## Lack of Experience with Exotic Infectious Diseases

In addition to the sheer lack of bodies, many doctors and other healthcare workers lack the knowledge and experience to recognize uncommon infectious diseases. Because these personnel are often the first line of defense in diagnosing and containing outbreaks, this deficiency in expertise can be highly deleterious. Again, the 2001 anthrax attacks provide a pertinent case in point. The New York Public Health Laboratory dismissed the initial diagnosis of cutaneous anthrax ascribed to Erin O'Connor, the National Broadcasting Company (NBC) employee who was one of the first to exhibit symptoms of the disease, because no spores were detected in her tissue samples. It was not until Robert Stevens contracted inhalation anthrax and Ms. O'Connor went to an infectious disease specialist that she was confirmed to have skin anthrax. The doctor who made the correct diagnosis had experience in developing countries, enabling him to recognize the characteristic anthrax lesion.[85]

## Shrinking Vaccine Production Capacity

One of the most effective tools in improving the U.S. ability to deal with infectious disease has been the widespread use of vaccines (especially in children), which played a large role in reducing polio, measles, mumps, rubella, chicken pox, and other serious diseases.

These gains are at risk for a number of reasons. First, because many infectious diseases are unknown in North America today, people are less willing to chance the rare adverse reaction to vaccines. Perceived risks have been further magnified by those who have legitimate, though not necessarily science-based, concerns about immunization safety as well as the political controversy surrounding the mandated anthrax vaccine program in the U.S. military (which was in place from May 1998 through early 2000). Second, funding for public health initiatives has declined substantially, and many vaccines no longer enjoy the financial support from states that they once did. Finally, the vaccine industry has become progressively more concentrated, with only four major pharmaceutical firms currently

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[85]Lawrence K. Altman, "A Nation Challenged: NBC; Doctor in City Reported Anthrax Case Before Florida," *New York Times,* October 18, 2001, p. B7.

engaging in production: Merck, Aventis-Pasteur, Glaxo, and Wyeth-Ayerst (although several smaller biotech companies are also involved in vaccine development). Many critical vaccines are also made by only one FDA-approved supplier, which has put the United States at great risk of losing an already limited manufacturing capability. Problems have already been encountered with the production of influenza, tetanus, diphtheria toxoid, and adenovirus vaccines.[86]

The time to develop new vaccines is long, and the cost is high: 10 to 15 years and $300 million to $500 million.[87] Given this reality, it is highly unlikely the United States will be able to quickly ramp up its vaccine production. This puts Americans at risk and means immigrants settling in the country may not be able to acquire immunity, which obviously places other susceptible individuals at risk.[88, 89]

## Insufficient Attention to the Provision of Global Healthcare Aid

While the United States has been engaged in various international efforts to prevent and control infectious disease, it has been relatively inactive in terms of global healthcare aid. Vaccine research and

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[86]Prior to February 2001, Aventis-Pasteur and Wyeth-Ayerst Laboratories produced tetanus and diphtheria toxoid, but Wyeth ceased production without warning. Although Aventis ramped up production, because the vaccine takes 11 months to produce, a shortage was created in the short term. "Notice to Readers: Deferral of Routine Booster Doses of Tetanus and Diphtheria Toxoids for Adolescents and Adults," *MMWR,* Vol. 50, No. 20, May 25, 2001, pp. 418, 427.

[87]According to one estimate by Pharmaceutical Research and Manufacturers of America, drug companies spend an average of 12 to 15 years to develop a new drug at an average cost of $500 million, http://www.phrma.org/publications/documents/factsheets/2001-03-01.210.phtml, accessed November 30, 2001.

[88]The Immigration and Naturalization Service has in fact currently waived the requirement for tetanus-diphtheria vaccination for immigrants due to the shortage in supply. See http://www.cdc.gov/ncidod/dq/technica.htm, accessed November 30, 2001; the deferral is in effect until March 31, 2002.

[89]For additional information on vaccine production challenges, see "Vaccines Research, Development, Production and Procurement Issues," in *Biological Threats and Terrorism: Assessing the Science and Response Capabilities*, Knobler, S. L., A. A. F. Mahmoud, and L. A. Pray, eds., Forum on Emerging Infections, Board on Global Health, 2002, pp. 85–121; *Calling the Shots,* Committee on Immunization Finance Policies and Practices, Division of Health Care Services and Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 2000.

development has tended to focus on viral strains prevalent in North America as opposed to Africa and Asia—precisely the areas where disease threat is most widespread—and has only recently and hesitantly begun to embrace the idea of subsidizing to ensure lower guaranteed dosage prices. Also, comparatively few resources have been made available to help poor countries boost the effectiveness of their overall public medical systems and address some of the conditions contributing to the emergence and spread of pathogenic agents within their borders.[90] Indeed, health issues have consistently failed to figure prominently in Washington's external aid priorities, the delineation of which has tended to be governed by a more reality-grounded focus on political concerns.

According to the World Bank's Commission on Macroeconomics and Health, $27 billion, which equates to just 0.1 percent of the collective GDP of the United States, Japan, and Europe, would be sufficient to ensure that cheap, tried-and-tested treatments, such as vaccines and gastrointestinal oral rehydration therapy, were made widely available throughout much of the developing world.[91] Certainly the United States should not be expected to shoulder the entire burden of this fiscal effort. The chief responsibility for fighting disease in poor states must, ultimately, lie with the governments of these countries. This being said, it is an area where Washington is better placed than most to play a meaningful role—particularly in light of the fact that it took Congress only three days following the September 11 attacks in New York and Washington to appropriate $40 billion for the war against global terrorism.[92] Moreover, the exercise of such leadership would create an opportunity to demonstrate an appealing style of benign American hegemony, whereby the United States could be seen (and recognized) as willing to articulate and act on shared interests rather than simple, narrowly defined, national priorities.[93]

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[90]See, for instance, CSIS, *Contagion and Conflict*, pp. 54–55, and "Terrorism Is Not the Only Scourge," *The Economist*, December 22, 2001.

[91]World Bank, "Macroeconomics and Health: Investing in Health for Economic Development," report of the World Bank Commission on Macroeconomics and Health, December 2001, available at http://www.cmhealth.org/index.html. See also World Bank Commission on Macroeconomics and Health, cited in "The Health of Nations," *The Economist*, December 22, 2001.

[92]"Terrorism Is Not the Only Scourge," *The Economist*.

[93]CSIS, *Contagion and Conflict*, p. 63.

## Lack of Coordination

The lack of clear leadership, coordination, and communication in the area of infectious disease clearly poses a threat to the United States. Within the federal government, numerous agencies and centers, including the CDC, FDA, NIH, DoD, USAID, USDA, U.S. Fish and Wildlife Services, and the Department of the Interior, work on various aspects of preparation and response. In addition, because public health is a state function, numerous agencies and mechanisms exist at the subfederal level. Add to this the responsibilities of the private sector and a highly complex patchwork arrangement emerges to deal with everything from prevention to surveillance to treatment and containment.

A lack of communication has frequently resulted in the delayed recognition of new or unusual diseases, as the 2001 anthrax cases illustrate. This problem has been compounded by the fact that hospitals often do not share adequate information with the local health department, generally waiting for laboratory- or specialist-based diagnoses before reporting incidents to the relevant authorities.[94]

Because infectious disease represents a ubiquitous, wide-ranging threat to the security of the United States, it is essential that this particular manifestation of the GAP challenge be dealt with in a coordinated and systematic manner. While some functions are clearly best performed at the local and state levels, standards and resources must flow from the federal government to ensure uniform protection of America and its citizens. Given the rapidity with which viral and bacterial agents spread and emerge or reemerge, it is critical that Washington move quickly to better integrate and augment the overall disease mitigation system at its disposal. The final chapter presents some initial policy recommendations for achieving such an outcome.

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[94]George Washington University, "Preparing for a Bioterrorist Incident: Linking the Public Health and Medical Communities," National Health Policy Forum, October 4–5, 1999, site visit to Baltimore and Fort Detrick, Maryland.