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Emergency Preparedness from a Health Perspective: Preparing for Bioterrorism at the Federal, State and Local Levels

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A background paper, with resource lists,
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Overview—*Despite the good intentions prior to and in the aftermath of September's atrocities, the existence of significant gaps in the country's emergency preparedness is clear. Further, the lack of coordination and seamless integration between public health, public safety, law enforcement, and the media has been highlighted by the events of the past few weeks. This background paper will provide an overview of the current state of emergency preparedness at all levels of government, by identifying both the gaps and the steps being taken to close them. A series of reference materials, including a suggested reading list and Web site addresses, are listed at the end of the paper.*

Bioterrorism is, of course, not new. Preparing for it on a grand scale in the United States, however, is. But the country is not starting from scratch. Over the years, experts have been calling for a more robust public health infrastructure, for a closer working relationship between the medical and public health communities, and for a broader research and development agenda in this area. Preparing for such an attack has taken on great urgency since September 11. Priorities have shifted, and the importance of the public health and safety infrastructure has become clearer than ever before.

DISTINGUISHING BIOTERRORISM FROM OTHER WEAPONS OF MASS DESTRUCTION

The intentional release, or threat of a release, of biological agents (that is viruses, bacteria, or their toxins) in order to terrorize a civilian population or manipulate a government is commonly referred to as bioterrorism or "the poor man's nuclear bomb." Although similar in its ability to cause devastating medical consequences as well as widespread panic and disruption, bioterrorism is very different from chemical terrorism (such as the 1995 Aum Shinrikyo Sarin gas attack in the Tokyo subway).

A chemical attack would be instantly obvious, whereas a biologic attack would take days, if not weeks, to become apparent. A chemical attack would rely on traditional first responders, such as fire, police, hazardous materials (HAZMAT) teams, and emergency medical technicians whereas first responders in a bioterror attack would be primarily epidemiologists, infectious disease specialists, emergency room personnel, and public health officials. In all cases, local medical personnel would also play a vital role.

In the case of a bioterrorist attack, a variety of biologic agents potentially could be used. But different government agencies have compiled different threat lists. Federal Bureau of Investigation intelligence officers have one list of likely threat agents, while the Centers for Disease Control and Prevention (CDC) have another. But as the September 2001 General Accounting Office (GAO) report *Bioterrorism: Federal Research and Preparedness Activities* points out, "different threat lists are appropriate because of the different focuses of these agencies." The report notes, for example, that while one list focuses on agents that would have the greatest impact on public health, others specify which agents may be more likely to be used by a terrorist group operating inside the United States, a terrorist group that is not foreign-sponsored. Despite the differences, most experts list anthrax, pneumonic plague, and botulism toxin as highly credible threats. Some lists also include smallpox, salmonellosis, tularemia, and West Nile virus, as well as others. (See Appendix I for more information on some of these agents.)

The distinction between bioterrorism and chemical terrorism, as well as that between radiologic and nuclear terrorism, is critical, for in the differences between them lie unique requirements for preparedness. While many of the issues and challenges are the same, regardless of the type of terror attack (for example, the ability of the health care system to deal with mass

BACKGROUND PAPER

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casualties and the "worried well," short and long-term mental health needs, and panic), the nature of an attack will determine the response and ultimately the level of preparedness. In the end, however, while the initial responses may start out differently, all emergency responses ultimately rely on the same health and safety infrastructure.

PREPAREDNESS—FEDERAL, STATE, AND LOCAL

Bioterror agents can be released into the environment, the food supply, the water supply, or in some cases passed directly from one person to another. With the very recent establishment of an Office of Homeland Security (an office which has no statutory or budget authority at this point), President Bush has signaled the importance of coordinated, centralized oversight of the safety of food, water, air, and personal health as well as national security. In fact, however, this responsibility is still divided among many government agencies and congressional committees—agencies and committees that, to some extent, compete for dollars and turf. According to some experts, while many critical programs have been effective, the lack of a unified strategy has resulted in a fractured system in which duplication of effort and inefficiencies abound.

In her October 5 testimony before the House Government Reform/Government Efficiency, Financial Management, and Intergovernmental Relations Subcommittee, Janet Heinrich, director, health care, for public health issues at GAO, summarized findings from the September 2001 GAO bioterrorism report. Heinrich testified that "over 40 federal departments and agencies have some role in combating terrorism, and coordinating their activities is a significant challenge."

Of the 40 departments, the Department of Health and Human Services (DHHS) plays a major role. Appendix II, taken from the September 2001 GAO bioterrorism report, lists all the activities of the various agencies within DHHS working on bioterrorism and emergency preparedness issues.

In addition to the vast efforts under way within DHHS, many other federal departments and agencies—the Departments of Veterans Affairs, Justice, Commerce, Energy, Defense, Agriculture, Transportation, and Treasury and the Environmental Protection and Federal Emergency Management Agencies—are also devoting significant resources to preparing for and preventing bioterrorism. In the nation's zeal to ramp up its counter-terrorism armamentarium, a significant amount of money has been earmarked for bioterror preparedness. Many caution, however, that dollars alone will not be enough.

Experts stress that it is not so much new programs that are needed, but rather a more coordinated approach that improves and augments current programs as our capabilities are honed. These programs, some of which are more developed than others, include but are not limited to the following:

- *National Laboratory System*—a demonstration program funded by the CDC in response to the growing public health threat posed by bioterrorism, food-borne diseases, and emerging infectious diseases.
- *Laboratory Response Network*—a national network composed of county, city, state, and federal public health laboratories.
- *Health Alert Network*—a nationwide program, developed by the CDC in partnership with the National Association of County and City Health Officials, the Association of State and Territorial Health Officials, and other health organizations, to establish the communications, information, distance-learning, and organizational infrastructure that will link local health departments to one another and to other relevant organizations.
- *National Pharmaceutical Stockpile*—a resource consisting of pharmaceutical, medical, surgical, and patient support supplies, as well as a cache of available vaccines, items that local physicians and health facilities might find in short supply in the event of a terrorist attack or other significant health incident.
- *National Disaster Medical System*—a partnership that brings together DHHS, the Department of Defense, the Federal Emergency Management Agency, and the Department of Veterans Affairs in order to provide medical response, patient evacuation, and medical care for mass casualty events.

Many other programs and teams are in place and ready to deploy should the need arise. The CDC would be available to assist state and local governments in their disease surveillance, identification, and control efforts, while the DHHS Office of Emergency Preparedness would be ready to assist state and local authorities in providing care for massive numbers of casualties.

While preparedness plans are under way at the federal level, health officials in the states and localities

are working to bring their facilities up to where they need to be. But preparedness gaps that still exist at the state and local levels have become a focal point of significant concern for congressional and state leaders.

Senate Appropriations Committee Chairman Robert Byrd (D-W.Va.) echoed this sentiment when he declared during an October 3 Subcommittee on Labor, Health and Human Services, and Education (Labor/HHS) hearing that "there is no more important job facing us as appropriators and authorizers than addressing perceived preparedness gaps in state and local emergency response systems."

Some of the most serious preparedness gaps exist within the public health infrastructure, considered by many to be the backbone of bioterrorism preparedness. Others, however, insist that what currently exists is not really a public health infrastructure, but rather an amalgam of agencies across the country that carry out the disparate functions known as public health.

SHORING UP THE PUBLIC HEALTH INFRASTRUCTURE

DHHS Secretary Tommy Thompson underscored the importance of public health when he declared at the October 3 congressional hearing that "public health is a national security issue." However, shoring up the public health infrastructure, which had been woefully underfunded and underappreciated before September 11, will require a commitment of resources—including the costs of hiring personnel, training staff, enhancing laboratories, and improving secure and reliable communication and data management systems. Analysts note that these resources must be viewed in the context of overall health spending, overall defense spending, and overall emergency preparedness spending—in short, a recalibration of the nation's priorities.

In an address over the Public Health Training Network, broadcast in mid-September 2001, CDC Director Jeffrey Koplan, M.D., identified seven priority areas for capacity building at the state and local levels. Patricia Quinlisk, M.D., medical director and state epidemiologist, Iowa Department of Public Health, summarized these priority areas in testimony before the October 3 Senate Labor/HHS Subcommittee hearing:

- ***A public health workforce*** that is well-trained, well-staffed, and fully prepared.
- ***Laboratory capacity*** to produce timely and accurate results for diagnosis and investigation.
- ***Epidemiology and surveillance*** to rapidly detect health threats.
- ***Information systems*** that are accessible and rapid and that permit effective analyses and interpretation of health data and provide public access to health information.
- ***Communication systems*** that enable a rapid, secure, two-way flow of information that includes the ability to provide timely, accurate information to the public and to advise health officials and policymakers in public health emergencies.
- ***Policy and evaluation*** that provides for routine assessment of how effective experts are at rapidly detecting health threats and making improvements.
- ***Preparedness and response*** mechanisms that develop plans and regularly test them in order to maintain a high level of preparedness.

Quinlisk explained that last year's enactment of the Public Health Threats and Emergencies Act (PHTEA) provided a process for accomplishing the seven priorities articulated by Koplan. She testified that, very soon, CDC will publish a document which identifies the core capacities needed by state and local health departments for terrorism preparedness and response. The next step, she said, would be the provision of CDC grants to states to help them assess themselves against these core capacities. However, she continued, although assessment tools have been developed for this purpose, "there are no federal resources for conducting this assessment of bioterrorism capacity." The final step authorized under PHTEA is for CDC to provide grants to states and local health departments to fill any gaps they have identified in their assessment process.

Quinlisk then provided several specific examples of what constitutes core epidemiologic capacity in state health departments. The items she discussed included the ability and the authority to:

- Collect personal information.
- Disseminate notifiable disease information and reporting.
- Establish systematic data collection protocols that monitor community health indicators (for example, aberrations in utilization trends or syndrome-based presentations).
- Educate health care providers on the medical effects and public health consequences of diseases caused by bioterrorism agents.

- Train public health, infection control, and clinical staff to collect and rapidly analyze surveillance data.

CROSSCUTTING PREPAREDNESS ISSUES

Many of the objectives inherent in bioterrorism preparedness apply to emergency preparedness and public health, broadly defined. Indeed, Jonathan B. Tucker, Ph.D., director of the Chemical and Biological Weapons Nonproliferation Project at the Center for Nonproliferation Studies, Monterey Institute of International Studies, testified at the October 3 Senate Labor/HHS Subcommittee hearing that "it is important to note that bioterorrism and the growing challenge of natural emerging infections are two sides of the same coin." Efforts to bolster bioterrorism preparedness, therefore, should ultimately yield improvements throughout the entire health care system. Investments in preparedness, much like previous prevention investments, could result in a "dual use," that is, delivering a multitude of returns on the initial investment. For example, if some drug-resistant bacteria were to emerge, independent of any terrorist activity, the capabilities developed to combat bioterrorism would be invaluable.

Similarly, public health and safety issues that were the subject of previous congressional agendas have again become the focus of hearings, but with a twist. The heightened concern over terrorism has sparked members of Congress to think differently about programs and areas of responsibility. In just the past few weeks since the September 11 attacks, for example, food safety, which was of some interest to the federal government before September, has become an item of paramount importance. Legislation has been introduced to create a single food safety entity, a move aimed at filling the numerous holes in the nation's food monitoring systems, responsibilities that currently are split between the Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

Among the many challenges facing officials at all levels of government and the private sector, two profoundly critical issues have emerged and captured the attention of health care professionals—(*a*) the adequacy of mental health services, both short- and long-term and (*b*) the recognition of the unique effects (including medical, psychological, and social effects) that bioterrorism and the threat of bioterrorism would have on children. Sens. Hillary Rodham Clinton (D-N.Y.) and Christopher Dodd (D-Conn.) and Rep. Louise Slaughter (D-N.Y.) introduced legislation on October 11 that would create a national task force to make sure the special health needs of children are taken into account in responding to the threat of terrorism. Issues that would be addressed include, for example, the devastating psychological affects of bioterrorism and the proper dosing of medications and vaccines specifically for children.

In addition, a host of thorny legal issues have emerged that will have to be addressed as the nation continues to prepare for possible bioterrorist attacks.

LEGAL AND REGULATORY ISSUES

In his recent article, "The Malevolent Use of Microbes and the Rule of Law: Legal Challenges Presented by Bioterrorism," published in the September 1, 2001, issue of *Clinical Infectious Diseases*, David P. Fidler, professor of law, Indiana University School of Law, points out that "What is often neglected in thinking about the threats bioweapons pose to public health is the foundation that law provides for effective public health activities." Among the host of legal concerns that could be triggered by a bioweapons event, according to Fidler, are "the liability of overrun hospitals and health care professionals operating in an emergency environment, the liability of drug and vaccine manufacturers, and the inevitability of lawsuits after the crisis" in addition to the concern that "an epidemic may require violation of individual rights through such acts as forced quarantine or isolation, compulsory treatment or vaccination, and seizure and destruction of property."

Two additional legal questions have been raised. The first concerns the question of who would be in charge during a bioterror attack. This has, during simulations and planning exercises, resulted in much confusion among experts. The second issue raised by preparedness officials involves the recently legislated Health Insurance Portability and Accountability Act (HIPAA) regulations governing the confidentiality of patient information. Experts are concerned that, should an attack occur and an epidemic ensue, HIPAA regulations could complicate the vital need to share private health information quickly and broadly.

Vaccines and Medicines

Vaccine development and use in bioterror-related events have called into question several legal and regulatory issues and will continue to do so. Because vaccines are difficult to develop, are a challenge to manufacture, have traditionally low profit margins, and have been the subject of a number of liability suits,

most drug makers have not heavily invested research and development dollars in them. Carl Feldman, president of the Biotech Industry Organization, was quoted in a recent *USA Today* article by Julie Appleby as saying that "The simple, sad fact is that vaccine development hasn't been a national or medical priority." In light of the tremendous pressure to be prepared, pharmaceutical and biotech companies are reassessing their product portfolios.

This renewed interest in vaccines, as well as drug and biotech products that could be used to treat bioterror-related diseases, have brought the issues of fast track approval into sharper focus. The FDA's antibioterrorism priorities now include making final the 1999 proposed rule entitled "Evidence Needed to Demonstrate Efficacy of New Drugs for Use against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted," assisting CDC in storing and tracking the antibioterrorism pharmaceutical stockpile, and running an animal model working group to test potential antibioterrorism agents in animals.

Calling into question the ability of the private sector to mass-produce vaccines that could be used against biological agents, some members of Congress, such as Rep. Richard Burr (R-N.C.), are considering the establishment of a federal program for vaccine manufacturing. Other options for improving the rapid availability of vaccines and medicines include public-private partnerships, partnerships with other countries (such as the one the United States now has with the United Kingdom), and partnerships with Defense Department research facilities.

It is clear that further legal analyses of all these complex issues are not only warranted but also a necessary component of preparedness.

APPENDIX I

Centers for Disease Control and Prevention Factsheets on Anthrax, Botulism, Pneumonic Plague, and Smallpox

Facts about Anthrax

Anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. Anthrax most commonly occurs in hoofed mammals and can also infect humans.

Symptoms of disease vary depending on how the disease was contracted, but usually occur within 7 days after exposure. The serious forms of human anthrax are inhalation anthrax, cutaneous anthrax, and intestinal anthrax.

Initial symptoms of inhalation anthrax infection may resemble a common cold. After several days, the symptoms may progress to severe breathing problems and shock. Inhalation anthrax is often fatal.

The intestinal disease form of anthrax may follow the consumption of contaminated food and is characterized by an acute inflammation of the intestinal tract. Initial signs of nausea, loss of appetite, vomiting, and fever are followed by abdominal pain, vomiting of blood, and severe diarrhea.

Direct person-to-person spread of anthrax is extremely unlikely, if it occurs at all. Therefore, there is no need to immunize or treat contacts of persons ill with anthrax, such as household contacts, friends, or coworkers, unless they also were also exposed to the same source of infection.

In persons exposed to anthrax, infection can be prevented with antibiotic treatment.

Early antibiotic treatment of anthrax is essential–delay lessens chances for survival. Anthrax usually is susceptible to penicillin, doxycycline, and fluoroquinolones.

An anthrax vaccine also can prevent infection. Vaccination against anthrax is not recommended for the general public to prevent disease and is not available.

Facts about Botulism

Botulism is a muscle-paralyzing disease caused by a toxin made by a bacterium called *Clostridium botulinum*.

There are three main kinds of botulism:

- Foodborne botulism occurs when a person ingests pre-formed toxin that leads to illness within a few hours to days. Foodborne botulism is a public health emergency because the contaminated food may still be available to other persons besides the patient.

- Infant botulism occurs in a small number of susceptible infants each year who harbor *C. botulinum* in their intestinal tract.

- Wound botulism occurs when wounds are infected with *C. botulinum* that secretes the toxin.

With foodborne botulism, symptoms begin within 6 hours to 2 weeks (most commonly between 12 and 36 hours) after eating toxin-containing food. Symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, muscle weakness that always descends through the body: first shoulders are affected, then upper arms, lower arms, thighs, calves, etc. Paralysis of breathing muscles can cause a person to stop breathing and die, unless assistance with breathing (mechanical ventilation) is provided.

Botulism is not spread from one person to another. Foodborne botulism can occur in all age groups.

A supply of antitoxin against botulism is maintained by CDC. The antitoxin is effective in reducing the severity of symptoms if administered early in the course of the disease. Most patients eventually recover after weeks to months of supportive care.

Facts about Pneumonic Plague

Plague is an infectious disease of animals and humans caused by the bacterium Y*ersinia pestis.* *Y. pestis*, is found in rodents and their fleas in many areas around the world.

Pneumonic plague occurs when *Y. pestis* infects the lungs. The first signs of illness in pneumonic plague are fever, headache, weakness, and cough productive of bloody or watery sputum. The pneumonia progresses over 2 to 4 days and may cause septic shock and, without early treatment, death.

Person-to-person transmission of pneumonic plague occurs through respiratory droplets, which can only infect those who have face-to-face contact with the ill patient.

Early treatment of pneumonic plague is essential. Several antibiotics are effective, including streptomycin, tetracycline, and chloramphenicol.

There is no vaccine against plague.

Prophylactic antibiotic treatment for 7 days will protect persons who have had face-to-face contact with infected patients.

Facts about Smallpox

Smallpox infection was eliminated from the world in 1977.

Smallpox is caused by variola virus. The incubation period is about 12 days (range: 7 to 17 days) following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2-3 days. The rash starts with flat red lesions that evolve at the same rate. Lesions become pus-filled and begin to crust early in the second week. Scabs develop and then separate and fall off after about 3-4 weeks. The majority of patients with smallpox recover, but death occurs in up to 30% of cases.

Smallpox is spread from one person to another by infected saliva droplets that expose a susceptible person having face-to-face contact with the ill person. Persons with smallpox are most infectious during the first week of illness, because that is when the largest amount of virus is present in saliva. However, some risk of transmission lasts until all scabs have fallen off.

Routine vaccination against smallpox ended in 1972. The level of immunity, if any, among persons who were vaccinated before 1972 is uncertain; therefore, these persons are assumed to be susceptible.

Vaccination against smallpox is not recommended to prevent the disease in the general public and therefore is not available.

In people exposed to smallpox, the vaccine can lessen the severity of or even prevent illness if given within 4 days after exposure. Vaccine against smallpox contains another live virus called vaccinia. The vaccine does not contain smallpox virus.

The United States currently has an emergency supply of smallpox vaccine.

There is no proven treatment for smallpox but research to evaluate new antiviral agents is ongoing. Patients with smallpox can benefit from supportive therapy (intravenous fluids, medicine to control fever or pain, etc.) and antibiotics for any secondary bacterial infections that occur.

APPENDIX II

Department of Health and Human Services
Bioterrorism Preparedness Activities

Excerpted from

U.S. General Accounting Office, "Department of Health and Human Services," Appendix VIII, in *Bioterrorism: Federal Research and Preparedness Activities,* GAO Report (GAO-01-915), September 2001, 48-66.

Department of Health and Human Services

Within HHS, five agencies or offices work on bioterrorism issues. The Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), and NIH are primarily involved in research activities, and CDC and OEP are primarily concerned with preparedness activities. HHS is the primary federal agency for the medical and public health response to emergencies, including major disasters and terrorist events, under the Federal Response Plan. In addition, the Secretary of HHS has recently appointed a Special Assistant for Bioterrorism to coordinate antibioterrorism efforts across the department.

The Secretary of HHS was authorized $221 million in fiscal year 2001 through the Public Health Improvement Act of 2000 for the medical and public health consequences of a bioterrorist attack. However, despite this authorization, there were no specific appropriations for such activities.

Agency for Healthcare Research and Quality

AHRQ's mission is to support research designed to improve the outcomes and quality of health care, reduce its costs, address safety and medical errors, and broaden access to effective services. Working through an informal interagency workgroup, AHRQ included officials across HHS (such as those in CDC, OEP, and the Office of the Assistant Secretary for Planning and Evaluation) in its anti-bioterrorism research planning efforts.

Research Activities

AHRQ received $5 million in fiscal year 2000 to develop research initiatives to identify effective and specific strategies for improving the clinical preparedness of health care providers and health care systems for a bioterrorist attack. For example, the agency funded research on the use of information systems and decision support systems to enhance preparedness for the delivery of medical care in the event of such an attack. AHRQ, along with other HHS agency partners, also provided funding to support a bioterrorism symposium sponsored by the Center for Civilian Biodefense Studies at Johns Hopkins University.

Centers for Disease Control and Prevention

HHS was designated to lead an effort to work with governmental and nongovernmental partners to upgrade the nation's capacity to respond to bioterrorism. Several centers, institutes, and offices within CDC work together on bioterrorism preparedness and response efforts. The principal priority of the Bioterrorism Preparedness and Response Program is to upgrade infrastructure and capacity to respond to a large-scale epidemic,

regardless of whether it is the result of a bioterrorist attack or a naturally occurring infectious disease outbreak. The program was started in fiscal year 1999 and was tasked with building and enhancing national, state, and local capacity; developing a national pharmaceutical stockpile; and conducting several independent studies on bioterrorism. It has focused on helping states with planning for a bioterrorist event; enhancing surveillance and laboratory capacity at the national, state, and local levels; and improving communications and training for bioterrorism preparedness. Examples of CDC's internal research activities include work on anthrax and smallpox. The agency also oversees a number of studies being conducted by universities and hospitals. Table 7 lists CDC's reported bioterrorism funding for fiscal years 1998 through 2001.

Table 7: Reported Funding for Activities on Bioterrorism at CDC (Dollars in millions)

Program/initiative[a]	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
Research activities				
Research and development	0	0	$40.5	$42.9
Independent studies[b]	0	$1.8	$7.7	$2.6
Worker safety	0	0	0	$1.1
Preparedness activities				
Upgrading state and local capacity	**0**	**$55.0**	**$56.9**	**$66.7**
Preparedness planning	0	$2.0	$1.9	$5.8
Surveillance and epidemiology	0	$12.0	$15.8	$16.1
Laboratory capacity	0	$13.0	$9.5	$12.8
Communications	0	$28.0	$29.7	$32.0
Upgrading CDC capacity	**0**	**$12.0**	**$13.9**	**$20.4**
Epidemiologic capacity	0	$2.0	$1.8	$4.0
Laboratory capacity	0	$5.0	$7.6	$11.4
Rapid toxic screen	0	$5.0	$4.5	$5.0
Preparedness and response planning	**0**	**$1.0**	**$2.3**	**$9.2**
Building the National Pharmaceutical Stockpile	**0**	**$51.0**	**$51.8**	**$51.0**
Total	**0**	**$120.8**	**$173.1**	**$193.9**

Note: We have not audited or otherwise verified the information provided.

[a]CDC received funding in fiscal year 1999, fiscal year 2000, and fiscal year 2001 for bioterrorism deterrence activities, such as implementing regulations restricting the importation of certain biological agents. However, since deterrence is outside the scope of our study, that funding is not included here.

[b]For instance, $1 million was specified in the fiscal year 2000 appropriations conference report for the Carnegie Mellon Research Institute to study health and bioterrorism threats.

Source: CDC.

The Bioterrorism Preparedness and Response Program was placed within the National Center for Infectious Diseases because of the likely similarity between a bioterrorist attack and a naturally occurring infectious disease outbreak. The National Center for Infectious Diseases oversees research, surveillance, laboratory, and epidemiological response efforts. The National Center for Environmental Health manages the National Pharmaceutical Stockpile Program and associated emergency preparedness and planning activities. Several other offices and institutes also contribute to the Bioterrorism Preparedness and Response Program, including the Epidemiology Program Office; the Public Health Practice Program Office, which focuses on communications and training; and the National Institute of Occupational Safety and Health. Program staff are

responsible for coordination within CDC and with other federal agencies and for policy development.

Research Activities

In fiscal year 2001, CDC was allocated $18 million to continue research on an anthrax vaccine and associated issues, such as scheduling and dosage. The agency also received $22.4 million in fiscal year 2001 to conduct smallpox research. In addition, CDC oversees a number of independent studies, which are specific lines in the budget that fund specific universities and hospitals to do research and other work on bioterrorism. For example, the Carnegie Mellon Research Institute received $1 million in fiscal year 2000 to study health and bioterrorism threats. Finally, CDC's National Institute for Occupational Safety and Health is developing standards for respiratory protection equipment used against biological agents by firefighters, laboratory technicians, and other potentially affected workers.

Preparedness Activities

Most of CDC's activities to counter bioterrorism are focused on building and expanding multipurpose public health infrastructure at the national, state, and local levels. For example, CDC reported receiving funding of $66.7 million in fiscal year 2001 to upgrade state and local capacity to detect and respond to a bioterrorist attack. CDC received an additional $20.4 million to upgrade its own capacity in these areas, $9.2 million for planning and response, and another $51 million for developing the National Pharmaceutical Stockpile. These activities may have a dual use, such as identifying and containing a naturally occurring emerging infectious disease in addition to responding to a bioterrorism attack.

Upgrading State and Local Capacity

In fiscal year 2000, CDC received $56.9 million to award to 50 states and 4 major metropolitan health departments for preparedness and response activities. CDC also provides technical assistance to these agencies to assist preparedness efforts. CDC is developing planning guidance for state public health officials to upgrade state and local public health departments' preparedness and response capabilities. In addition, CDC has worked with DOJ to complete a public health assessment tool, which is being used to determine the ability of state and local public health agencies to respond to biological and chemical agents, as well as other public health emergencies.

States have received funding from CDC to increase staff, provide better access to data sources, enhance capacity to detect the release of a biological agent or an emerging infectious disease, and improve

communications infrastructure. In fiscal year 1999, for example, a total of $7.8 million was awarded to 41 state and local health agencies to improve the state and local public health agencies' ability to link different sources of data, such as sales of certain pharmaceuticals, which could be helpful in detecting a covert bioterrorist event.

Rapid identification and confirmatory diagnosis of biological agents are critical to ensuring that prevention and treatment measures can be implemented quickly. CDC was allocated $13 million in fiscal year 1999 to enhance state and local laboratory capacity. CDC has established a Laboratory Response Network that maintains state-of-the-art capabilities for biological agent identification and characterization. CDC has provided technical assistance and training in identification techniques to state and local public health laboratories. In addition, five state health departments received awards totaling $3 million in fiscal year 2000 to enhance chemical laboratory capabilities. These funds were used to purchase equipment and provide training.

CDC is working with state and local health agencies to build a modern electronic infrastructure for public health communications that will improve the collection and transmission of information related to a bioterrorism incident as well as other events. For example, $21 million was awarded to states in fiscal year 1999 to begin implementation of the Health Alert Network, which will support the exchange of key information over the Internet and provide a foundation for distance training that could potentially reach a large segment of the public health community.

Upgrading CDC Capacity

CDC is upgrading its own epidemiologic and disease surveillance capacity. It has deployed, and is continuing to develop, a surveillance system to increase surveillance and epidemiological capacities before, during, and after special events (such as the 1999 World Trade Organization meeting in Seattle, Washington). The agency is also increasing its veterinary surveillance. In addition, CDC monitors unusual clusters of illnesses, such as influenza in June. While these clusters may not be a cause for concern, they can indicate a potential problem.

CDC has strengthened its own laboratory capacity. For example, it is developing and validating diagnostic tests as well as creating agent-specific protocols. In collaboration with the Association of Public Health Laboratories and DOD, CDC has operationalized a secure Internet-based network that allows state, local, and other public health laboratories access to guidelines for analyzing biological agents. The site also allows

authenticated users to order critical reagents needed in performing laboratory analysis of samples.

The agency has also operationalized a Rapid Response and Advance Technology Laboratory, which screens samples for the presence of suspicious biological agents and evaluates new technology and protocols for the detection of biological agents. These technology assessments and protocols, as well as reagents and reference samples, are being shared with state and local public health laboratories.

Preparedness and Response Planning

In fiscal year 1999, at the start of CDC's bioterrorism program, the agency received funding to develop an overall preparedness plan. CDC received $2.3 million in fiscal year 2000 for preparedness and response training and $9.2 million in fiscal year 2001. Among the activities to be undertaken is the initial implementation of a national bioterrorism response training plan. This plan will focus on preparing CDC officials to respond to bioterrorism and will include the development of exercises to assess progress in achieving bioterrorism preparedness at the federal, state, and local levels. The agency will also develop a crisis communications/media response curriculum for bioterrorism as well as core capabilities guidelines to assist states and localities in their efforts to build comprehensive anti-bioterrorism programs.

CDC has developed a bioterrorism Web site. This site provides emergency contact information for possible bioterrorism events, a list of critical agents, summaries of state and local bioterrorism projects, general information about CDC's bioterrorism initiative, and links to documents on bioterrorism preparedness and response.

Building the National Pharmaceutical Stockpile Program

The National Pharmaceutical Stockpile Program maintains a repository of life-saving pharmaceuticals, antidotes, and medical supplies, known as 12-Hour Push Packages, that can be delivered to the site of a biological (or other) attack within 12 hours of deployment for the treatment of civilians. These Push Packages are prepackaged and contain products that could be used in a variety of scenarios.[1] Additional antibiotics, antidotes, other drugs, medical equipment, and supplies known as Vendor Managed Inventory, can be delivered within 24 to 36 hours after the appropriate

[1]The first emergency use of the National Pharmaceutical Stockpile occurred on September 11, 2001. In response to the terrorist attack on the World Trade Center, CDC released one of the eight Push Packages.

vendors are notified. The Vendor Managed Inventory can be tailored to an individual incident (that is, only products needed for a particular incident would be sent). The program received $51.0 million in fiscal year 1999, $51.8 million in fiscal year 2000, and $51.0 million in fiscal year 2001. CDC and OEP have encouraged state and local representatives to consider stockpile assets in their emergency planning for a biological attack and have trained representatives from state and local authorities in using the stockpile. The program also provides technical advisers in response to an event to ensure the appropriate and timely transfer of stockpile contents to authorized state representatives.[2]

Food and Drug Administration

FDA's responsibilities and activities on bioterrorism are spread throughout the agency. These activities include safeguarding the food supply, ensuring that new vaccines and drugs are safe and effective, and conducting research for diagnostic tools and treatment of disease outbreaks.

Under the Health and Medical Services Annex of the Federal Response Plan, FDA is the lead HHS agency for ensuring the safety of regulated foods, drugs, medical devices, and biological products. In an emergency, FDA would arrange for the seizure, removal, and/or destruction of any contaminated and unsafe products. FDA is revising its Emergency Operations Response Plan to include bioterrorism preparedness and response elements.

Congress has earmarked $5 million for FDA for activities on bioterrorism in fiscal year 2001. These funds were for FDA to continue previously initiated work on bioterrorism that had been supported by departmental and general purpose funds. HHS has allocated other funds to FDA's activities on bioterrorism. For example, the Center for Biologics Evaluation and Research received $7.5 million in fiscal year 2000 from departmental funds specifically for vaccine projects (see table 8).

[2]For more information on the National Pharmaceutical Stockpile Program, see *Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement* (GAO-01-463, Mar. 30, 2001).

Table 8: Reported Funding for Activities on Bioterrorism at FDA (Dollars in millions)

Program/initiative	Fiscal year 1998[a]	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
Center for Biologics Evaluation and Research				
Research activities				
Premarket evaluation of vaccines, develop vaccines	[a]	$1.2	$7.5	$7.0
Center for Devices and Radiological Health				
Research activities				
Develop data requirements for approving devices intended to detect exposure to or infection with biological agents	[a]	$0.1	$0.8	$0.9
Center for Drug Evaluation and Research				
Research activities				
Determine procedures for allowing use of not-yet-approved drugs, specify data needed for approval and labeling, gather and supply information	[a]	$0.2	$0.4	$0.7
Center for Food Safety and Applied Nutrition				
Preparedness activities				
Monitor food supply, communicate with state and local officials	[a]	0	0	$0.3
Center for Veterinary Medicine				
Preparedness activities				
Communicate with state officials, held meeting on bioterrorism risk	[a]	$0.1	$0.1	$0.3
National Center for Toxicological Research				
Research activities				
Define biological mechanisms of action underlying toxicity of products, identify indications of toxicity associated with biological agents	[a]	$0.2	$0.1	$0.5
Preparedness activities				
Participate in training meetings	[a]	[b]	[b]	[b]
Office of Regulatory Affairs				
Preparedness activities				
Communicate with other agencies and the public, conduct investigations	[c]	[c]	[c]	$1.5
Total[d]	**[a]**	**$1.9**	**$9.0**	**$11.2**

Note: We have not audited or otherwise verified the information provided.

[a]Agency officials told us that in fiscal year 1998 funds were expended on bioterrorism-related activities, but they did not report these levels to us.

[b]We were unable to allocate funding within this program for research and preparedness based on the information provided by FDA. Instead, we list all the funding under research because the preponderance of activities within that program are best categorized there.

[c]FDA reported that activities on bioterrorism were conducted by the Office of Regulatory Affairs, but it did not specify how much was spent on them.

[d]Individual entries may not sum to totals because of rounding.

Source: FDA.

Center for Biologics Evaluation and Research

The mission of the Center for Biologics Evaluation and Research is to ensure the safety, efficacy, potency, and purity of biological and related products, including vaccines, that could be used in case of a bioterrorist attack.

Research Activities

Among its responsibilities, the Center for Biologics Evaluation and Research regulates the development and licensure of new vaccines for anthrax, smallpox, and the associated vaccinia immune globulin used to treat serious vaccinia infections or other adverse events caused by the smallpox vaccine. In addition to premarketing evaluation, vaccine products require review of lot release data, inspection of manufacturing facilities, assessment of product availability, and surveillance and compliance activities. The center works closely with other government agencies such as CDC and DOD to assist in ensuring that sufficient quantities of medical products are available for military and civilian use during a bioterrorism attack, and that the use is controlled under an acceptable clinical protocol when the biological product is not licensed by FDA or is being used "off label."[3] It also coordinates with industry and government agencies to prepare surveillance methods for adverse event monitoring associated with the use of biological products in a bioterrorism attack. The center engages in vaccine research activities related to the regulation of the development of vaccines for plague, tularemia, and encephalitis-causing viruses.[4] (See app. I for a discussion of specific biological agents mentioned in this report.)

Since high-risk bioterrorism pathogens either do not exist naturally or do not cause significant disease in large populations, the traditional human testing and ultimate approval of products for mitigating a disease in humans caused by a bioterrorist pathogen is neither ethical nor feasible. The center is working with CDC, NIH, and DOD, as well as academia and

[3]"Off label" refers to the treatment of conditions other than those listed on FDA's approved drug label.

[4]Encephalitis is inflammation of the brain.

industry to develop regulations that will define the type of nonhuman research data required to demonstrate the potential efficacy of new products on humans affected by biological WMDs.

Officials have noted that while there is a clear need to develop vaccines for biological agents, there are limited commercial interests or market incentives for addressing the problem. Consequently, it falls upon the federal government to develop such vaccines. The Center for Biologics Evaluation and Research has research projects under way dealing with vaccines for anthrax, plague, and smallpox.

Center for Devices and Radiological Health

The mission of the Center for Devices and Radiological Health is to ensure the safety and effectiveness of medical devices, including those that could be used in the event of a bioterrorist attack.

Research Activities

The center provided comments on a research protocol to evaluate a device intended to identify anthrax in human specimens. It has also conducted an advisory panel meeting to discuss data requirements for approval of devices intended to detect exposure to or infection with biological agents. In addition, the center is working with CDC on a process that would allow the use of investigational diagnostic devices in the event of a bioterrorist attack.

Center for Drug Evaluation and Research

The Center for Drug Evaluation and Research helps ensure the availability of safe and effective human drugs. The center reviews research to take appropriate action on the marketing of drugs, including those that would be used in the event of a bioterrorist attack.

Research Activities

The center is working with CDC on a process that would satisfy the requirements for allowing the use of investigational drugs (not approved by FDA) in the event of a bioterrorist attack. Testing drugs that might be used in case of a bioterrorist attack is difficult because the diseases caused by the biological agents rarely occur naturally and it would be unethical to infect healthy volunteers with the disease when there is no known cure. The center is working with other government agencies and the manufacturers of these drugs to determine what studies are needed to generate sufficient safety and efficacy data to permit labeling of these drugs. For products that might still be in the investigational stage, but potentially the only therapies available for a specific disease caused by a

bioterrorist event, the center is working with CDC to determine additional methods of data collection and analysis to evaluate the products' safety and efficacy if it were necessary for them to be used.

Although some drugs that would be used in the case of a bioterrorist attack have been approved to treat diseases caused by a biological agent, use of a number of these drugs would be "off-label." The center is determining what data are needed to enable approval of a label indicating that a drug would treat a disease that might be caused by a bioterrorist attack. It has a program in this area, but there has been limited funding for these activities. The center has worked to facilitate the labeling of ciproflaxacin for the treatment of inhalational anthrax and is now working to assess what is needed in the way of studies to produce sufficient data for labeling gentamicin to treat pneumonic plague. It is also determining what types of nonclinical (nonhuman) data are acceptable for product marketing approval if traditional clinical studies are not feasible or ethical.

At the request of the National Security Council, the center has compiled a list of and information on drugs that might be effective in case of a bioterrorist attack. The information includes manufacturers, inventories, lead time for producing the drugs, and bulk suppliers. Center officials noted that they do not regularly collect this information. It is also working with CDC to implement a shelf-life extension program for the maintenance of stockpiled supplies.

Center for Food Safety and Applied Nutrition

The Center for Food Safety and Applied Nutrition is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and appropriately labeled. The center has been involved in preparing for a bioterrorist attack on the food supply.

Preparedness Activities

The Center for Food Safety and Applied Nutrition has undertaken activities regarding contaminated food that are important for bioterrorism response readiness. For example, the agency has developed a procedures manual for dealing with foodborne attacks. The center works with other federal and state agencies to monitor the safety of the U.S. food supply. The agency has been involved in the development and support of two surveillance systems for identifying and characterizing contaminated food, FoodNet and PulseNet. FoodNet is a collaborative project of FDA, CDC, USDA, and nine state health departments. It is an effort to capture a more accurate and complete picture of trends in the occurrence of foodborne illness and

provides information about the number of persons who were diagnosed with specific infections that are likely to be foodborne. PulseNet is a collaborative project of FDA, CDC, USDA, and state health department food safety laboratories to facilitate subtyping bacterial foodborne pathogens for epidemiological purposes.

The center (along with the Office of Regulatory Affairs) is leading an effort to improve coordination and communication among federal, state, and local public health and food regulatory officials. The efforts are targeted at outbreaks of illness caused by foodborne pathogens and are meant to contribute to more effective implementation of existing food safety programs.

Center for Veterinary Medicine

The Center for Veterinary Medicine regulates the manufacture and distribution of food additives and drugs that will be given to animals. These include animals from which human foods are derived as well as food additives and drugs for pet (or companion) animals. Since animals raised for food are a potential target for a bioterrorist attack, the center has initiated activities to increase its preparedness.

Preparedness Activities

The Center for Veterinary Medicine has established and maintains lines of communication with state regulatory officials and personnel in state veterinary diagnostic laboratories. The center co-sponsored a meeting to review the risks to U.S. and world food and agriculture from plant and animal disease and bioterrorism.

National Center for Toxicological Research

The National Center for Toxicological Research conducts scientific research that supports and anticipates FDA's current and future regulatory needs. This involves fundamental and applied research on biological mechanisms of action underlying the toxicity of products regulated by FDA.

Research Activities

The National Center for Toxicological Research has examined proteins in food to determine the existence of bacteria. It has also worked on approaches to identify indications of toxicity associated with biological agents.

Preparedness Activities

In the event of an attack, the center has the ability to respond with animal studies and microbiological surveillance to identify the agent.

Representatives from the National Center for Toxicological Research participate in meetings with FEMA and Arkansas public health officials to plan training activities for responding to bioterrorism threats.

Office of Regulatory Affairs

Among its responsibilities, the Office of Regulatory Affairs responds to emergencies involving products regulated by FDA. If a bioterrorist event were to take place, the office would be involved in the investigation.

Preparedness Activities

FDA would be involved in the management of a response to any attack that targets a FDA-regulated product. The Office of Regulatory Affairs' Office of Criminal Investigations would conduct the criminal investigation and serve as the liaison to the FBI and other law enforcement agencies.

The Office of Regulatory Affairs maintains a 24-hour emergency hotline, in part for receiving information about a bioterrorist attack. It has also established a notification system with the FBI for bioterrorist events.

National Institutes of Health

NIH conducts medical research in its own laboratories and supports the research of nonfederal scientists in universities, medical schools, hospitals, and research institutions throughout the United States and abroad. NIH is composed of 27 separate institutes and centers. One of these is the National Institute of Allergy and Infectious Diseases (NIAID), which has a program to support research related to organisms likely to be used as biological weapons. This program includes research devoted to the development of (1) rapid, accurate diagnostics, (2) effective therapy for those infected, and (3) vaccines for those at risk of exposure.

All of NIH's research on bioterrorism has been funded out of general appropriations. Table 9 gives the amounts of reported funding for NIH's activities on bioterrorism for fiscal year 1998 through fiscal year 2001.

Table 9: Reported Funding for Activities on Bioterrorism at NIH (Dollars in millions)

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001 (estimate)
Research activities				
Diagnostics	$0.3	$1.3	$0.9	$1.1
Vaccines	$3.0	$6.6	$6.8	$7.0
Antibiotics/antivirals	$0.4	$3.3	$5.6	$6.1
Basic research (genomics and pathogenesis)	$13.2	$21.4	$29.7	$35.4
Total[a]	**$17.0**	**$32.6**	**$43.0**	**$49.7**

Note: We have not audited or otherwise verified the information provided.

[a]Individual entries may not sum to totals because of rounding.

Source: NIH.

Research Activities

The initial focus of NIAID's research efforts on bioterrorism was on smallpox and anthrax. The agency collaboratively funded (along with DOD, DOE, and CDC) activities on smallpox, including research to develop and test antiviral drugs against smallpox viruses, extend the usefulness of the currently available, older vaccine, and to develop a vaccine that can be used in all segments of the civilian population (for instance, pregnant women and the immune-suppressed). For anthrax, NIAID has formed the Working Group on Anthrax Vaccines to develop and test a new vaccine that could be used to replace the currently licensed vaccine.

In addition to these ongoing activities, NIAID provided support to sequence the genomes of all bacterial pathogens considered by CDC to have the potential to be used as bioterrorism agents. The results of such research, along with other information, are expected to facilitate pursuit of a variety of critical goals, including the development of rapid diagnostic methods, antimicrobial therapies, and new vaccines for the most likely bioterrorist agents.

NIAID also conducts and sponsors research in the areas of diagnostics, therapeutics, and vaccines, as well as basic research on the origination and development of diseases from biological agents. In diagnostics research, the development of detection systems for smallpox antigens has been emphasized. Therapeutics research has covered a number of areas including the development of a replacement therapy for treating the serious complications that would result from immunizing the civilian population

against smallpox. NIAID continues to work on vaccines for smallpox and anthrax to prevent illness resulting from a terrorist attack. The agency has collaborated with the U.S. Army Medical Research Institute of Infectious Diseases on the development of a new anthrax vaccine to protect the American public. NIAID is also conducting basic research in a number of areas, including the genetic basis for the virulence of potential bioterrorist agents.

Office of Emergency Preparedness

OEP coordinates the medical and public health response to emergencies, including all kinds of terrorist attacks and natural disasters. OEP has taken an "all-hazards" approach to emergency preparedness and response because it is involved in the health response to many different types of situations, including bioterrorism. See table 10 for OEP's reported funding for activities on terrorism.

Table 10: Reported Funding for Activities on Terrorism at OEP (Dollars in millions)

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
Research activities				
Infrastructure—research and development	$0.1	$0.1	0	0
Smallpox study	$0.1	0	0	0
Special activities	0	0	0	$4.6
Preparedness activities				
Combating terrorism	**$0.3**	**$19.0**	**$20.0**	**$27.2**
National Medical Response Teams	0	$1.5	$1.5	$1.5
U.S. Public Health Service Noble Training Center	0	$3.0	$1.0	$2.9
VA WMD training	0	0	0	$0.8
Pharmaceutical Cache	0	0	$1.0	$1.2
Metropolitan Medical Response System	0	$14.5	$16.5	$17.4
Special events	0	0	0	$2.0
Surveillance and laboratory support	$0.3[a]	0	0	0
Special activities	0	0	0	$1.4

(Continued From Previous Page)

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
Infrastructure	**$9.7**	**$12.6**	**$15.3**	**$18.9**
Office/regions	$5.0	$7.5	$8.8	$12.3
Planning and evaluation	$1.2	$1.0	$1.0	$1.0
Training and exercises	0	$0.8	$2.5	$2.5
Disaster Medical Assistance Team development	$2.5	$2.5	$2.5	$2.6
Communications	$1.0	$0.8	$0.5	$0.5
Total[b]	**$10.2**	**$31.7**	**$35.3**	**$50.7**

Note: We have not audited or otherwise verified the information provided.

[a]This money was transferred to CDC, FDA, and HHS' Agency for Toxic Substances and Disease Registry. This funding stopped once these agencies began receiving bioterrorism funding.

[b]Individual entries may not sum to totals because of rounding.

Source: OEP.

Research Activities

OEP has participated in research and evaluation activities. It has worked with the Institute of Medicine to develop an assessment methodology and performance measures for the Metropolitan Medical Response System. OEP also oversees $4.6 million in fiscal year 2001 for research special activities, which are earmarks in the budget for specific universities, hospitals, or response systems to conduct studies (see table 10).

Preparedness Activities

HHS coordinates many of its medical response activities with other agencies through the National Disaster Medical System. OEP leads this system, a partnership among HHS, DOD, VA, FEMA, state and local governments, and the private sector, which is intended to ensure that resources are available to provide medical services following a disaster that overwhelms the local health care resources. The overall purpose of the system is to establish a single, integrated national medical response capability to (1) assist state and local authorities in dealing with the medical and health effects of major peacetime disasters and (2) provide support to the military and VA medical systems in caring for casualties evacuated to the United States from overseas armed conflicts. About 2,000 civilian hospitals have pledged resources that could be marshaled in any domestic emergency under the system.

In addition to providing additional capacity in the event of an emergency, the National Disaster Medical System also has response teams that can

provide support at the site of a disaster. Disaster Medical Assistance Teams can deploy to disaster sites with sufficient supplies and equipment to sustain themselves for 72 hours while providing medical care at a fixed or temporary site.[5] In mass casualty events, the teams would perform triage, provide medical care, and prepare patients for evacuation. In other types of situations, the teams may also provide primary health care and/or serve to augment overloaded local health care staffs.

There are also specialized Disaster Medical Assistance Teams. Some of the specialized teams deal with specific medical conditions, such as burns or mental health. Disaster Mortuary Operational Response Teams provide mortuary services and victim identification. There are four National Medical Response Teams located around the country that are specially equipped and trained to provide medical care for victims of WMDs. Three of these are deployable anywhere in the country, and all four teams have a stockpile of pharmaceuticals and medical supplies to treat up to 5,000 people. However, these stockpiles are primarily for treating victims of a chemical weapon.

OEP received $2 million in fiscal year 2001 that was transferred to VA to provide funding for VA to manage caches of pharmaceuticals for the National Medical Response Teams and for training of National Disaster Medical System hospitals in response to WMD events. OEP also received approximately $2.9 million in fiscal year 2001 to provide management staff and operating funds for the U.S. Public Health Service Noble Training Center in Alabama. This center is developing curricula and providing training activities for physicians, nurses, and emergency medical technicians. This facility will primarily provide training in response to a chemical incident, but will also have some bioterrorism response duties.

The office received $2.6 million in fiscal year 2001 for Disaster Medical Assistance Team development, which funds training programs for the teams and other specialty teams (see table 10 for detailed budget information). OEP received an additional $1.5 million to expand the National Medical Response Teams, primarily by providing additional team members and purchasing equipment. Some funding from both of these

[5]Disaster Medical Assistance Teams were dispatched to the New York City and Washington, D.C., areas on September 11, 2001. The initial units included more than 300 medical and mortuary personnel.

sources was also used to provide management and oversight of the annual National Disaster Medical System conference.

OEP was allocated received $2.5 million in fiscal year 2001 to provide additional training and exercise activities for Disaster Medical Assistance Teams and local responders to ensure that teams are operational in a field setting, and that the community and response teams can work together to achieve an integrated approach to medical care during a terrorist event. These funds also provide for coordinated training and exercises with other departments, such as DOD and DOE, during response to special events.

The office also deploys teams from the National Disaster Medical System to high-security events, such as visits by heads of state. In fiscal year 2001, OEP received $2 million to support the costs of deploying teams to a number of special events, including $1 million for the Olympic games and $1 million for other special events, such as the presidential inauguration.

OEP's Metropolitan Medical Response System emphasizes enhancement of local planning and response capability, tailored to each jurisdiction, to care for victims of a terrorist incident involving WMDs. The program includes a focus on response to bioterrorism, including disease surveillance, mass casualty care, and mass fatality management. OEP, under the Metropolitan Medical Response System, has entered into contracts with 97 local areas to develop and coordinate local medical response capabilities. This program works at the local level because of the rapid response time that would be required to manage the consequences of a terrorist attack. OEP received approximately $17 million in fiscal year 2001 to expand the program to 25 additional communities and continue development in 25 existing areas begun in fiscal year 2000. In addition, 47 of the areas received additional funding to plan for an appropriate health system response to a bioterrorist attack. Planning and evaluation funds were used, in part, to provide oversight and technical assistance for response system activities. In fiscal year 2001, OEP is overseeing $1.4 million that was earmarked in the budget for the Charlotte, North Carolina, Metropolitan Medical Response System. The funds will be used to coordinate and enhance preparedness of community health care facilities, for provider training, and to integrate the public health system into a mass casualty response system.

OEP received approximately $12 million in fiscal year 2001 for general emergency preparedness infrastructure development and maintenance. This includes headquarters and regional staff salaries, rent, and other

operating costs. It also received $500,000 to maintain and enhance systems to communicate during disasters and special events.

APPENDIX III

Suggested Reading List

(This list is not intended to be comprehensive.)

Five articles from the *Journal of the American Medical Association,* available for viewing free of charge at http://www.ama-assn.org/ama/pub/category/6232.html.

Thomas V. Inglesby et al., "Anthrax as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* 281, no. 18 (May 12, 1999): 1735-45.

Donald A. Henderson et al., "Smallpox as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* 281, no. 22 (June 9, 1999): 2127-37.

Thomas V. Inglesby et al., "Plague as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* 283, no. 17 (May 3, 2001): 2281-90.

Stephen S. Arnon et al., "Botulinum Toxin as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* 285, no. 8 (February 28, 2001): 1059-70.

David T. Dennis, "Tularemia as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* 281, no. 21 (June 6, 2001): 2763-73.

Annie Fine and Marcelle Layton, "Lessons from the West Nile Viral Encephalitis Outbreak in New York City, 1999: Implications for Bioterrorism Preparedness," *Clinical Infectious Diseases,* 2001;32:277-82; available at http://www.journals.uchicago.edu/CID/journal/issues/v32n2/001285/001285.web.pdf.

Institute of Medicine and National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, National Academy Press, Washington, D.C., 1999; available at http://www.nap.edu/catalog/6364.html.

Amy Smithson and Leslie-Ann Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response,* Stimson Center Report No. 35, Henry L. Stimson Center, Washington, D.C., October 2000; available at http://www.stimson.org/cwc/ataxia.htm.

Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Toward a National Strategy for Combating Terrorism,* Second Annual Report to the President and the Congress, RAND, Arlington, Virginia, December 15, 2000; available at http://www.rand.org/organization/nsrd/terrpanel.

U.S. General Accounting Office, *Bioterrorism: Federal Research and Preparedness Activities*, GAO Report (GAO-01-915), Washington, D.C., September 2001; available at http://www.gao.gov.

U.S. General Accounting Office, *Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination,* GAO Report (GAO/RCED-00-3), October 27, 1999; available at http://www.gao.gov.

U.S. General Accounting Office, *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks,* GAO Report (GAO/NSIAD-99-163), September 14, 1999; available at http://www.gao.gov.

Food and Drug Administration, "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted," proposed rule, *Federal Register,* 64, no. 192 (October 5, 1999): 53960-53970; available at http://www.access.gpo.gov/su_docs/aces/aces140.html.

David P. Fidler, "The Malevolent Use of Microbes and the Rule of Law: Legal Challenges Presented by Bioterrorism," *Clinical Infectious Diseases,* 2001;33:686-9; available at http://www.journals.uchicago.edu/CID/journal/issues/v33n5/010328/010328.web.pdf.

APPENDIX IV

Bioterrorism Related Web-site Addresses (accessed 10/14/01)

Updated links available on NHPF Web site: http://www.nhpf.org

(This list of links was prepared with the assistance of Ginger Pennick Para, Senior Research Associate, NHPF.)[*]

GENERAL

http://www.stimson.org/cwc/terror$.htm
Henry L. Stimson Center, Chemical and Biological Weapons Nonproliferation Project, *What Is the U.S. Government Spending to Combat Terrorism?*

http://stimson.org/cwc/ataxia.htm
Henry L. Stimson Center, Chemical and Biological Weapons Nonproliferation Project, Report #35: *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response*

http://www.homelanddefense.org/journal/Commentary/commentary.cfm?commentary=3
Al Mauroni, "A Rebuttal to 'Ataxia,' the Smithson Report on U.S. Response to CB Terrorism," ANSER Institute for Homeland Security

http://www.homelandsecurity.org/library.cfm?cat_format=1&category1_id=17
ANSER Institute for Homeland Security, *Virtual Library*

http://www.apic.org

http://www.cdc.gov/nciod/diseases/bioterr.htm

http://www.cdc.gov/ncidod/dbmd/anthrax.htm

http://www.cdc.gov/nciod/diseases/foodborn/botu.htm

http://www.cdc.gov/nciod/srp/drugservice/immuodrugs.htm

http://www.defenselink.mil/specials/anthrax/anth.htm

http://www.hopkins-id.edu/bioterr/bioterr_1.html

http://www.hopkins-biodefense.org

http://www.hopkins-biodefense.org/pages/library/resources.html
Johns Hopkins University, Center for Civilian Biodefense Studies: Library

http://www.tacda.org/jcd/
American Civil Defense Association, *Journal of Civil Defense*

http://www.rand.org/publications/MR/MR505/
Kevin Jack Riley and Bruce Hoffman, *Domestic Terrorism: A National Assessment of State and Local Preparedness*, RAND's Criminal Justice Research Program

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[*] *This list is not intended to be comprehensive, and inclusion on it does not imply endorsement by the National Health Policy Forum.*

http://www.cbaci.org/CDCSectionLinksMain.htm
Chemical and Biological Arms Control Institute, *Bioterrorism in the United States—Threat, Preparedness, and Response*

http://chembio.janes.com/chembio_home.html
Jane's Chem-Bio Website

http://www.emedicine.com
eMedicine Homepage

http://www.miis.edu/
Monterey Institute of International Studies Homepage

http://www.slu.edu/colleges/sph/bioterrorism/
St. Louis University School of Public Health, Center for the Study of Bioterrorism and Emerging Infections

http://www.mipt.org/p-cmi.html
Oklahoma City National Memorial Institute for the Prevention of Terrorism, "Preparedness/Consequence Management Information"

http://www.mipt.org/infrastructure.html
Oklahoma City National Memorial Institute for the Prevention of Terrorism, "Infrastructure Protection/Computer Security"

http://www.mipt.org/ttclinks.html
Oklahoma City National Memorial Institute for the Prevention of Terrorism, "Think Tanks and Centers"

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