

September 2001

# BIOTERRORISM

## Federal Research and Preparedness Activities





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**Abbreviations**

AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
CONPLAN	U.S. Government Interagency Domestic Terrorism Concept of Operations Plan
DOD	Department of Defense
DOE	Department of Energy
DOJ	Department of Justice
DOT	Department of Transportation
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OEP	Office of Emergency Preparedness
OJP	Office of Justice Programs
TOPOFF 2000	Top Officials 2000 exercise
USDA	U.S. Department of Agriculture
VA	Department of Veterans Affairs
WMD	weapon of mass destruction



September 28, 2001

### Congressional Committees

A number of incidents involving biological agents, including at least one completed bioterrorist act and numerous threats and hoaxes,<sup>1</sup> have occurred domestically. In 1984, a group intentionally contaminated salad bars in local restaurants in Oregon with salmonella bacteria<sup>2</sup> to prevent people from voting in a local election.<sup>3</sup> Although no one died, 751 people were diagnosed with foodborne illness. As was the case with this incident, determining whether an outbreak occurred naturally or was the product of an intentional release may be difficult unless someone announces the release beforehand or claims responsibility for it. Given the terrorist attacks of September 11, 2001, in addition to the terrorist bombings in New York City in 1993 and in Oklahoma City in 1995, some experts predict that domestic bioterrorist attacks are likely to occur. Others consider the likelihood of bioterrorist attacks to be low because of various difficulties, including those involved in processing the biological agents into lethal forms and successfully delivering them to achieve large-scale casualties. However, the ease with which these agents can be concealed and their potential to affect large segments of the population beyond those initially exposed may increase their appeal to terrorists.

Bioterrorism is the threat or intentional release of biological agents (viruses, bacteria, or their toxins) for the purpose of influencing the conduct of government, or intimidating or coercing a civilian population. These agents can be released by way of the air (as aerosols), food, water, or insects. The intentional release of a biological agent may not be recognized for several days, if ever, during which time a communicable biological agent (such as smallpox) can spread to others who were not initially exposed. Some biological agents (such as anthrax and plague) produce symptoms that can be easily confused with influenza or other, less virulent

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<sup>1</sup>For example, in January 2000, threatening letters were sent to a variety of recipients, including the Planned Parenthood office in Naples, Florida, warning of the release of anthrax. Federal authorities found no signs of anthrax or any other traces of harmful substances and determined these incidences to be hoaxes.

<sup>2</sup>See app. I for a description of salmonella and other biological agents and pathogens mentioned in this report.

<sup>3</sup>See *Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination* (GAO/RCED-00-3, Oct. 27, 1999), p. 4.

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illnesses, leading to a delay in diagnosis or identification. In addition to widespread medical consequences, a bioterrorist attack also could bring about behavioral, social, economic, and psychological consequences, such as mass panic. Health care providers could be the first authorities to see victims as they seek treatment of their symptoms. If large numbers of people are affected, local and state officials may turn to the federal government for assistance with disease surveillance,<sup>4</sup> epidemiologic investigation,<sup>5</sup> health care delivery, quarantine management, remediation, and mass fatality management.

Many federal departments and agencies, including the Departments of Health and Human Services (HHS) and Justice (DOJ), would have roles in responding to a domestic bioterrorist attack against the U.S. population. These departments and agencies are involved in a range of activities related to the public health and medical consequences of a bioterrorist attack on the civilian population.<sup>6</sup> These activities are part of the federal government's overall effort to combat terrorism.

Because of the concerns about bioterrorism, the Public Health Improvement Act of 2000 (P.L. 106-505, sec. 102) mandates that we describe federal activities related to the public health and medical consequences of a bioterrorist attack against the civilian population. We are therefore providing information on (1) federal activities and funding related to the public health and medical consequences of a bioterrorist attack against the civilian population, (2) how these activities are coordinated among federal agencies and whether there are any shortcomings in the current coordination structure, and (3) existing evaluations of the effectiveness of these activities in preparing state and local authorities.

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<sup>4</sup>Disease surveillance systems provide for the ongoing collection, analysis, and dissemination of data to prevent and control disease.

<sup>5</sup>Epidemiological investigation is the study of patterns of health or disease and the factors that influence these patterns.

<sup>6</sup>Public health and medical consequences refers to the effects of a biological agent on the population as well as on the individual. See app. I for the medical effects of the biological agents and pathogens mentioned in this report.



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In carrying out our work, we relied on federal departments and agencies to identify relevant programs and provide budget information.<sup>7</sup> We have not audited or otherwise verified the information provided. We interviewed agency officials, obtained documents, and reviewed reports prepared by others (such as *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response*<sup>8</sup> and *Toward a National Strategy for Combating Terrorism*<sup>9</sup>), as well as our previous reports (see Related GAO Products at the end of this report). Although there are generally no specific appropriations for activities on bioterrorism, some departments and agencies did provide estimates of the funds they were devoting to activities on bioterrorism. Other departments and agencies provided estimates for overall terrorism activities but were unable to provide funding amounts for activities on bioterrorism specifically. Still others stated that their activities were relevant for bioterrorism, but they were unable to specify the funding amounts. As a result, departments and agencies provided funding information in various forms—appropriations, obligations, expenditures. For a given fiscal year, this information is not necessarily additive across agencies.<sup>10</sup> For this reason, we have summarized funding by agency, but not across the federal government.<sup>11</sup> (See app. II for details regarding our scope and methodology.) We conducted our work from January through September 2001 in accordance with generally accepted government auditing standards.

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<sup>7</sup>We conducted interviews with and obtained information from the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Justice, Transportation, the Treasury, and Veterans Affairs; the Environmental Protection Agency; and the Federal Emergency Management Agency.

<sup>8</sup>Amy Smithson and Leslie-Ann Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response* (Washington, DC: The Henry L. Stimson Center, Oct. 2000).

<sup>9</sup>Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Toward a National Strategy for Combating Terrorism*, Second Annual Report (Arlington, VA: RAND, Dec. 15, 2000).

<sup>10</sup>For example, an agency providing appropriations is not necessarily indicating the level of its commitments (that is, obligations) or expenditures for that year—only the amount of budget authority made available to it by the Congress. Similarly, an agency which provided expenditure information for fiscal year 2000 may have obligated the funds in fiscal year 1999 based on an appropriation for fiscal year 1998. To simplify presentation, we generally refer to the budget data we received from agencies as “reported funding” and report this information for the agencies separately.

<sup>11</sup>Funding levels for activities on terrorism, including bioterrorism, were reported for activities prior to September 11, 2001 and do not include any funds approved by the Congress after that date.

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## Results in Brief

A variety of federal research and preparedness activities related to the public health and medical consequences of a bioterrorist attack are under way. Research activities focus on various biological agents that could be used as weapons of terrorism; detection of such agents; development of new or improved vaccines, antibiotics, and antivirals; and performance standards for emergency response equipment. Preparedness activities include increasing state and local response capabilities, improving federal response capacity, developing response teams, increasing the availability of medical treatments, participating in and sponsoring exercises, aiding victims, and providing support at special events, such as presidential inaugurations and Olympic games. Activities in many departments and agencies have a dual use, being not only relevant for bioterrorism but also for other types of terrorism, emergencies, and infectious disease surveillance. For example, the Federal Emergency Management Agency (FEMA) has a broad emergency and terrorist response system, which includes a bioterrorist response system. HHS has programs on emerging infectious diseases that benefit its activities on bioterrorism as well as research endeavors such as research on diagnoses, vaccines, and new therapies.

Federal departments and agencies use a variety of methods to coordinate their activities to combat terrorism. Departments and agencies are developing interagency response plans, participating in a variety of interagency work groups, and entering into formal agreements with other agencies to share resources and capabilities in order to improve coordination. However, coordination of federal terrorism research, preparedness, and response programs is fragmented, as we have discussed in a previous report.<sup>12</sup> As we noted, several different agencies are responsible for various coordination functions, which limits accountability and hinders unity of effort. For bioterrorism, different agencies have developed separate threat lists of biological agents, several agencies have not been included in bioterrorism-related policy and response planning, and agencies have developed programs to provide assistance to state and local governments that are similar and potentially duplicative. However, the Office of Management and Budget and the National Security Council have created a process to reduce overlap and improve coordination as part of the annual budget cycle. In addition, the Vice President was asked by the

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<sup>12</sup>See *Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001), p. 40.

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President in May 2001 to lead an interagency effort to improve coordination. Also, on September 20, 2001, the President announced the creation of the Office of Homeland Security to lead, oversee, and coordinate a comprehensive national strategy to safeguard the country against terrorism.

The reports that we reviewed identified concerns about the preparedness of states and local areas to respond to a bioterrorist attack. These concerns include insufficient state and local planning for response to terrorist events and a lack of hospital participation in training on terrorism and emergency response planning. Some federal programs have begun to provide funding to state and local governments to improve preparedness.

We provided a draft of this report to the eleven departments and agencies for their review in August 2001. HHS stated that many of the services needed in response to a bioterrorist attack would be needed to respond to other emergencies, including natural disasters and other types of terrorist attacks, and we added this information to the report. We also modified the report in response to a DOJ comment that it is appropriate for different agencies to maintain separate lists of biological threats, noting that such lists may have different purposes. Most agencies provided technical comments.

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## Background

Although the probability of a domestic bioterrorist attack has been considered to be low, some characteristics of biological agents may make them appealing to terrorists. The information for the production of agents is readily available on the Internet, and the agents are relatively easy to grow and conceal. According to intelligence agencies, the possibility that terrorists may use chemical or biological materials may increase over the next decade.<sup>13</sup>

However, other characteristics of biological agents may limit their appeal to terrorists. For example, they are difficult to obtain, process into a lethal form, and deliver to achieve large-scale casualties. Processing biological agents into the right particle size and delivering them effectively require expertise in a wide range of scientific disciplines. Additional hurdles to deployment include disruptions caused by environmental and

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<sup>13</sup>See *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks* (GAO/NSIAD-99-163, Sept. 14, 1999), p. 17.

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meteorological conditions. For example, if wind conditions are too strong or erratic, agents released as aerosols might dissipate rapidly or fail to reach the desired area.

With any emergency, including natural disasters and terrorist attacks, states can call upon services related to emergency management, public safety, emergency medical services, health care delivery, and fatality management. Most states rely on local public health agencies to identify and respond to naturally occurring disease outbreaks, and these are the same agencies that are responsible for bioterrorism preparedness and response. Just as in naturally occurring outbreaks, a bioterrorist attack could involve public health officials in disease surveillance, epidemiologic investigation, health care delivery, quarantine management, remediation, and mass fatality management.

Unless a terrorist announces the release of a biological agent, the cause of an outbreak might be detected only after an epidemiologic investigation and laboratory identification. Officials from the Centers for Disease Control and Prevention (CDC) and the National Association of County and City Health Officials have stated that the capacities needed by local public health agencies to prepare for a bioterrorist incident should be built on the systems used to respond to naturally occurring disease outbreaks. Such a “dual-use” response infrastructure improves the capacity of local public health agencies to respond to all hazards.

In response to past domestic terrorist events and bioterrorism cases, including hoaxes, the federal government has become more involved in bioterrorism preparedness. From 1989 through 1996, Congress passed several laws aimed at preventing the acquisition and use of chemical or biological weapons by groups or individuals. In addition, the National Defense Authorization Act for Fiscal Year 1997 (P.L. 104-201) authorized \$97 million for domestic emergency assistance programs, including the implementation of programs providing advice, training, and the loan of equipment to state and local emergency response agencies and assistance to major cities in establishing medical strike teams. The act also authorized the Department of Defense (DOD) to establish military domestic terrorism rapid response teams. In the event of a bioterrorist attack against the civilian population, DOD will use these teams to provide support to the primary federal agency as defined under the Federal Response Plan.

The Federal Response Plan, originally drafted in 1992 and updated in 1999, is authorized under the Robert T. Stafford Disaster Relief and Emergency

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Assistance Act (Stafford Act; P.L. 93-288, as amended). The plan lays out the manner in which the federal government responds to domestic situations in which the President has declared an emergency requiring federal disaster assistance. Presidential Decision Directive 39, which was issued after the Oklahoma City bombing in 1995, provides a framework for how the federal government will respond to weapons of mass destruction (WMD)<sup>14</sup> terrorism within the United States, reaffirming the Federal Response Plan. The plan is an “all-hazards” (that is, for any emergency or disaster) approach document, with an annex specific to terrorism, which was added by FEMA in 1997. In 1998, Presidential Decision Directive 62 was issued, which describes federal agency roles in preparing for and responding to WMD terrorism. In 2001, the U.S. Government Interagency Domestic Terrorism Concept of Operations Plan was issued, which explains agencies’ responsibilities under Presidential Decision Directives 39 and 62 in more detail. HHS is currently developing a bioterrorism annex to this plan. (See app. III for more information on these federal policy and planning documents.)

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## Departments and Agencies Reported a Variety of Actions and Funding for Research and Preparedness Activities

The federal government is conducting a variety of activities related to research on and preparedness for the public health and medical consequences of a bioterrorist attack against the civilian population. Research activities focus on detection, treatment, vaccination, and emergency response equipment. Preparedness efforts include increasing state and local response capabilities, improving federal response capacity, developing response teams, increasing availability of medical treatments, participating in and sponsoring exercises, planning for victim aid, and providing support during special events such as presidential inaugurations and Olympic games.

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## Research Activities Focus on Detection, Treatment, Vaccination, and Equipment

The federal government is involved in a range of research activities related to the public health and medical consequences of a bioterrorist attack on the civilian population. Studies are currently being done to enable the rapid identification of biological agents in a variety of settings; develop new or improved vaccines, antibiotics, and antivirals to improve treatment and

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<sup>14</sup>Throughout this report, we use the term WMDs to refer to chemical, biological, radiological, or nuclear agents or weapons. Some agencies define it to include large conventional explosives as well.

vaccination for infectious diseases caused by biological agents; and develop and test emergency response equipment. Table 1 provides information on the total reported funding for all the departments and agencies carrying out research and examples of this research for these departments and agencies. In addition, DOD and the Department of Transportation (DOT) have some relevant research activities, but were not able to specify the associated funding. More detail on each department's and agency's activities is provided in appendixes IV through XIV.

**Table 1: Total Reported Funding for Research on Bioterrorism and Terrorism by Federal Departments and Agencies, Fiscal Year 2000 and Fiscal Year 2001 (Dollars in millions)**

Department or agency	Fiscal year 2000 funding	Fiscal year 2001 funding	Sample activities
U.S. Department of Agriculture—Agricultural Research Service	0	\$0.5	Improving detection of biological agents
Department of Energy	\$35.5	\$39.6	Developing technologies for detecting and responding to a bioterrorist attack  Developing models of the spread of and exposure to a biological agent after release
HHS—Agency for Healthcare Research and Quality	\$5.0	0	Examining clinical training and ability of front-line medical staff to detect and respond to a bioterrorist threat  Studying use of information systems and decision support systems to enhance preparedness for medical care in the event of a bioterrorist event
HHS—CDC	\$48.2	\$46.6	Developing equipment performance standards  Conducting research on smallpox and anthrax viruses and therapeutics
HHS—Food and Drug Administration	\$8.8	\$9.1	Licensing of vaccines for anthrax and smallpox  Determining procedures for allowing use of not yet approved drugs and specifying data needed for approval and labeling
HHS—National Institutes of Health	\$43.0	\$49.7	Developing new therapies for smallpox virus  Developing smallpox and bacterial antigen detection system
HHS—Office of Emergency Preparedness	0	\$4.6	Overseeing a study on response systems
DOJ—Office of Justice Programs	\$0.7	\$4.6	Developing a biological agent detector
DOJ—Federal Bureau of Investigation	0	\$1.1	Conducting work on detection and characterization of biological materials

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Department or agency	Fiscal year 2000 funding	Fiscal year 2001 funding	Sample activities
Department of the Treasury—Secret Service	0	\$0.5	Developing a biological agent detector
Environmental Protection Agency	0	\$0.5	Improving detection of biological agents

Note: Total reported funding refers to budget data we received from agencies. Agencies reported appropriations, actual or estimated obligations, or actual or estimated expenditures. An agency providing appropriations is not necessarily indicating the level of its commitments (that is, obligations) or expenditures for that year—only the amount of budget authority made available to it by the Congress. Similarly, an agency which provided expenditure information for fiscal year 2000 may have obligated the funds in fiscal year 1999 based on an appropriation for fiscal year 1998.

Source: Information obtained from departments and agencies.

The U.S. Department of Agriculture (USDA), DOD, Department of Energy (DOE), HHS, DOJ, Department of the Treasury, and the Environmental Protection Agency (EPA) have all sponsored or conducted projects to improve the detection and characterization of biological agents. These detection devices and tests are designed to identify biological agents in food, the environment, and clinical samples (such as blood). For example, EPA is sponsoring research to improve its ability to detect biological agents in the water supply.

Departments and agencies are also conducting or sponsoring studies to improve treatment and vaccination for diseases caused by biological agents. These projects include basic research to develop drugs and diagnostics and applied research to improve health care delivery systems. Several agencies also reported working to develop vaccines to prevent infection caused by biological agents. For example, HHS funded research to determine if the currently available stock of smallpox vaccine could be extended by dilution and yet remain effective. HHS is also developing a new vaccine for smallpox and collaborating with DOD on the development of a new anthrax vaccine.

In addition, several agencies are conducting research that focuses on developing performance standards and methods for testing the performance of emergency response equipment, such as respirators, personal protective equipment, and chemical and biological agent detectors and decontamination equipment.

## Preparedness Efforts Include Multiple Actions

Departments and agencies are undertaking activities to increase preparedness for the public health and medical consequences of a bioterrorist attack. Preparing for a bioterrorist attack includes activities such as planning, purchasing equipment, training, and participating in exercises simulating a bioterrorist attack. Federal departments and agencies have undertaken the following preparedness activities: increasing state and local response capabilities, improving federal response capacity, developing response teams, increasing availability of medical treatments, participating in and sponsoring exercises, planning for victim aid, and providing support during special events. Table 2 contains information on total reported funding for all the departments and agencies with bioterrorism preparedness activities in fiscal year 2000 and fiscal year 2001 and examples of preparedness activities for these departments and agencies. In addition, the Department of the Treasury has some relevant preparedness activities, but was not able to specify the associated funding. More information on these activities is given in appendix IV through appendix XIV.

**Table 2: Total Reported Funding for Preparedness Activities on Bioterrorism and Terrorism by Federal Departments and Agencies, Fiscal Year 2000 and Fiscal Year 2001 (Dollars in millions)**

Department or agency	Fiscal year 2000 funding	Fiscal year 2001 funding	Sample activities
USDA—Animal and Plant Health Inspection Service	0	\$0.2	Developing educational materials and training programs specifically dealing with bioterrorism
DOD—Joint Task Force for Civil Support	\$3.4	\$8.7	Planning, and when directed, commanding and controlling DOD's WMD and high-yield explosive consequence management capabilities in support of FEMA
DOD—National Guard	\$70.0	\$93.3	Managing response teams that would enter a contaminated area to gather samples for on-site evaluation
DOD—U.S. Army	\$29.5	\$11.7	Maintaining a repository of information about chemical and biological weapons and agents, detectors, and protection and decontamination equipment
HHS—CDC	\$124.9	\$147.3	Awarding planning grants to state and local health departments to prepare bioterrorism response plans  Improving surveillance methods for detecting disease outbreaks  Increasing communication capabilities in order to improve the gathering and exchanging of information related to bioterrorist incidents



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Department or agency	Fiscal year 2000 funding	Fiscal year 2001 funding	Sample activities
HHS—Food and Drug Administration	\$0.1	\$2.1	Improving capabilities to identify and characterize foodborne pathogens  Identifying biological agents using animal studies and microbiological surveillance
HHS—Office of Emergency Preparedness	\$35.3	\$46.1	Providing contracts to increase local emergency response capabilities  Developing and managing response teams that can provide support at the site of a disaster
DOJ—Office of Justice Programs	\$7.6	\$5.3	Helping prepare state and local emergency responders through training, exercises, technical assistance, and equipment programs  Developing a data collection tool to assist states in conducting their threat, risk, and needs assessments, and develop their preparedness strategy for terrorism, including bioterrorism
EPA	\$0.1	\$2.0	Providing technical assistance in identifying and decontaminating biological agents  Conducting assessments of water supply vulnerability to terrorism, including contamination with biological agents
FEMA	\$25.1	\$30.3	Providing grant assistance and guidance to states for planning and training  Maintaining databases of safety precautions for biological, chemical, and nuclear agents

Note: Total reported funding refers to budget data we received from agencies. Agencies reported appropriations, actual or estimated obligations, or actual or estimated expenditures. An agency providing appropriations is not necessarily indicating the level of its commitments (that is, obligations) or expenditures for that year—only the amount of budget authority made available to it by the Congress. Similarly, an agency which provided expenditure information for fiscal year 2000 may have obligated the funds in fiscal year 1999 based on an appropriation for fiscal year 1998.

Source: Information obtained from departments and agencies.

Several federal departments and agencies have programs to increase the ability of state and local authorities to successfully respond to a bioterrorist attack. Some of these programs have focused on developing plans for dealing with a terrorist attack or emergency in general. Departments and agencies also contribute to state and local jurisdictions by helping them pay for equipment, providing technical assistance, increasing communications capabilities, and conducting training courses.

In addition to increasing the preparedness of state and local entities, federal departments and agencies have been increasing their own capacity

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to identify and deal with a bioterrorist incident. They are improving surveillance methods for detecting disease outbreaks in humans and animals. They have also established laboratory response networks to maintain state-of-the-art capabilities for biological agent identification and characterization of human clinical samples, as well as attempted to increase their communications capabilities in order to improve the gathering and exchanging of information related to a bioterrorist incident as well as other events.

Some federal departments and agencies have developed teams to directly respond to terrorist events. HHS' Office of Emergency Preparedness (OEP) and DOD have created response teams that would provide medical treatment and assistance in the event of a bioterrorist attack against the civilian population in the United States. Four teams led by OEP, known as National Medical Response Teams, are specially trained and equipped to respond to incidents involving WMDs—chemical, biological, radiological, or nuclear agents or weapons. The DOD teams would assist a local incident commander in case of a domestic bioterrorist incident. DOD coordinates with OEP in planning medical support for a civilian bioterrorist incident.

Several agencies are involved in increasing the availability of medical supplies that could be used in the event of a bioterrorist attack. CDC and OEP maintain repositories of pharmaceutical and other supplies that can be delivered to the site of a terrorist incident. CDC's National Pharmaceutical Stockpile Program consists of two components. The first component is the 12-Hour Push Packages, which contain pharmaceuticals, antidotes, and medical supplies and can be delivered to any site in the United States within 12 hours of a federal decision to deploy assets. These supplies are prepackaged and cannot be tailored to an individual incident.<sup>15</sup> The second component is the Vendor Managed Inventory. Through the Department of Veterans Affairs (VA), CDC has contracted with vendors to store pharmaceutical and medical supplies that could be used in a terrorist incident. These products can be tailored to an individual incident (that is, only pharmaceuticals and supplies needed for a particular incident would be sent) and would be available 24 to 36 hours after the National

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<sup>15</sup>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.

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Pharmaceutical Stockpile staff notifies the appropriate vendors.<sup>16</sup> OEP's National Medical Response Teams have stockpiles that can be deployed with the teams. Each team has the capability of carrying enough pharmaceutical and medical supplies to treat up to 5,000 people, with the focus on the medical response to chemical incidents. The Food and Drug Administration (FDA) also has initiatives to increase the availability of medical countermeasures. For example, FDA is developing an approach that would allow drugs still in the FDA approval system to be used in the field during a bioterrorist attack. FDA is also working with CDC to implement a shelf-life extension program for the maintenance of stockpiled pharmaceuticals and medical supplies.

Bioterrorism response exercises are conducted across the country, both as on-site and as "tabletop" exercises. For example, in May 2000, many departments and agencies took part in the Top Officials 2000 exercise (TOPOFF 2000) in Denver, Colorado, which featured the simulated release of a biological agent.<sup>17</sup> Participants included local fire departments, police, area hospitals, the Colorado Department of Public Health and the Environment, the Colorado Office of Emergency Management, the Colorado National Guard, the American Red Cross, the Salvation Army, HHS, DOD, FEMA, the Federal Bureau of Investigation (FBI), and EPA. DOJ reported funding that facilitated 52 tabletop exercises on bioterrorism in fiscal year 2001. These 1-day exercises involve public health, fire, law enforcement, and emergency management agencies. Participants work through a simulation of a bioterrorism incident, starting with the incubation period (the time between initial exposure to a biological agent and onset of symptoms), followed by the recognition and initial response, and finally the challenges of integrating federal assets with local response and recovery efforts. Medical surveillance, epidemiologic investigation, quarantine management, remediation, and mass fatality management are addressed.

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<sup>16</sup>For more information on management of the National Pharmaceutical Stockpile Program, see *Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement* (GAO-01-463, Mar. 30, 2001).

<sup>17</sup>In addition to simulating a bioterrorism attack in Denver, the exercise also portrayed a chemical weapons incident in Portsmouth, New Hampshire. A concurrent exercise, referred to as National Capital Region 2000, simulated a radiological event in the greater Washington, D.C., area.

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Under the Victims of Crime Act of 1984, DOJ's Office of Justice Programs (OJP) manages a program that provides assistance to victims of terrorism, including a bioterrorist attack. Under this program, funds can be used to provide mental health services. In addition, FEMA can provide supplemental funds to state and local mental health agencies to provide crisis counseling to eligible survivors of presidentially declared major disasters.<sup>18</sup>

Federal departments and agencies also provide support at special events to improve response in case of an emergency.<sup>19</sup> For example, OEP deployed teams from the National Disaster Medical System to provide medical services if required during the presidential inauguration of 2001. In addition, CDC is developing a surveillance system to provide increased surveillance and epidemiological capacity before, during, and after a special event. Besides improving emergency response at the events, department and agency participation provides them with valuable experience working together to develop and practice plans to combat terrorism. OEP reported funding of \$2 million in fiscal year 2001 for special events. It was the only agency that reported funding for these activities.

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## Despite Efforts to Coordinate Federal Programs, Fragmentation Remains

Federal departments and agencies are using a variety of methods to coordinate their activities to combat terrorism. Departments and agencies are developing interagency response plans, participating in a variety of interagency work groups, and entering into formal agreements with other agencies to share resources and capabilities in order to improve coordination. However, during this and our previous work we found evidence that coordination of federal terrorism research, preparedness, and response programs is fragmented. Several different agencies are responsible for various coordination functions, which limits accountability and hinders unity of effort. Different agencies have developed separate threat lists of biological agents, several agencies have not been included in

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<sup>18</sup>HHS can also address emotional and mental health consequences of terrorist attacks. On September 13, 2001, in response to the attack on the World Trade Center, HHS released \$1 million in funding for New York to support mental health services and strategic planning for comprehensive and long-term support.

<sup>19</sup>Presidential Decision Directive 62 created a category of special events called National Security Special Events, which are events of such significance that they warrant greater federal planning and protection than other special events. Such events include presidential inaugurations and major political party conventions.

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bioterrorism-related policy and response planning, and agencies have developed programs to provide assistance to state and local governments that are similar and potentially duplicative. For example, FEMA, DOJ, CDC, and OEP all offer separate assistance to state and local governments in planning for emergencies, including potential bioterrorist incidents. Congress and the President have recently taken steps to improve oversight and coordination. For example, in May 2001, the President asked the Vice President to lead an interagency effort to improve coordination of federal programs to deal with the consequences of a potential use of a WMD.

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### Departments and Agencies Use a Variety of Methods to Coordinate Activities

Departments and agencies use several approaches to coordinate their activities on terrorism. Interagency plans for responding to a terrorist incident help outline agency responsibilities and identify resources that could be used during a response. For example, the Federal Response Plan, which has been in effect for almost a decade, provides a broad framework for coordinating the delivery of federal disaster assistance to state and local governments when a major disaster or emergency, including a bioterrorist attack, overwhelms their ability to respond effectively.<sup>20</sup> The Federal Response Plan designates primary and supporting federal agencies for a variety of emergency support operations. For example, HHS is the primary agency for coordinating federal assistance to supplement state and local resources in response to public health and medical care needs in an emergency, including a bioterrorist attack. HHS could receive support from USDA, DOD, DOE, DOJ, DOT, VA, EPA, FEMA, and other agencies and organizations to assist state and local jurisdictions.

Interagency work groups are being used by federal departments and agencies to attempt to minimize duplication of funding and effort in federal activities on terrorism. For example, the Technical Support Working Group,<sup>21</sup> which receives funds from DOD and other agencies, is chartered to coordinate interagency and international research and development requirements for combating terrorism—including efforts to reduce vulnerability, collect and disseminate terrorism-related information, and prevent, deter, and respond to terrorist acts of any kind—in order to

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<sup>20</sup>See app. III for more details on selected federal policy and planning documents.

<sup>21</sup>A description of the funding for the Technical Support Working Group is not included in this report because it does not primarily focus on the public health and medical consequences of a bioterrorist attack.

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prevent duplication of effort between agencies.<sup>22</sup> The Technical Support Working Group, among other projects, helped to identify research needs and fund a project to develop a means to detect biological agents in the food supply that can be used by both DOD and USDA. Another example of an interagency work group was provided by OEP officials, who told us that DOD, DOJ, DOE, OEP, FEMA, and VA meet as necessary to review equipment requests of state and local jurisdictions to ensure that duplicative funding is not being given for the same activities.

Formal agreements between departments and agencies are being used to share resources and knowledge. For example, CDC contracts with VA to purchase drugs and medical supplies for the National Pharmaceutical Stockpile because of VA's purchasing power and ability to negotiate large discounts from manufacturers that sell pharmaceuticals, equipment, and supplies to the VA hospital system. USDA's Animal and Plant Health Inspection Service is negotiating an agreement with DOD's Armed Forces Medical Intelligence Center to share information and expertise on tracking diseases that can be transmitted from animals to people and could be used in a bioterrorist attack.

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## Coordination Remains Fragmented Within the Federal Government

Overall coordination of federal programs to combat terrorism, including bioterrorism, is fragmented within the federal government.<sup>23</sup> For example, several agencies have coordination functions, including DOJ, FBI, FEMA, and the Office of Management and Budget. Officials from a number of the agencies that combat terrorism told us that the coordination roles of these various agencies are not always clear and sometimes overlap, leading to a fragmented approach. The Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (also known as the Gilmore Panel) also concluded that the current coordination structure does not provide for the requisite authority or accountability to

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<sup>22</sup>See GAO-01-822, Sept. 20, 2001, p. 79. Coordination of federal research and development efforts to combat terrorism is still limited by a number of factors, raising the potential for duplicative efforts among federal agencies.

<sup>23</sup>See also *Combating Terrorism: Comments on Counterterrorism Leadership and National Strategy* (GAO-01-556T, Mar. 27, 2001), p. 1.

make policy changes and to impose the discipline necessary among the numerous federal agencies involved.<sup>24</sup>

The multiplicity of federal assistance programs requires focus and attention to minimize redundancy of effort.<sup>25</sup> Table 3 describes some of the federal programs providing assistance to state and local governments for emergency planning that would be relevant to responding to a bioterrorist attack. While the programs vary somewhat in their target audiences, the potential redundancy of these federal efforts highlights the need for scrutiny. In a recent report, we recommended that the President, working closely with Congress, consolidate some of the activities of the DOJ's OJP under FEMA.<sup>26</sup>

**Table 3: Selected Federal Activities Providing Assistance to State and Local Governments for Emergency Planning Relevant to a Bioterrorist Attack**

Department or agency	Activities	Target audience
HHS—CDC	Provides grants, technical support, and performance standards to support bioterrorism preparedness and response planning.	State and local health agencies
HHS—OEP	Enters into contracts to enhance medical response capability. The program includes a focus on response to bioterrorism, including early recognition, mass postexposure treatment, mass casualty care, and mass fatality management.	Local jurisdictions, including fire, police, emergency medical services, hospitals, and public health agencies
DOJ—OJP	Assists states in developing strategic plans. Includes funding for training, equipment acquisition, technical assistance, and exercise planning and execution to enhance state and local capabilities to respond to terrorist incidents.	States, including fire, law enforcement, emergency medical services, hazardous materials response services, hospitals, and public health departments

<sup>24</sup>See Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, p. 7.

<sup>25</sup>See also *Combating Terrorism: Issues in Managing Counterterrorist Programs* (GAO/T-NSIAD-00-145, Apr. 6, 2000), p. 8.

<sup>26</sup>See GAO-01-822, Sept. 20, 2001, p. 104.

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(Continued From Previous Page)

Department or agency	Activities	Target audience
FEMA	Provides grant assistance to support state and local consequence management planning, training, and exercises for all types of terrorism, including bioterrorism.	State emergency management agencies

Source: Information obtained from departments and agencies.

Fragmentation is also evident in the different threat lists of biological agents developed by federal departments and agencies. Several different agencies have or are in the process of developing biological agent threat lists, which differ based on the agencies' focus. For example, CDC collaborated with law enforcement, intelligence, and defense agencies to develop a critical agent list that focuses on the biological agents that would have the greatest impact on public health. The FBI, the National Institute of Justice, and the Technical Support Working Group are completing a report that lists biological agents that may be more likely to be used by a terrorist group working in the United States that is not foreign sponsored. In addition, an official at USDA's Animal and Plant Health Inspection Service told us that it uses two lists of agents of concern for a potential bioterrorist attack developed through an international process (although only some of these agents are capable of making both animals and humans sick). According to agency officials, separate threat lists are appropriate because of the different focuses of these agencies. In prior reports, we have recommended that the federal government conduct multidisciplinary and analytically sound threat and risk assessments to define and prioritize requirements and properly focus programs and investments in combating terrorism.<sup>27</sup>

Fragmentation has also hindered unity of effort. Officials at USDA, FDA, and DOT told us that their departments and agencies have often been overlooked in bioterrorism-related planning and policy. USDA officials told us that as federal policy and coordination were developed in Presidential Decision Directive 62, the department was not included even though it

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<sup>27</sup>See *Combating Terrorism: Threat and Risk Assessments Can Help Prioritize and Target Program Investments* (GAO/NSIAD-98-74, Apr. 9, 1998), *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks* (GAO/NSIAD-99-163, Sept. 14, 1999), and *Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001).



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would have key responsibilities if terrorists targeted the food supply. FDA officials told us that FDA was involved in some issues with the National Pharmaceutical Stockpile, but was not involved in the selection of all items procured for the stockpile. DOT officials noted that even though its programs cross many areas and the nation's transportation centers for a significant percentage of potential terrorist targets, the department was not part of the founding group of agencies that worked on bioterrorism issues and has not been included in bioterrorism response plans. DOT officials also told us that the department is supposed to deliver supplies for FEMA under the Federal Response Plan, but it was not brought in early enough to understand the extent of its responsibilities in the transportation process. It did not learn these details until its participation in TOPOFF 2000.

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## Recent Actions Seek to Improve Coordination Across Federal Departments and Agencies

In 1997, we reported that the amount of funds being spent to combat terrorism was unknown and difficult to determine and no priorities had been set for funding terrorism-related programs.<sup>28</sup> As a result, there was no assurance that agencies' requests were funded through a coordinated and focused approach. Subsequently, Congress required the Office of Management and Budget to establish a reporting system on the budgeting and expenditure of funds to combat terrorism.<sup>29</sup> The Office of Management and Budget and the National Security Council created a process to reduce overlap and improve coordination as part of the annual budget cycle in 1999. As part of this process, the Office of Management and Budget started issuing an *Annual Report to Congress on Combating Terrorism*, which details agency activities and funding. These reports potentially represent a significant step toward improved coordination by providing strategic oversight of the magnitude and direction of spending for activities on terrorism. However, as we have testified, we have not yet seen evidence that these reports have established priorities or identified duplication of effort.<sup>30</sup>

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<sup>28</sup>See *Combating Terrorism: Spending on Governmentwide Programs Requires Better Management and Coordination* (GAO/NSIAD-98-39, Dec. 1, 1997), pp. 3-5.

<sup>29</sup>Section 1051 of the National Defense Authorization Act for Fiscal Year 1998 (P.L. 105-85).

<sup>30</sup>See *Combating Terrorism: Observations on Options to Improve the Federal Response* (GAO-01-660T, Apr. 24, 2001), p. 8.

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In May 2001, the President asked the Vice President to oversee the development of a coordinated national effort dealing with WMDs.<sup>31</sup> At the same time, the President asked the Director of FEMA to establish an Office of National Preparedness to implement the results of this effort that deal with programs within DOD, HHS, DOJ, DOE, EPA, and other federal agencies that address consequence management resulting from the use of WMDs. The purpose of this effort is to better focus policies and ensure that programs and activities are fully coordinated and integrated in support of building the needed preparedness and response capabilities.<sup>32</sup> We have previously recommended that the President appoint a single focal point for all critical leadership and coordination functions to combat terrorism.<sup>33</sup>

On September 20, 2001, the President announced the creation of the Office of Homeland Security. The head of the office will lead, oversee, and coordinate a comprehensive national strategy to safeguard the country against terrorism and respond to any attacks that may occur.

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## Despite Federal Efforts, Concerns Exist Regarding Preparedness at State and Local Levels

The reports that we reviewed identified concerns about the preparedness of states and local areas to respond to a bioterrorist attack. These concerns include insufficient state and local planning for response to terrorist events, inadequacies in the public health infrastructure, a lack of hospital participation in training on terrorism and emergency response planning, insufficient capacity for treating mass casualties from a terrorist act, and the timely availability of medical teams and resources in an emergency. Some federal programs have begun to provide funding to state and local governments to try to improve preparedness.

Questions exist regarding how much progress has been made in improving terrorism preparedness at the state and local levels. Most of the states surveyed by the National Governors' Association in 1996 reported that they had neither the equipment and trained personnel to detect a biological hazard nor the protective equipment that would be necessary during an attack. In 1997, FEMA identified planning and equipment for response to

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<sup>31</sup>According to the Office of the Vice President, as of June 2001, details on the Vice President's efforts had not yet been determined.

<sup>32</sup>See GAO-01-822, Sept. 20, 2001, p. 36.

<sup>33</sup>See GAO-01-822, Sept. 20, 2001, p. 41.

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nuclear, biological, and chemical incidents as an area in need of significant improvement at the state level. The federal government has several programs to train and equip state and local authorities to respond to terrorist WMD incidents.<sup>34</sup> All 50 states and approximately 255 local jurisdictions will receive at least some federal assistance, including training and equipment grants, to help them prepare for a terrorist WMD incident. However, survey results presented in an October 2000 report indicated that even those cities receiving federal aid are still not adequately prepared to respond to a bioterrorist attack.<sup>35</sup>

According to the October 2000 report, components of the nation's infectious disease surveillance system are still not well prepared to detect a covert bioterrorist attack.<sup>36</sup> This report concluded that reductions in public health laboratory staffing and training have affected the ability of state and local authorities to identify biological agents. CDC began taking steps to improve the nation's public health infrastructure for responding to bioterrorism in fiscal year 1999. In fiscal year 2000, CDC awarded grants totaling approximately \$11 million to 48 states and four major urban health departments to improve and upgrade their surveillance and epidemiological capabilities.

As we previously reported, even the initial West Nile virus outbreak in 1999, which was relatively small and occurred in an area with one of the nation's largest local public health agencies, taxed the federal, state, and local laboratory resources.<sup>37</sup> Both the New York state and CDC laboratories were quickly inundated with requests for tests during the West Nile outbreak, and because of the limited capacity at the New York laboratories, the CDC laboratory handled the bulk of the testing. Officials indicated that the CDC laboratory would have been unable to respond to another outbreak, had one occurred at the same time. In order to improve laboratory capacity for biological agents, CDC awarded grants during fiscal year 2000 totaling approximately \$6 million to 42 states and two major urban health departments. At the same time, it began to upgrade its own laboratory

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<sup>34</sup>See GAO-01-822, Sept. 20, 2001, p. 90

<sup>35</sup>Smithson and Levy, p. 245.

<sup>36</sup>Smithson and Levy, p. 245.

<sup>37</sup>See *West Nile Virus Outbreak: Lessons for Public Health Preparedness* (GAO/HEHS-00-180, Sept. 11, 2000), p. 21.

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capacity. CDC officials told us that the grants are beginning to improve state and local public health agencies' abilities to detect and identify biological agents. We plan to examine the efforts in preparing state and local authorities to address the public health and medical consequences of a bioterrorist attack in a future report.

Inadequate training and planning for bioterrorism response by hospitals is a major problem, according to recent reports and to federal officials. The Gilmore Panel concluded that the level of expertise in recognizing and dealing with a terrorist attack involving a chemical or biological agent is problematic in many hospitals.<sup>38</sup> Other recent reports have concluded that hospitals need to improve their preparedness for mass casualty incidents, such as a bioterrorist attack.<sup>39</sup> In addition, a recent study found that hospitals often lack the basic tools, such as Internet access, to communicate effectively with field units, health departments, and laboratories.<sup>40</sup> Local officials told us that it has been difficult to get hospitals and medical personnel to participate in local training, planning, and exercises to improve their preparedness.

Several federal and local officials reported that there is little or no excess capacity in the health care system in most communities for accepting and treating mass casualty patients. A recent study concluded that the patient load of a regular influenza season in the late 1990s overtaxed primary care facilities,<sup>41</sup> and other studies have reported that emergency rooms in major metropolitan areas such as Boston are routinely filled and unable to accept patients in need of urgent care.<sup>42</sup> According to a local official, the health care system might not be able to handle the aftermath of a disaster, attack,

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<sup>38</sup>Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, p. 32.

<sup>39</sup>American Hospital Association, *Hospital Preparedness for Mass Casualties*, Summary of an Invitational Forum, Aug. 2000. D.C. Wetter, W.E. Daniell, and C.D. Treser, "Hospital Preparedness for Victims of Chemical or Biological Terrorism," *American Journal of Public Health*, Vol. 91 (2001), pp. 710-16.

<sup>40</sup>Smithson and Levy, p. 273.

<sup>41</sup>Smithson and Levy, p. 262.

<sup>42</sup>J. Richards, M. Navarro, and R. Derlet, "Survey of Directors of Emergency Departments in California on Overcrowding," *Western Journal of Medicine*, Vol. 172 (2000), pp. 385-388. R. Derlet, J. Richards, and R. Kravitz, "Frequent Overcrowding in U.S. Emergency Departments," *Academic Emergency Medicine*, Vol. 8, No. 2 (2001), pp. 151-55.

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or epidemic because of the problems caused by overcrowding and the lack of additional capacity. OEP officials told us that its Metropolitan Medical Response System (a program to improve local medical response capabilities) can assist communities in planning, including identifying alternative care facilities for treating victims, identifying reserve medical personnel that could be brought in during an emergency, and planning to treat mass casualties within and outside of hospitals.<sup>43</sup> CDC, working with the Association for Professionals in Infection Control and Epidemiology, has developed guidance for individual hospitals on how to plan for a sudden and significant increase in infectious disease patients, relevant for the handling of anthrax, botulism, plague, and smallpox cases.

According to one report, local officials are also concerned about whether the federal government could quickly deliver enough medical teams and resources to help after a biological attack.<sup>44</sup> Federal officials said that assets, such as the Disaster Medical Assistance Teams, could be on site within 12 to 24 hours. Local officials who have deployed with such teams said that cities would probably be on their own for the first 24 to 72 hours, and that the number of medical workers that could arrive even in that time frame might fall far short of what would be needed.<sup>45</sup> Local officials also told us that they were concerned about the time and resources required to prepare and distribute drugs from the National Pharmaceutical Stockpile during an emergency. Partially in response to these concerns, CDC has developed training for state and local officials on using the stockpile and will deploy a small staff with the supplies to assist the local jurisdiction with distribution.

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## Agency Comments

We provided a draft of this report to the eleven departments and agencies for their review in August 2001. The Department of Commerce, DOD, HHS, and DOJ submitted written comments that are provided in appendixes XV through XVIII. They also provided technical comments. The Department of the Treasury, VA, and FEMA provided technical comments only. The audit liaison from DOT provided oral technical comments on a draft of this

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<sup>43</sup>See app. VIII for a description of the Metropolitan Medical Response System.

<sup>44</sup>Smithson and Levy, p. 227.

<sup>45</sup>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.

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report; the audit liaison from EPA responded that the agency had no comments on the report. The technical liaison from DOE provided oral comments noting the department's concurrence with the draft report. USDA did not provide comments on the report. Written and oral comments from all of these agencies have been incorporated in the report, as appropriate.

The Department of Commerce stated that the report did not sufficiently discuss its integrated efforts with DOD, DOJ, and FEMA to develop chemical and biological protective equipment standards. We have provided additional detail on this activity in appendix V. In its technical comments DOD expressed a concern that the report did not reflect some of DOD's bioterrorism research and preparedness activities which are focused on battlefield scenarios and crisis management. We have not included these activities because they are outside the scope of our work, which focuses on the public health and medical consequences of a bioterrorist attack on the civilian population. HHS noted the importance of the systems and programs described in the report that could provide assistance to state and local governments in the event of a bioterrorist attack. HHS also stated that many of the services needed in response to a bioterrorist attack would be needed to respond to other emergencies, including natural disasters and other types of terrorist attacks, and we added this information to the report. In response to a DOJ technical comment, we also modified the report to indicate that the department stated it is appropriate for different agencies to maintain separate lists of biological threats, noting that such lists may have different purposes.

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We are sending copies of this report to the Secretaries of Agriculture, Commerce, Defense, Energy, Health and Human Services, Transportation, the Treasury, and Veterans Affairs; the Attorney General; the Administrator of the Environmental Protection Agency; the Director of the Federal Emergency Management Agency; and other interested officials.

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If you or your staffs have any questions about this report, please call me at (202) 512-7118. Another contact and key contributors are listed in appendix XIX.

A handwritten signature in black ink that reads "Janet Heinrich". The signature is written in a cursive, flowing style.

Janet Heinrich  
Director, Health Care—Public Health Issues

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## List of Committees

The Honorable Edward M. Kennedy  
Chairman  
The Honorable Judd Gregg  
Ranking Minority Member  
Committee on Health, Education,  
Labor, and Pensions  
United States Senate

The Honorable Robert C. Byrd  
Chairman  
The Honorable Ted Stevens  
Ranking Minority Member  
Committee on Appropriations  
United States Senate

The Honorable W. J. "Billy" Tauzin  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable C.W. Bill Young  
Chairman  
The Honorable David Obey  
Ranking Minority Member  
Committee on Appropriations  
House of Representatives



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# Biological Agents and Pathogens Mentioned in This Report

Agent/pathogen	Description
Anthrax ( <i>Bacillus anthracis</i> )	Transmission is possible through three different routes: direct skin contact with contaminated animals, ingestion of contaminated meat, or inhalation of airborne particles. Cutaneous anthrax causes itching, followed by papular lesions (red elevation on skin) and then vesicular lesions (blisterlike elevation on skin containing fluid). Untreated infections may spread to lymph nodes and to the bloodstream, leading to septicemia (presence of pathogenic microorganisms in the blood). Untreated cutaneous anthrax has a case fatality rate between 5 and 20 percent. Gastrointestinal anthrax has a mortality rate of 25 to 60 percent. Patients present with nausea, vomiting, severe diarrhea, fever, abdominal pain, and gastrointestinal bleeding. Inhalatory anthrax causes necrotizing hemorrhagic mediastinitis (destruction of the structures of the middle chest caused by the toxin). Initial presentation resembles viral syndrome—fever, malaise, fatigue, nonproductive cough. Treatment after onset of symptoms of inhalatory anthrax is not effective, with mortality of 90 percent.
Plague ( <i>Yersinia pestis</i> )	Transmission is through the bite of infected fleas or handling of tissues of infected animals, such as rodents and rabbits. After bite of infected flea, patient usually develops bubonic plague, in which patients present with malaise, high fever, and tender lymph nodes. This may progress spontaneously to septicemic plague, with fever, chills, absolute exhaustion, abdominal pain, shock, and bleeding into skin and other organs. Neither bubonic nor septicemic plague spreads person-to-person. A small percentage of patients go on to develop pneumonic plague, which can be spread by respiratory droplet. For untreated pneumonic plague, mortality approaches 100 percent.
Salmonellosis ( <i>Salmonella</i> )	Transmission is by ingestion of infected food, including food contaminated by feces of an infected animal or person. Symptoms include headache, nausea, vomiting, chills, diarrhea, fever, and abdominal cramping. Deaths are uncommon.

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**Appendix I**  
**Biological Agents and Pathogens Mentioned**  
**in This Report**

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(Continued From Previous Page)

<b>Agent/pathogen</b>	<b>Description</b>
Smallpox ( <i>variola major</i> )	Transmission is person-to-person, and the disease is highly contagious. The disease was eradicated, and routine immunizations have ceased. Any immunity conferred by the vaccine has waned. Patients present with high fever, malaise, absolute exhaustion, headache, and backache. A maculopapular rash (discolored spots on skin; some raised, some not raised) appears on mucosa of the mouth and pharynx, face, and forearms and spreads to trunk and legs. Within 1 to 2 days, the rash becomes vesicular, and later, pustular (small elevation on skin containing pus), which leaves pitting scars after recovery. Mortality rate is 30 percent or more.
Tularemia ( <i>Francisella tularensis</i> )	Transmission is through the bite of infected ticks, by drinking contaminated water, or rarely through the bite of coyote, squirrel, skunk, hog, cat, or dog whose mouth presumably was contaminated by eating an infected animal. Most times, patients present with painless ulcers at the site of introduction and swelling regional lymph node. Ingestion of organisms in contaminated water or food may produce painful pharyngitis (inflammation of the throat area), abdominal pain, diarrhea, and vomiting. Inhalation of infectious material may be followed with pneumonic involvement or a primary septicemic syndrome with a 30 to 60 percent mortality rate if untreated.
West Nile virus (flavivirus)	Transmission is through the bite of an infected mosquito. Most infections are mild, and symptoms include fever, headache, and body aches, often with skin rash and swollen lymph glands. More severe infections may be marked with headache, high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, and paralysis. The virus is rarely fatal.

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# Scope and Methodology

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We began our work by identifying the federal departments and agencies that have a role in the public health and medical consequences of a bioterrorist attack on the civilian population. We reviewed the Office of Management and Budget's *Annual Report to Congress on Combating Terrorism* to determine which federal agencies receive funding for activities on terrorism.<sup>1</sup> We then reviewed the Federal Response Plan to understand the roles of each agency in the consequence management of a possible bioterrorist attack. See appendix III for more information regarding the Federal Response Plan. We also reviewed each agency's performance plan to determine its specific activities on bioterrorism.

We identified the following federal departments and agencies as having a role in the public health and medical consequences of a bioterrorist attack on the civilian population: the Departments of Agriculture (USDA), Commerce, Defense (DOD), Energy (DOE), Health and Human Services (HHS), Justice (DOJ), Transportation (DOT), the Treasury, and Veterans Affairs (VA); the Environmental Protection Agency (EPA); and the Federal Emergency Management Agency (FEMA). We interviewed program directors at each department and agency about their activities related to the research on and preparedness for the public health and medical consequences of a bioterrorist attack against the civilian population in fiscal year 1998 through fiscal year 2001. We asked them to identify activities with dual-use purposes, such as preparedness activities for biological and chemical attacks, and surveillance activities for emerging infectious diseases. We also asked program directors about the coordination of interagency activities and requested copies of memorandums of understanding and memorandums of agreement to identify working relationships between departments and agencies.

We asked the program directors to provide the amount of authorized, appropriated, and obligated federal funds for activities on bioterrorism in fiscal year 1998 through fiscal year 2001. Some departments and agencies could not provide the categories of funding we requested. For example, some agencies could only provide appropriations estimates, while others could only provide expenditure data. Because these different characterizations of budget data are not necessarily additive across agencies for specific fiscal years, we have provided budgetary information summarized only by agency and refer to this generally as "funding

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<sup>1</sup>The report does not differentiate between biological, chemical, nuclear, and radiological terrorism.

information.” We relied on the departments and agencies to identify relevant programs and to provide funding information. We have not audited or otherwise verified the information provided.

Information concerning the effectiveness of federal efforts to prepare state and local authorities for a bioterrorist event was obtained by reviewing our previous work, as well as reports from training exercises, including the multiagency Top Officials 2000 exercise (TOPOFF 2000). We interviewed officials who participated in TOPOFF 2000. We also reviewed reports by the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (also known as the Gilmore Panel), and the Henry L. Stimson Center and articles from peer-reviewed journals.

We conducted our work from January through September 2001 in accordance with generally accepted government auditing standards.

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# Summaries of Selected Federal Policy and Planning Documents

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The Federal Response Plan, originally drafted in 1992 and updated in 1999, is authorized under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 93-288, as amended). The Stafford Act authorizes the President to provide financial and other forms of assistance to state and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following presidentially declared major disasters and emergencies. The Federal Response Plan lays out the manner in which the federal government responds to domestic situations in which the President has declared an emergency requiring federal disaster assistance. Presidential Decision Directive 39 was issued after the Oklahoma City bombing in 1995, and it provides a framework for how the federal government will respond to weapons of mass destruction (WMD) terrorism within the United States, reaffirming the Federal Response Plan. The Federal Response Plan is an all-hazards approach document, with an annex specific to terrorism added by FEMA in 1997. In 1998, Presidential Decision Directive 62 was issued, which further describes the federal agency roles in preparing for and responding to WMD terrorism. In 2001, the U.S. Government Interagency Domestic Terrorism Concept of Operations Plan (CONPLAN) was issued, which explains agencies' responsibilities under Presidential Decision Directives 39 and 62 in more detail.<sup>1</sup>

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## Federal Response Plan With Terrorism Incident Annex

The Federal Response Plan lays out the manner in which the federal government responds to domestic situations in which the President has declared an emergency requiring federal disaster assistance. The plan outlines the planning assumptions, policies, concept of operations, organizational structures, and specific assignment of responsibilities to lead departments and agencies in providing federal assistance. The plan is intended to be the single source for an all-hazards response to terrorism, categorizing the types of federal assistance into specific emergency support functions. Primary and supporting agencies are listed for each emergency support function. Emergency support function number 8 is the Health and Medical Services Annex. HHS is the primary agency for this annex and could receive support from USDA, DOD, DOE, DOJ, DOT, VA, EPA, FEMA, and other agencies and organizations to assist state and local jurisdictions. Through the Health and Medical Services Annex, coordinated

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<sup>1</sup>For a more complete discussion on these and other documents, see *Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001), pp. 131-136.

federal assistance is provided to supplement state and local resources in response to public health and medical care needs following a major disaster or emergency. The Terrorism Incident Annex establishes a general concept of operations for the federal response to a terrorist incident, including the concurrent operation under other federal plans.

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### Presidential Decision Directive 39, U.S. Policy on Counterterrorism

Under Presidential Decision Directive 39, which was issued in 1995, DOJ, acting through the Federal Bureau of Investigation (FBI), is the overall lead federal agency for domestic terrorist incidents. The FBI is the lead agency for crisis management and FEMA is the lead agency for consequence management in cases of terrorism.<sup>2</sup> This directive states that the director of FEMA shall ensure that the Federal Response Plan is adequate to respond to the consequences of terrorism, including terrorism involving WMDs directed against the U.S. population.

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### Presidential Decision Directive 62, Combating Terrorism

Presidential Decision Directive 62, which was issued in 1998, organizes and clarifies the roles and activities of many agencies responsible for combating a wide range of terrorism preparedness and response activities. This directive calls for the provision of necessary equipment and training to state and local responders and the development of stockpiles of vaccines and specialized medicines. It also created a category of special events called National Security Special Events, which are events of such significance that they warrant greater federal planning and protection than other special events. Such events have included presidential inaugurations, major political party conventions, and Olympic games. The U.S. Secret Service is responsible for the design, planning, and implementation of security at designated National Security Special Events.

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<sup>2</sup>Crisis management is predominantly a law enforcement function and includes measures to identify, acquire, and plan the use of resources needed to anticipate, prevent, and/or resolve a threat or act of terrorism. Crisis management also includes assurance of public health and safety. Consequence management includes measures to protect public health, safety, and the environment; to restore essential government services; and to provide emergency relief to governments, businesses, and individuals affected by the consequences of terrorism.

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## U.S. Government Interagency Domestic Terrorism Concept of Operations Plan

The U.S. Government Interagency Domestic Terrorism Concept of Operations Plan (CONPLAN) was primarily developed through the efforts of DOD, DOE, HHS, DOJ, EPA, and FEMA. It was ratified in January 2001 and is designed to provide overall guidance to federal, state, and local agencies concerning how the federal government would respond to a potential or actual terrorist threat or incident that occurs in the United States, particularly one involving a WMD. As a follow-up to the Federal Response Plan Terrorism Incident Annex, it facilitates interdepartmental coordination of crisis and consequence management activities and states in more detail the responsibilities of primary and supporting agencies during a terrorist attack. HHS is currently developing a bioterrorism annex to this plan, which will address issues concerning the appropriate response to acts of bioterrorism.



# Department of Agriculture

USDA has become involved in activities on bioterrorism because of the increasing realization that the food supply may become a vehicle for a biological attack against the civilian population.<sup>1</sup> Biological attacks on the health of animals and plants are also important to recognize because there are a number of diseases and toxins that can cause illness or death in humans, such as West Nile virus, that can be carried or spread by animals and plants. However, USDA receives little funding specifically for activities on bioterrorism. Most of the agency's activities on terrorism are conducted using general program funds (see table 4).

**Table 4: Reported Funding for Activities on Bioterrorism at USDA (Dollars in millions)**

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>Agricultural Research Service</b>				
<b>Research activities</b>				
Detection of biological agents	0	0	0	\$0.5
<b>Animal and Plant Health Inspection Service</b>				
<b>Preparedness activities</b>				
Education and training programs	0	0	0	\$0.2
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>\$0.7</b>

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

Source: USDA.

## Office of Crisis Planning and Management

The Office of Crisis Planning and Management is a department-level office under the Assistant Secretary for Administration. The office is responsible for coordinating activities on terrorism across USDA. The Director of the Office of Crisis Planning and Management serves as the department's Emergency Coordinator and coordinates USDA's response to all disasters, crises, and emergencies. The office coordinates emergency management activities with other federal agencies, including FEMA, and coordinates USDA's role under the Federal Response Plan. The office also operates the

<sup>1</sup>For example, USDA and DOD jointly planned and conducted a multiagency simulation of a terrorist deliberately contaminating food with a biological agent. See *Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination* (GAO/RCED-00-3, Oct. 27, 1999).

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department's Emergency Operations Centers, where representatives of organizational elements of USDA gather to manage and coordinate emergency response functions.

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## Agricultural Research Service

The Agricultural Research Service conducts research for several federal agencies, including agencies within USDA, such as the Animal and Plant Health Inspection Service and the Food Safety and Inspection Service.

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### Research Activities

The Agricultural Research Service is working on a system to improve on-site rapid detection of biological agents in animals, plants, and food in cooperation with DOD and HHS. The agency received \$500,000 in fiscal year 2001 to sponsor this research (see table 4).

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### Preparedness Activities

The Agricultural Research Service is also repairing and modernizing the Plum Island Animal Disease Center in New York state to improve detection capacity for diseases and toxins that could affect animals and humans. The center provides definitive diagnoses of foreign animal diseases in North America.

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## Animal and Plant Health Inspection Service

The Animal and Plant Health Inspection Service is responsible for the health of animals and plants and has a role in responding to biological agents that are zoonotic, that is, capable of infecting both animals and humans.

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### Preparedness Activities

If a disease outbreak occurred in humans, this agency would work with other federal, state, and local departments and agencies to determine the source of the exposure to the disease. If the exposure was determined to be related to an animal, the agency's veterinary epidemiologists would be responsible for tracing back the source of the animal exposure. They would then be responsible for controlling and eradicating the outbreak to minimize further exposure to both animals and humans. The Animal and Plant Health Inspection Service reported funding of \$150,000 in fiscal year 2001 to develop educational materials and training programs specifically dealing with activities on bioterrorism (see table 4).

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**Food Safety Inspection Service**

The Food Safety Inspection Service provides emergency preparedness for foodborne incidents, including a bioterrorist attack.

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**Preparedness Activities**

The Food Safety Inspection Service routinely responds to actual and potential food-borne disease outbreaks. Its response to a bioterrorist incident would be the same as its response to any food-borne disease outbreak. The Food Safety Inspection Service has not received any funding for activities on bioterrorism.

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# Department of Commerce

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Activities on bioterrorism within the Department of Commerce center on developing performance standards for emergency response equipment and are carried out in conjunction with DOD, DOJ, and HHS.

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## Office of Law Enforcement Standards

The Office of Law Enforcement Standards at the Department of Commerce's National Institute of Standards and Technology is the principal agent for equipment standards development for the criminal justice and public safety communities, including biological response equipment. The office develops standards, test procedures, and user guides that help ensure that the equipment the communities purchase and the technologies they use are safe, dependable, and effective. The department reported receiving \$0.5 million in fiscal year 2000 and \$4.6 million in fiscal year 2001 from DOJ for research. It reported funding, also from DOJ, of \$0.3 million annually in fiscal year 1999 and fiscal year 2000 for preparedness activities.

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## Research Activities

The Office of Law Enforcement Standards develops performance standards and evaluates test methods and procedures for WMD and explosive emergency response equipment. The office manages research projects with the National Institute for Occupational Safety and Health and the U.S. Army Soldier Biological and Chemical Command to develop standards for respiratory and other personal protective equipment, and detectors and decontamination equipment designed to protect against biological and chemical agents

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## Preparedness Activities

The Office of Law Enforcement Standards also issues technical reports and publishes user guides for WMD and explosive response equipment. The office is the executive agent of the Standards Coordination Committee of the Interagency Board for Equipment Standardization and Interoperability. The Interagency Board, which is co-chaired by DOD and DOJ, develops and maintains a Standardized Equipment List, which lists essential items for responding to terrorist WMD attacks. Other agencies participating in this effort include HHS, DOE, DOT, EPA, and FEMA. The Standardized Equipment List can be used by local public safety organizations when developing response plans and acquiring response equipment.

# Department of Defense

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Although DOD is primarily responsible for service members in the battlefield, it would provide support to the primary federal agency under the Federal Response Plan in the event of an emergency, including a bioterrorist attack on the civilian population. Research at DOD is targeted for the battlefield, but is often shared with other agencies to benefit the civilian population. DOD has civil support responsibilities through the Defense Advanced Research Projects Agency, the Joint Task Force for Civil Support, the National Guard, and the U.S. Army. The Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict provides oversight by supervising policy, requirements, priorities, resources, and programs to ensure adherence to approved policy and planning guidelines. See table 5 for DOD's reported funding for activities on domestic terrorism. In addition, we provide information on other activities for which DOD could not provide funding data

Table 5: Reported Funding for Activities on Domestic Terrorism at DOD (Dollars in millions)

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>Joint Task Force for Civil Support</b>				
<b>Preparedness activities</b>				
Training, exercises, travel, contingency operations, garrison support, communications, support contracts	0	0	\$3.4	\$6.5
Communication link system	0	0	0	\$2.2
<b>National Guard</b>				
<b>Preparedness activities</b>				
Weapons of Mass Destruction—Civil Support Teams	0	\$73.0	\$70.0	\$93.3
<b>U.S. Army</b>				
<b>Preparedness activities<sup>a</sup></b>				
Program management	\$3.0	\$2.5	\$3.3	\$0.9
Expert assistance	\$6.3	\$4.8	\$4.7	\$1.9
Training	\$21.6	\$30.8	\$10.9	0
Director of military support travel	0	0	\$0.3	\$0.1
Exercises and testing	\$10.2	\$7.9	\$8.4	\$6.2
Chemical Biological—Rapid Response Teams	\$1.9	\$1.9	\$1.9	\$2.6
<b>Total</b>	<b>\$43.0</b>	<b>\$120.9</b>	<b>\$102.9</b>	<b>\$113.7</b>

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

<sup>a</sup>Funding for preparedness activities has decreased over time due to a transfer of responsibility for these activities under the Domestic Preparedness Program from DOD to DOJ beginning October 1, 2000.

Source: DOD.

## Defense Advanced Research Projects Agency

The Defense Advanced Research Projects Agency is the central research and development organization for DOD. It manages and directs basic and applied research and development projects for the department. Success of the projects may provide military advances as well as civilian applications.

## Research Activities

The Defense Advance Research Projects Agency's current work includes genetic sequencing to enable the identification of molecular targets for the design of detection, diagnostic, and therapeutic strategies that will aid service members and may be used for the civilian population. The agency's objectives include developing the capacity to detect the presence of infection by a biological agent, differentiate the agent from other

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pathogens, and identify the pathogen in the absence of recognizable clinical signs. The agency often shares research results with other agencies to benefit the civilian population. DOD has initiated discussions on how best to evaluate and transition select technology for bioterrorism defense. The agency does not receive funding to conduct research on the public health and medical consequences of a bioterrorist attack against civilian populations.

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## Joint Task Force for Civil Support

The mandate of the Joint Task Force for Civil Support at the Joint Forces Command is to plan for and integrate DOD's support to FEMA for WMD events in the continental United States.

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## Preparedness Activities

The Joint Task Force for Civil Support plans and, when directed, commands and controls DOD's WMD and high-yield explosive consequence management capabilities in providing support during a domestic bioterrorist incident. The Joint Task Force for Civil Support provides support through FEMA and the Federal Response Plan during an incident and works with other federal agencies on planning and exercises. The Joint Task Force for Civil Support and the Joint Forces Command are working in support of FEMA and HHS' Office of Emergency Preparedness (OEP) to plan Force Packages, which are groupings of units that the military would designate to respond to an incident. It also coordinates with OEP on the planning for medical support for any WMD incident. Reported funding for Joint Task Force activities on terrorism was \$3.4 million for fiscal year 2000 (see table 5). It rose to \$8.7 million for fiscal year 2001, including \$6.5 million for individual unit training, exercises, travel, contingency operations, garrison support, purchased communications, and general support contracts, and \$2.2 million for the establishment of a communication link system.

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## National Guard

The National Guard Weapons of Mass Destruction—Civil Support Teams are meant to deploy to assist local responders in determining the precise nature of an attack and provide medical and technical advice. The teams also help pave the way for the identification and arrival of follow-on state and federal military response assets.

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## Preparedness Activities

The National Guard Weapons of Mass Destruction—Civil Support Team program is intended to help prepare the United States against terrorist use of WMDs. Originally, 10 civil support teams (formerly called Rapid Assessment and Initial Detection teams) were located in alignment with the 10 FEMA regional offices.<sup>1</sup> Congress authorized an additional 17 civil support teams in fiscal year 2000, and another 5 in fiscal year 2001.<sup>2</sup> DOD reported funding of \$70 million and \$93.3 million for these teams in fiscal year 2000 and fiscal year 2001, respectively (see table 5).

Although the teams are federally funded and trained, they are primarily under the command and control of the governors of the states in which they are located, to facilitate their rapid deployment. Their roles can include entering a contaminated area to gather air, soil, and other samples for on-site evaluation. They also are to assist a local incident commander in determining the nature and extent of an attack or incident, provide expert technical advice on WMD response operations, and help identify and support the arrival of follow-on state and federal military response assets. Teams are designed to be ready to deploy within 4 hours to anywhere within their area of responsibility, with their own detection and decontamination equipment, medical supplies, and protective gear. As of August 15, 2001, six civil support teams have been certified as fully mission capable.

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## U.S. Army

The U.S. Army engages in research and preparedness activities on bioterrorism that have benefits for both military and civilian populations.

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## Research Activities

The U.S. Army Medical Research Institute of Infectious Diseases is a biological research facility that deals with militarily relevant infectious diseases and biological agents. The institute conducts research to develop vaccines, drugs, and diagnostics for laboratory and field use, as well as

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<sup>1</sup>The civil support teams are located in California, Colorado, Georgia, Illinois, Massachusetts, Missouri, New York, Pennsylvania, Texas, and Washington.

<sup>2</sup>The 17 additional teams for fiscal year 2000 are located in Alaska, Arizona, Arkansas, California (creating a second team), Florida, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Maine, Minnesota, New Mexico, Ohio, Oklahoma, South Carolina, and Virginia. As of January 2001, team locations had not been determined for the additional five teams for fiscal year 2001.



formulates strategies, information, procedures, and training programs for medical defense against biological agents. The institute has a Biosafety Level 4 laboratory, which is used for dangerous, exotic agents that pose a high risk of life-threatening diseases and have no vaccines or drugs available for treatment. The institute also provides definitive identification of biological agents and diagnosis of the diseases they produce. It provides professional expertise on issues related to technologies, therapeutics, prophylactics, and education that could be used to support readiness for a bioterrorist incident.

The institute helps supply diagnostic reagent<sup>3</sup> sets to the Centers for Disease Control and Prevention (CDC) and serves CDC's Laboratory Response Network as a confirmatory diagnostic laboratory and subject matter expert.<sup>4</sup> It provides support for the development of an anthrax vaccine by the National Institutes of Health (NIH). Other ongoing work with CDC and NIH includes the development of a database for genetically engineered threats. It works with CDC and the FBI to assist with potential bioterrorism incidents on a consultation or confirmatory basis. The institute, along with the U.S. Army Soldier Biological and Chemical Command, the Director of Military Support, and the Joint Task Force for Civil Support, is currently working on plans to provide support in the event of a domestic bioterrorist incident. The institute does not receive funding to conduct research on the public health and medical consequences of a bioterrorist attack against civilian populations.

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## Preparedness Activities

The Domestic Preparedness Program<sup>5</sup> was formed in response to the National Defense Authorization Act of Fiscal Year 1997 (P.L. 104-201) and required DOD to enhance the capability of federal, state, and local emergency responders regarding terrorist incidents involving WMDs and high-yield explosives.

The program was developed through work groups with expertise with WMD response skills. Work groups were composed of experts from

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<sup>3</sup>A reagent is a substance used to detect the presence of another substance.

<sup>4</sup>For more information on the Laboratory Response Network, see app. VIII.

<sup>5</sup>For more information concerning the Domestic Preparedness Program, see *Combating Terrorism: Opportunities to Improve Domestic Preparedness Program Focus and Efficiency* (GAO/NSIAD-99-3, Nov. 12, 1998).

municipalities, counties, and states and federal first responders having responsibility for responding to WMD terrorism incidents. The work groups developed courses and training in accordance with the Occupational Safety and Health Administration, the National Fire Protection Agency, and standards set by the Joint Commission for the Accreditation of Healthcare Organizations.

DOD created the Domestic Preparedness Program with four major elements: the City Training Program, the Exercises Program, the Expert Assistance Program, and the Chemical Biological—Rapid Response Team. The City Training Program provides training for senior local officials and emergency first responders and trainers in 120 cities. It includes equipment loans to the local areas by DOD.

The Exercises Program includes the federal, state, and local exercise and the Biological Warfare—Improved Response Program. The Improved Response Program is a multiagency, intergovernmental, and interdisciplinary effort designed to improve our nation's ability to respond to domestic acts of terrorism involving biological agents. Program activities include testing and evaluating biological agent response concepts, developing technical and operational requirements for first responder equipment, and conducting exercises to test the major components and integrated response plan. Lessons learned from biological weapons tabletop exercises<sup>6</sup> on the medical consequence management of a biological attack have been applied to the Improved Response Program.

Expert Assistance Program activities include the emergency responders' WMD help line (which provides nonemergency planning and technical information), a hot line (a component of the National Response Center, which is located at the Coast Guard's Headquarter Command Center and allows the caller to alert federal agencies and speak with technical experts who can provide critical incident management information), a Web page (which provides information about the Domestic Preparedness Program), equipment testing and reports, a chemical-biological database (a repository of information about chemical and biological weapons and agents,

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<sup>6</sup>With tabletop exercises, participants work through a simulation of a bioterrorism incident, starting with the incubation period (the time between initial exposure to a biological agent and the onset of symptoms), followed by the recognition and initial response, and finally the challenges of integrating federal assets in the response and recovery efforts.

detectors, and protection and decontamination equipment), and subject matter experts (who provide support for technical inquiries).

The Chemical Biological—Rapid Response Team coordinates and manages all DOD technical capabilities tasked to support a crisis response or consequence management operation. The Rapid Response Team delivers skills, training, and equipment to the scene of a chemical or biological incident.

As of October 1, 2000, the City Training Program, portions of the Improved Response Program, and the help line, hot line, and Web page elements of the Expert Assistance Program were transferred from DOD to DOJ. DOD will retain responsibility for the chemical-biological database and equipment testing and the Chemical Biological—Rapid Response Team. DOD also will retain responsibility for the annual federal, state, and local exercise through fiscal year 2001. DOD will share responsibility for the Improved Response Program with DOJ.

# Department of Energy

DOE is developing new capabilities to counter chemical and biological threats. DOE expects the results of its research to be public and possibly lead to the development of commercial products in the domestic market. Table 6 lists funding for DOE's research activities on terrorism.

**Table 6: Reported Funding for Activities on Terrorism at DOE (Dollars in millions)**

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>Chemical and Biological National Security Program</b>				
<b>Research activities</b>				
Chemical and biological detection	\$7.3	\$7.5	\$9.5	\$10.9
Modeling and prediction	\$2.3	\$3.0	\$4.7	\$5.5
Decontamination and restoration	\$1.8	\$1.7	\$2.2	\$1.5
Biological foundations	\$4.5	\$5.0	\$10.0	\$10.9
System analysis (includes Domestic Demonstration and Application Programs)	\$1.7	\$1.8	\$5.5	\$9.1
Other	\$0.4	0	\$3.6	\$1.7
<b>Total</b>	<b>\$18.0</b>	<b>\$19.0</b>	<b>\$35.5</b>	<b>\$39.6</b>

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

Source: DOE.

## The Office of Defense Nuclear Nonproliferation

Among other duties, the Office of Defense Nuclear Nonproliferation is responsible for reducing global danger from WMDs. Within this office is the Chemical and Biological National Security Program, which participates in research related to bioterrorism.

## Research Activities

The mission of the Chemical and Biological National Security Program is to develop, demonstrate, and deliver technologies and systems that will lead to major improvements in the United States' capability to prepare for and respond to chemical or biological attacks. The program was begun in 1997 to involve DOE and its laboratories in research and demonstrations of terrorism preparedness, including, but not limited to, bioterrorism.

The Chemical and Biological National Security Program is divided into three components: analytical studies, technology development, and Domestic Demonstration and Application Programs. Analytical studies

help guide the overall program direction as well as individual technical areas. In general, these studies use analytical and simulation models to assess the value of technology in system applications. Technology development is the core research and development program element, with the purpose of enhancing response capabilities across the full spectrum of chemical and biological terrorism. In general, development is focused on technologies for which the basic science is already understood. Technology development is categorized into four areas: (1) chemical and biological detection, (2) modeling and prediction, (3) decontamination and restoration, and (4) biological foundations (that is, molecular biology-based capabilities to support efforts in advanced detection, attribution, and medical countermeasures). Finally, Domestic Demonstration and Application Programs seek to integrate current technology into capable, prototype operational systems directed at specific applications in 2 to 3 years.

One current demonstration project is the Biological Aerosol Sentry and Information System. This portable system is intended to provide early warning of airborne biological incidents for special events such as large assemblies and dignitary visits. This system is planned for use in civilian settings to detect a biological incident within a few hours of an attack, early enough to mount an effective medical response. This system is intended to estimate where an attack occurred, exposure levels, and duration, all of which would assist the public health system in identifying the population requiring treatment.

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# Department of Health and Human Services

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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.

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## 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.

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## 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.

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## 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.

**Appendix VIII**  
**Department of Health and Human Services**

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

<b>Program/initiative<sup>a</sup></b>	<b>Fiscal year 1998</b>	<b>Fiscal year 1999</b>	<b>Fiscal year 2000</b>	<b>Fiscal year 2001</b>
<b>Research activities</b>				
Research and development	0	0	\$40.5	\$42.9
Independent studies <sup>b</sup>	0	\$1.8	\$7.7	\$2.6
Worker safety	0	0	0	\$1.1
<b>Preparedness activities</b>				
<b>Upgrading state and local capacity</b>	<b>0</b>	<b>\$55.0</b>	<b>\$56.9</b>	<b>\$66.7</b>
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
<b>Upgrading CDC capacity</b>	<b>0</b>	<b>\$12.0</b>	<b>\$13.9</b>	<b>\$20.4</b>
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
<b>Preparedness and response planning</b>	<b>0</b>	<b>\$1.0</b>	<b>\$2.3</b>	<b>\$9.2</b>
<b>Building the National Pharmaceutical Stockpile</b>	<b>0</b>	<b>\$51.0</b>	<b>\$51.8</b>	<b>\$51.0</b>
<b>Total</b>	<b>0</b>	<b>\$120.8</b>	<b>\$173.1</b>	<b>\$193.9</b>

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

<sup>a</sup>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.

<sup>b</sup>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.

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## 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.

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## 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.

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## 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.<sup>1</sup> 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

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<sup>1</sup>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.<sup>2</sup>

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## 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).

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<sup>2</sup>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).

**Appendix VIII**  
**Department of Health and Human Services**

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

<b>Program/initiative</b>	<b>Fiscal year 1998<sup>a</sup></b>	<b>Fiscal year 1999</b>	<b>Fiscal year 2000</b>	<b>Fiscal year 2001</b>
<b>Center for Biologics Evaluation and Research</b>				
<b>Research activities</b>				
Premarket evaluation of vaccines, develop vaccines	a	\$1.2	\$7.5	\$7.0
<b>Center for Devices and Radiological Health</b>				
<b>Research activities</b>				
Develop data requirements for approving devices intended to detect exposure to or infection with biological agents	a	\$0.1	\$0.8	\$0.9
<b>Center for Drug Evaluation and Research</b>				
<b>Research activities</b>				
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
<b>Center for Food Safety and Applied Nutrition</b>				
<b>Preparedness activities</b>				
Monitor food supply, communicate with state and local officials	a	0	0	\$0.3
<b>Center for Veterinary Medicine</b>				
<b>Preparedness activities</b>				
Communicate with state officials, held meeting on bioterrorism risk	a	\$0.1	\$0.1	\$0.3
<b>National Center for Toxicological Research</b>				
<b>Research activities</b>				
Define biological mechanisms of action underlying toxicity of products, identify indications of toxicity associated with biological agents	a	\$0.2	\$0.1	\$0.5
<b>Preparedness activities</b>				
Participate in training meetings	a	b	b	b
<b>Office of Regulatory Affairs</b>				
<b>Preparedness activities</b>				
Communicate with other agencies and the public, conduct investigations	c	c	c	\$1.5
<b>Total<sup>d</sup></b>	<b>a</b>	<b>\$1.9</b>	<b>\$9.0</b>	<b>\$11.2</b>

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

<sup>a</sup>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.

<sup>b</sup>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.

<sup>c</sup>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.

<sup>d</sup>Individual entries may not sum to totals because of rounding.

Source: FDA.

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## 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.”<sup>3</sup> 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.<sup>4</sup> (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

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<sup>3</sup>“Off label” refers to the treatment of conditions other than those listed on FDA’s approved drug label.

<sup>4</sup>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.

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## 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.

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## 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.

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## 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.

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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.

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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.

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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.

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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.

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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)
<b>Research activities</b>				
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
<b>Total<sup>a</sup></b>	<b>\$17.0</b>	<b>\$32.6</b>	<b>\$43.0</b>	<b>\$49.7</b>

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

<sup>a</sup>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
<b>Research activities</b>				
Infrastructure—research and development	\$0.1	\$0.1	0	0
Smallpox study	\$0.1	0	0	0
Special activities	0	0	0	\$4.6
<b>Preparedness activities</b>				
<b>Combating terrorism</b>	<b>\$0.3</b>	<b>\$19.0</b>	<b>\$20.0</b>	<b>\$27.2</b>
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 <sup>a</sup>	0	0	0
Special activities	0	0	0	\$1.4

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<b>Program/initiative</b>	<b>Fiscal year 1998</b>	<b>Fiscal year 1999</b>	<b>Fiscal year 2000</b>	<b>Fiscal year 2001</b>
<b>Infrastructure</b>	<b>\$9.7</b>	<b>\$12.6</b>	<b>\$15.3</b>	<b>\$18.9</b>
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
<b>Total<sup>b</sup></b>	<b>\$10.2</b>	<b>\$31.7</b>	<b>\$35.3</b>	<b>\$50.7</b>

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

<sup>a</sup>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.

<sup>b</sup>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.<sup>5</sup> 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

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<sup>5</sup>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

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



# Department of Justice

DOJ has a variety of responsibilities for combating terrorism. The Office of Justice Programs (OJP) administers programs to provide equipment, training, exercises, and technical assistance to first responders, including some components of the Domestic Preparedness Program that were transferred from DOD,<sup>1</sup> and to provide assistance to victims of terrorism. Under Presidential Decision Directive 39, DOJ, acting through the FBI, is the overall lead federal agency for domestic terrorism incidents. The FBI is the lead agency for crisis management of any terrorist incident within the domestic United States and houses the National Domestic Preparedness Office, which was established to coordinate all federal efforts to assist state and local first responders in preparing for a terrorist incident. See table 11 for DOJ's reported funding for activities on bioterrorism.

**Table 11: Reported Funding for Activities on Bioterrorism at DOJ (Dollars in millions)**

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>OJP</b>				
<b>Research activities</b>				
Biological agent detection	\$0.2	\$1.1	\$0.2	0
Development of equipment performance standards and test protocols for emergency response equipment	0	0	\$0.5	\$4.6
<b>Preparedness activities</b>				
Development of chemical/biological agent list	\$0.3	0	0	0
Exercises	0	0	\$6.1 <sup>a</sup>	\$3.2
Development of an emergency response to domestic biological incidents	0	0	\$0.5	\$1.0
Metropolitan Medical Response System outreach plan	0	0	\$0.3	0
Veterinary Laboratory Network for rapid analysis of biological agents	0	0	\$0.4	0
Hospital Provider Course Development And Delivery	0	0	0	\$0.9
Biological Planning Guide	0	0	0	\$0.2
Development of equipment guides	0	\$0.3	\$0.3	0

<sup>1</sup>See app. VI for more information on the Domestic Preparedness Program.

(Continued From Previous Page)

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>FBI</b>				
<b>Research activities</b>				
Detecting and characterizing biological agents	0	0	0	\$1.1
<b>Total</b>	<b>\$0.5</b>	<b>\$1.4</b>	<b>\$8.3</b>	<b>\$11.0</b>

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

<sup>a</sup>OJP could not report how much of \$6.1 million for exercises was only for activities on bioterrorism.

Source: DOJ.

## Office of Justice Programs

OJP sponsors research on emergency response equipment, provides grants and technical assistance, and can provide assistance to victims of terrorism.

## Research Activities

The National Institute of Justice within OJP conducts research activities on terrorism. Among its programs, the institute conducts operational testing and assessment of new technologies and supports efforts to develop lower cost, more effective emergency response equipment. It is also working with the Office of State and Local Domestic Preparedness Support, the FBI, and the Technical Support Working Group on a study to determine the chemical and biological agents that terrorists are most likely to use.

## Preparedness Activities

The Anti-Terrorism and Effective Death Penalty Act of 1996 (P.L. 104-132, sec. 822) authorized OJP and FEMA to fund and develop a terrorism emergency response training program for fire, emergency medical service, and public safety personnel. The 1998 Commerce, Justice, and State Appropriations Act (P.L. 105-119) provided funding used to create an equipment acquisition grant program as well as two training centers for emergency responders. The grant and training programs target the nation's 120 largest metropolitan jurisdictions. The Office for State and Local Domestic Preparedness Support administers the Domestic Preparedness Program and the grant and training programs. This office assists state and local jurisdictions in enhancing their domestic preparedness capabilities by providing assistance to jurisdictions to acquire equipment, technical assistance, exercises, and training. For example, this office has developed an on-line data collection tool to assist states in conducting their threat,

risk, and needs assessments<sup>2</sup> and to develop their WMD preparedness strategy, which is designed to be used by the states to target grant funds in order to improve preparedness.

OJP reported \$5.3 million in fiscal year 2001 as being related to the public health and medical consequences of a bioterrorist attack against the civilian population, as shown in table 11. However, the funding in table 11 represents only part of DOJ's more general-purpose spending on activities on terrorism, which could also benefit preparedness for a bioterrorism event. DOJ reported \$3.2 million was used to facilitate biological tabletop exercises in 52 cities in fiscal year 2001. These 1-day exercises involve public health, fire, law enforcement, and emergency management agencies. Participants work through a simulation of a bioterrorism incident, starting with the incubation period (the time between initial exposure to a biological agent and the first onset of symptoms), followed by the recognition and initial response, and finally the challenges of integrating federal assets in the response and recovery efforts. Medical surveillance, epidemiology, quarantine, patient tracking, remediation, and mass fatality management are addressed.

OJP also reported funding of \$1.0 million in fiscal year 2001 to develop and deliver a course on planning a response to a bioterrorist attack (see table 11). The office reported about \$0.3 million to develop a plan to enhance awareness of the Metropolitan Medical Response System and approximately \$0.4 million to establish a Veterinary Laboratory Network for the rapid analysis of biological and infectious disease agents in fiscal year 2000.<sup>3</sup>

OJP may also provide assistance to victims of terrorism under the Victims of Crime Act of 1984 (P.L. 98-473, ch. 14, as amended). These funds could be used, for example, to provide mental health treatment to victims of terrorism.

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<sup>2</sup>During the threat and risk assessment process, states identify the threat and risk posed to a community by the terrorist use of a WMD device and integrate vulnerability, threat, and public health performance information to yield a risk profile. The needs assessment outlines a state's needs for training, equipment, and other resources.

<sup>3</sup>See app. VII for more information on the Metropolitan Medical Response System.

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## Federal Bureau of Investigation

The FBI conducts some bioterrorism-related research, is the lead agency for crisis management, and houses the National Domestic Preparedness Office.

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## Research Activities

The Hazardous Materials Response Unit conducts research on detecting and characterizing biological materials for law enforcement reasons, such as associating some person, group, or geographical region with the biological material. This research could also have benefits in identifying biological agents for public health and medical systems. In fiscal year 2001, the Hazardous Materials Response Unit awarded \$500,000 for research activities related to detection and characterization of biological materials (\$250,000 each to the Massachusetts Institute of Technology and the U.S. Soldier Biological and Chemical Command). It has an additional \$585,000 in awards pending. This amount includes \$150,000 for CDC's Laboratory Response Network for bioterrorism.<sup>4</sup> The FBI participated in the creation of protocols used by the Laboratory Response Network to ensure uniformity in testing and the establishment of the proper chain of custody for biological, evidentiary samples.

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## Preparedness Activities

In the FBI's role as lead agency for crisis management, it conducts interagency threat assessments of WMDs (a process established to determine the credibility of WMD threats), and provides a situational assessment during a WMD incident. The FBI has designated a WMD coordinator in each of its 56 field offices. If necessary, the FBI coordinates deployment of the Domestic Emergency Support Team in response to an emergency under the U.S. Government Interagency Domestic Terrorism Concept of Operations Plan (CONPLAN).

The FBI also houses the National Domestic Preparedness Office, which was established to coordinate all federal efforts to assist state and local emergency responders with planning, training, equipment, medical and health, and exercise needs necessary to respond to a WMD incident. The office serves as a single point of contact and clearinghouse for WMD-related information for state and local responders, including fire, hazardous materials, law enforcement, public health, and medical

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<sup>4</sup>See app. VII for more information on the Laboratory Response Network.

personnel. It also provides emergency responders with access to subject matter experts and links to federal resources.

The FBI and CDC are engaged in a series of four regional meetings to identify the core capacities required to prepare for and respond to an act of bioterrorism. These sessions will assist in prioritizing the capabilities of the public health community and identify how law enforcement can promote and benefit from these programs. The FBI and CDC are also developing guidelines that will assist CDC in disseminating information to the public health departments through the communications system, Epi-X. Epi-X is a secure, moderated, Web-based communications network for public health officials that is intended to simplify and expedite the exchange of routine and emergency public health information between CDC and state health departments. Following the guidelines should allow the public health community to obtain necessary information without releasing case specific or law enforcement sensitive information not relevant to the health related concerns.

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# Department of Transportation

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DOT is responsible for reducing vulnerabilities to terrorism affecting the security of all airports in the United States, all aircraft and passengers, and all maritime shipping under the U.S. flag or registration, or operating within the territory of the United States. DOT also coordinates security measures for rail, highway, mass transit, and pipeline facilities. Through the National Response Center, which is staffed by the Coast Guard and located in the Coast Guard's Headquarters Command Center, DOT also serves as the sole national point of contact for reporting all biological, oil, chemical, radiological, and disease-causing discharges into the environment anywhere in the United States and its territories. DOT received \$800,000 in fiscal year 1999 and \$800,000 in fiscal year 2000 for preparedness activities on bioterrorism from DOD.

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## Research Activities

DOT is conducting research on the ability of metropolitan areas to respond to attacks on local transit systems. Most of the WMD research at DOT is focused on chemical, not biological, agents.

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## Preparedness Activities

The National Response Center serves as the first-alert center for all releases of biological agents, maintains incident databases, and provides private and secure conferencing for the law enforcement, emergency response, and public health sectors on an incident-specific basis. It is also the communications and operations center for the National Response Team. Both the National Response Center and the National Response Team are components of the National Response System. The system is the government's mechanism for emergency response to discharges of oil and the release of chemicals into the navigable waters or environment of the United States and its territories. It provides a framework for coordination among federal, state, and local responders and responsible parties. The National Response Team provides a national planning, policy, and coordinating body to provide guidance before and assistance during an incident. Its membership consists of 16 federal agencies<sup>1</sup> with expertise in various aspects of emergency response to pollution incidents. The National Response Center participates in terrorism exercises as requested by other

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<sup>1</sup>The 16 federal agencies are the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, the Interior, Justice, Labor, State, Transportation, and the Treasury; the Environmental Protection Agency; the Federal Emergency Management Agency; the General Services Administration; the Nuclear Regulatory Commission, and the U.S. Coast Guard.

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agencies. Some emergency response and management training courses at DOT have a bioterrorism component, but there are no training courses dedicated to bioterrorism.

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# Department of the Treasury

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Within the Department of the Treasury, the U.S. Secret Service receives funding for activities on bioterrorism.

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## U.S. Secret Service

The U.S. Secret Service is responsible for the protection of the President, the Vice President, and their families; heads of state and other designated individuals; the investigation of threats against these protectees; and protection of the White House, the Vice President's Residence, foreign missions, and other buildings within Washington, D.C. The U.S. Secret Service is also responsible for design, planning, and implementation of security at designated National Security Special Events.

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## Research Activities

The U.S. Secret Service reported funding of \$450,000 for fiscal year 2001 to support the development of a biological agent detector. It reported funding of an additional \$60,000 for laboratory identification of biological and chemical agents.

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## Preparedness Activities

The Hazardous Agent Mitigation and Medical Emergency Response teams, which are part of the Secret Service's Chemical, Biological, Radiological, and Nuclear Countermeasures program, travel with the presidential motorcade and respond to chemical and biological events. The Secret Service has a role to protect the civilian population in special events such as the Olympic games.



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# Department of Veterans Affairs

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VA manages one of the nation's largest health care systems and is the nation's largest drug purchaser. The department purchases pharmaceuticals and medical supplies for the National Pharmaceutical Stockpile Program and the National Medical Response Team stockpiles and it participates in other bioterrorism preparedness activities.

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## Preparedness Activities

VA purchases pharmaceuticals and medical supplies for federal stockpiles because of its purchasing power and ability to negotiate large discounts from manufacturers that sell pharmaceuticals, equipment, and supplies to the VA hospital system.<sup>1</sup> VA is under contract with CDC to purchase drugs for the National Pharmaceutical Stockpile Program and manages a spectrum of contracts for the storage, rotation, security, and transportation of the stockpile. The CDC contracts included an estimated \$14 million for fiscal year 2000 and another \$60 million for fiscal year 2001.

VA also works with OEP by agreement to purchase, store, and maintain drugs for the four National Medical Response Teams, and to train the National Disaster Medical System civilian hospital staff. VA received \$0.9 million in fiscal year 2000 and \$1.2 million in fiscal year 2001 from OEP for the purchase, storage, and maintenance of drugs. Also in fiscal year 2001, VA received \$0.8 million from OEP to begin developing training for staff in the National Disaster Medical System hospitals.

In addition, VA hospitals throughout the United States participate in local community emergency planning. VA personnel have been deployed to many presidentially declared emergencies (for example, the Oklahoma City bombing).

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<sup>1</sup>See app. VIII for more information on the stockpiles.

# Environmental Protection Agency

EPA has responsibilities to prepare for and respond to emergencies involving oil, hazardous substances, pollutants, or contaminants (which include chemical, biological, and radiological materials) that also could be components of a WMD attack. If necessary, EPA can assist the FBI in determining what sort of hazardous substance may be, or has been, released in a terrorist incident. Following an incident, EPA can help with environmental monitoring, sampling, decontamination efforts, and long-term site cleanup activities. In addition, Presidential Decision Directive 63 gives EPA responsibility for the protection of the U.S. water supply from terrorist attack, including the protection of water supplies from biological contamination.

EPA's participation in a potential bioterrorist event would vary on a case-by-case basis. EPA might advise the national, state, or local government on what the agent might be and could have a role in the potential cleanup and decontamination if asked to assist by other agencies. For example, this might include testing the water system for contaminants, including biological agents, if an outbreak of a disease occurred. EPA works with CDC on a case-by-case basis to tailor its response to address the specific agent.

EPA received little funding specifically for activities on bioterrorism during fiscal year 1998 through fiscal year 2001 (see table 12).

**Table 12: Reported Funding for Activities on Bioterrorism at EPA (Dollars in millions)**

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>Research activities</b>				
Detection of biological agents	0	0	0	\$0.5
<b>Preparedness activities</b>				
Vulnerability assessments	\$0.01	0	\$0.1	\$2.0
<b>Total</b>	<b>\$0.01</b>	<b>0</b>	<b>\$0.1</b>	<b>\$2.5</b>

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

Source: EPA.

## Research Activities

EPA reported funding of \$500,000 in fiscal year 2001 to sponsor research to investigate methods to detect and identify biological agents in water.

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## Preparedness Activities

EPA is training its staff to respond to a WMD incident. EPA has approximately 220 On-Scene Coordinators across the country, who are the on-location staff responsible for coordinating EPA's response to a hazardous material spill or release into the environment. The coordinators are responsible for bringing in the necessary resources, including EPA contractors, or tasking other agencies for support. The coordinators and EPA contractors are receiving training on WMD agents, especially biological agents, in order to get more specific, in-depth knowledge to enhance their overall ability to handle a bioterrorist incident. EPA is coordinating with CDC to add a bioterrorism module to EPA's training on terrorism. EPA is considering additional training for its coordinators to provide them with the in-depth knowledge they need to lead an appropriate response. However, because situations with biological agents are unique, it is hard to make generalizations about how to respond. For example, weather conditions can alter the need to decontaminate a site because temperature, among other factors, can render biological agents harmless.

EPA has also been working with DOE and the American Water Works Association—Research Foundation to develop a vulnerability assessment methodology for the water supply sector. In fiscal year 1998, EPA received \$10,000 to partially fund the development of the National Infrastructure Assurance Plan—Water Supply (see table 12). EPA received \$66,000 in fiscal year 2000 to fund the development of the vulnerability assessment methodology and to co-sponsor a workshop on water infrastructure protection with DOE. EPA reported funding of \$2.0 million to continue the development of this methodology and related water issues in fiscal year 2001.

# Federal Emergency Management Agency

FEMA is the lead federal agency for consequence management preparedness and response to terrorist incidents involving WMDs, and it is helping to build a bioterrorist response system that is part of a broader terrorist response system. FEMA reported funding for activities on terrorism of \$25.1 million for fiscal year 2000 and \$30.3 million for fiscal year 2001 (see table 13).

**Table 13: Reported Funding for Activities on Terrorism at FEMA (Dollars in millions)**

Program/initiative	Fiscal year 1998	Fiscal year 1999	Fiscal year 2000	Fiscal year 2001
<b>Preparedness activities</b>				
Response and recovery	<sup>a</sup>	\$2.0	\$2.0	\$6.3
Preparedness, training, and exercises	<sup>a</sup>	\$0.5	\$1.8	\$2.3
Fire prevention and training	<sup>a</sup>	\$4.0	\$4.9	\$5.1
Emergency management planning grants	<sup>a</sup>	\$8.3	\$16.4	\$16.6
<b>Total</b>		<b>\$14.8</b>	<b>\$25.1</b>	<b>\$30.3</b>

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

<sup>a</sup>FEMA did not supply us with funding amounts for fiscal year 1998.

Source: FEMA.

## Preparedness Activities

At the federal level, FEMA is involved with preparedness activities in coordination with other departments and agencies, using the structures of the Federal Response Plan. At the state and local levels, preparedness activities include the provision of grants to the states and the delivery of first-responder and emergency management training programs to support their terrorism-related planning, training, exercise, equipment, and assessment requirements.

## Planning

FEMA works with other departments and agencies to support consequence management planning at the national and regional levels. FEMA coordinates the federal response planning through the Emergency Support Functions Leaders Group, which is the principal body that addresses Federal Response Plan planning and implementation at the working level, and the Catastrophic Disaster Response Group, which provides guidance and policy direction on response coordination and operational issues. Also, FEMA plans and participates in activities to address consequence

management for special events such as the Olympic games. FEMA has been actively engaged in the development and review of major organizational and operational support documents, such as the CONPLAN (see app. III for details regarding the CONPLAN). FEMA and DOJ's OJP are working to incorporate a bioterrorist response element into their terrorist response system.

At the state and local levels, FEMA provides assistance to support terrorism-related emergency response planning. FEMA gives Emergency Management Planning grants to support the development of terrorism-specific annexes to existing state and local emergency operations plans. The grant money can be used for activities such as planning, training, and conducting exercises. FEMA negotiates a work plan for funding with each state, and states have been given wide latitude in targeting this assistance. FEMA can also provide supplemental funds to state and local mental health agencies to provide crisis counseling to eligible survivors of presidentially declared major disasters.

FEMA also updates and maintains the Rapid Response Information System, which is authorized under the National Defense Authorization Act of Fiscal Year 1997 (P.L. 104-201, sec. 1417). This information system contains databases of characteristics and safety precautions for nuclear, biological, and chemical agents and materials and can be used as a resource guide for response to such an incident.

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## Training

FEMA has developed and delivered terrorism-related courses for state and local emergency management personnel and first responders. It has provided grant assistance to the states to support this training. Training is provided through the Emergency Management Institute and the National Fire Academy. The Institute also conducts a Senior Officials Course for local government officials as part of the Domestic Preparedness Program.<sup>1</sup>

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## Exercises

FEMA participates in federal interagency terrorism response exercises sponsored by the FBI, DOD, and others. FEMA also provides funding to states to support terrorism response exercises. FEMA participates in

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<sup>1</sup>See app. VI for more information on the Domestic Preparedness Program.

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special events such as the Olympic games, where it has the opportunity to detect and correct weaknesses in its system.

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## Equipment

FEMA, in conjunction with DOD and DOJ, assisted in the development and is currently helping to refine the Standardized Equipment List to support acquisition of equipment for fire, police, and emergency medical responders. This equipment will conform to appropriate and applicable laws, regulations, and to-be-developed national standards including those issued by the National Institute of Justice, the National Institute for Occupational Safety and Health, and the National Fire Protection Association.

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## Assessment

FEMA and the National Emergency Management Association have created a partnership to develop an emergency management readiness and capability assessment system for state and local emergency managers. This self-assessment is intended to help governments determine strengths and weaknesses of their emergency management program. The baseline report was released on March 2, 1998. In summary, it found that although states have the basic capabilities in place to effectively respond to disasters that normally confront them, there are areas that require attention and improvement, such as planning and equipment for response to a terrorist incident.

# Comments From the Department of Commerce



**THE SECRETARY OF COMMERCE**  
Washington, D.C. 20230

SEP 14 2001

Ms. Janet Heinrich  
Director, Health Care-Public Health Issues  
U.S. General Accounting Office  
441 G Street, N.W., Room 5A14  
Washington, D.C. 20548

Dear Ms. Heinrich:

Thank you for your letter requesting our review and comments on the General Accounting Office (GAO) draft report entitled "Bioterrorism: Federal Research and Preparedness Activities" (GAO-01-915).

The Office of Law Enforcement Standards of the National Institute of Standards and Technology (NIST) has reviewed the GAO draft report. Our comments on this report are enclosed. We hope these suggestions strengthen your final report and assist you in addressing this important issue.

If you have any questions or require additional information regarding our comments, please contact Albert Conerly of the NIST Management and Organization Division at (301) 975-4050.

Warm regards,

A handwritten signature in black ink, appearing to read "Donald L. Evans".

Donald L. Evans

Enclosure

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**Appendix XV  
Comments From the Department of  
Commerce**

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**Department of Commerce Comments on Draft GAO Report - Bioterrorism: Federal Research and Preparedness Activities (GAO-01-915)**

The National Institute of Standards and Technology (NIST) Electronics and Electrical Engineering Laboratory, Office of Law Enforcement Standards (OLES) has reviewed the draft GAO Report entitled: Bioterrorism: Federal Research and Preparedness Activities (GAO-01-915), and is providing the following comments.

**General Comment:** The integrated nature of the ongoing program to develop a suite of chemical and biological protective national standards is not reflected in this report. The major player within NIST, the Office of Law Enforcement Standards, is managing programs through interagency agreements with the National Institute for Occupational Safety and Health (NIOSH), and the U.S. Army Soldier Biological and Chemical Command (SBCCOM) and is participating in the Interagency Board for Equipment Standardization and Interoperability (IAB). The IAB is co-chaired by representatives from DOD and DOJ (FBI). OLES's efforts are conducted with funding from DOJ's National Institute of Justice. However, discussion of the NIOSH involvement is absent from the CDC portion of Appendix VIII; and there is no mention of either DOD's or DOJ's roles as co-chairs of the IAB in Appendix VI or Appendix IX. The document does not show the funding provided by DOD to support the IAB, nor does it show the funding provided by NIJ to OLES. In many cases, current funding levels and programs do not reflect purely bioterrorism research and preparedness activities, but many of the chemical agent protective measures will be directly applied to bioterrorism prevention standards development, or can be built upon in subsequent programs. The current document makes it difficult to cross-reference multi-agency programs or to gain appreciation for the integrated efforts currently under way to develop chemical and biological agent protective standards.



# Comments From the Department of Defense



SPECIAL OPERATIONS/  
LOW-INTENSITY CONFLICT

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE  
WASHINGTON, D.C. 20301-2500

SEP 4 2001

Ms. Janet Heinrich  
Director  
Health Care – Public Health Issues  
United States General Accounting Office  
441 G. Street, NW, Rm 5A14  
Washington, DC 20548

Dear Ms. Heinrich:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report, "BIOTERRORISM: Federal Research and Preparedness Activities," undated (GAO Code 290018/OSD Case 01-915). There are no specific recommendations expressed in this report for our concurrence or comment. However, we would like to emphasize that DoD is working to improve biological terrorism response capabilities, and many are already in place, trained, and available to bolster federal, state and local bioterrorism preparedness efforts. This support and cooperative effort is key – our servicemembers and their families are as vulnerable to attack as the general populace and may be called upon to support worldwide operations at a moment's notice. Keeping them safe at our installations and in the surrounding communities is vital to national security. By facilitating federal agency cooperation and resource sharing, to include DOD, the safety of all U.S. citizens is enhanced.

Technical comments for accuracy and clarification of the report have been provided separately. The Department appreciates the opportunity to comment on the draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Gallington", written over the word "Sincerely,".

Daniel J. Gallington  
Special Assistant to the Secretary for Policy  
Matters (Performing the Duties of  
ASD/SOLIC)

# Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 13 2001

Ms. Janet Heinrich  
Director, Health Care--Public  
Health Issues  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft report, "Bioterrorism: Federal Research and Preparedness Activities." The comments present the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Michael Mangano".

Michael F. Mangano  
Principal Deputy Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

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**Appendix XVII**  
**Comments From the Department of Health**  
**and Human Services**

Comments of the Department of Health and Human Services  
on the Draft GAO Report Entitled,  
“Bioterrorism: Federal Research and Preparedness Activities”

The Department of Health and Human Services appreciates the opportunity to comment on the General Accounting Office’s (GAO) draft report on bioterrorism. We believe that GAO has provided substantial factual information about Federal preparations should a significant bioterrorism attack against the civilian population occur in the United States. However, we would like to make several general observations about the draft report.

First, the Department is the principal public health agency in the Federal Government and therefore has an important role in providing technical advice to law enforcement agencies dealing with a bioterrorism crisis and in assisting State and local authorities respond to the human health consequences of an attack. Unlike other agencies that participate in the United States’ Federal Response Plan, the Department brings to bioterrorism preparedness our unique capabilities and expertise in infectious disease surveillance and control that are unequalled elsewhere in the Federal Government. The Secretary of Health and Human Services has also recently appointed a Special Assistant for Bioterrorism to coordinate anti-bioterrorism efforts across the Department.

Quite possibly a bioterrorist attack may initially be observed as a naturally-occurring epidemic of unknown origin. In this case, the Department, and particularly our Centers for Disease Control and Prevention (CDC), would likely assist State and local governments in their disease surveillance, identification, and control efforts before a determination of terrorist origins was made. Should local health care resources be overwhelmed, the Department, through our Office of Emergency Preparedness (OEP), would already be assisting State and local authorities in providing care for massive numbers of casualties. The Department appreciates GAO’s recognition of these systems and possible event characteristics.

Second, the capacity to respond to a bioterrorism event is dependent, at all levels, and in large part, on the ability of governments and health agencies to perform effective outbreak detection, control an epidemic, and respond to mass casualty-producing emergencies, whatever the cause. There are unique requirements for an effective response to a bioterrorist attack, including those related to disease surveillance, detection, laboratory identification, population prophylaxis, public health information, and possibly victim isolation and quarantine. However, there are additional aspects of an effective bioterrorism response that are dependent on effective preparations to respond to other types of emergencies, as well, including those related to emergency management, public safety, emergency medical services, health care delivery and fatality management. The report might benefit from clearly describing these commonalities and distinctions.

Third, because there are many common features of responses to biological, chemical, and other emergencies that can overwhelm local resources, the Federal Government takes an all-hazards approach to emergency response planning and management. Frequently it is difficult to partition budgets among preparations to respond to one or another type of emergency. Therefore, we have suggested changes to the report’s resource table presentations to clarify, as much as possible, these allocations and expenditures.

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**Appendix XVII**  
**Comments From the Department of Health**  
**and Human Services**

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Fourth, one of the most important aspects of State and local capacity-building is response planning for biological, chemical and other causes of mass casualty-producing events. In general, effective responses must include the community's public safety, public health and health care delivery resources. Because of the complex nature of coordinating these responses, the Department's OEP and CDC have emphasized preparedness and response planning in their systems development support.

Fifth, the Department has met with Federal law enforcement and intelligence agencies in our analyses of the most consequential chemical and biological agent threats. From these meetings, lists of agents were developed which were used as the basis for pharmaceutical stockpile acquisitions. Part of the consideration for stockpile planning is the potential size of the population that might be affected and the likely inadequacy of local resources to be able to meet the demand for pharmaceuticals.

The Department has emphasized public health and medical response planning and capacity-building at Federal, State, and local levels. Unfortunately, health concerns have frequently been under-emphasized in emergency management planning, resource development and exercise execution. Therefore, the Department appreciates the efforts of GAO to focus attention once again on the all-important need to assure that the Nation's health infrastructure will be able to respond to whatever challenge may confront it.

# Comments From the Department of Justice



U. S. Department of Justice

Washington, DC 20530

August 31, 2001

Janet Heinrich  
Director  
Health Care - Public Health Issues  
U.S. General Accounting Office  
441 G Street, NW  
Washington, DC 20548

Dear Ms. Heinrich:

On August 10, 2001, the General Accounting Office (GAO) provided the Department of Justice copies of its draft report entitled "BIOTERRORISM: Federal Research and Preparedness Activities." The draft was reviewed by representatives of the Office of Justice Programs, the Criminal Division, and the Federal Bureau of Investigation. While the Department generally agreed with the substance of the document, it believed some areas could be clarified or strengthened. We are providing several comments for these purposes. We understand that they will be incorporated as appropriate.

I hope the comments will be beneficial in completing the final document. If you have any questions concerning the Department's comments, you may contact me on (202) 514-0469.

Sincerely,

A handwritten signature in cursive script that reads "Vickie L. Sloan".

Vickie L. Sloan  
Director, Audit Liaison Office  
Justice Management Division

Enclosure

# GAO Contacts and Staff Acknowledgments

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## GAO Contacts

Janet Heinrich, (202) 512-7118  
Marcia Crosse, (202) 512-3407

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## Acknowledgments

In addition to those named above, Barbara Chapman, Robert Copeland, Greg Ferrante, LaKesha Jimmerson, Deborah Miller, and Roseanne Price made key contributions to this report.

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# Related GAO Products

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*Combating Terrorism: Selected Challenges and Related Recommendations* (GAO-01-822, Sept. 20, 2001).

*Combating Terrorism: Comments on H.R. 525 to Create a President's Council on Domestic Terrorism Preparedness* (GAO-01-555T, May 9, 2001).

*Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement* (GAO-01-666T, May 1, 2001).

*Combating Terrorism: Observations on Options to Improve the Federal Response* (GAO-01-660T, Apr. 24, 2001).

*Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement* (GAO-01-463, Mar. 30, 2001).

*Combating Terrorism: Comments on Counterterrorism Leadership and National Strategy* (GAO-01-556T, Mar. 27, 2001).

*Combating Terrorism: FEMA Continues to Make Progress in Coordinating Preparedness and Response* (GAO-01-15, Mar. 20, 2001).

*Combating Terrorism: Federal Response Teams Provide Varied Capabilities; Opportunities Remain to Improve Coordination* (GAO-01-14, Nov. 30, 2000).

*West Nile Virus Outbreak: Lessons for Public Health Preparedness* (GAO/HEHS-00-180, Sept. 11, 2000).

*Combating Terrorism: Linking Threats to Strategies and Resources* (GAO/T-NSIAD-00-218, July 26, 2000).

*Chemical and Biological Defense: Observations on Nonmedical Chemical and Biological R&D Programs* (GAO/T-NSIAD-00-130, Mar. 22, 2000).

*Combating Terrorism: Need to Eliminate Duplicate Federal Weapons of Mass Destruction Training* (GAO/NSIAD-00-64, Mar. 21, 2000).

*Combating Terrorism: Chemical and Biological Medical Supplies are Poorly Managed* (GAO/T-HEHS/AIMD-00-59, Mar. 8, 2000).

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**Related GAO Products**

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*Combating Terrorism: Chemical and Biological Medical Supplies Are Poorly Managed* (GAO/HEHS/AIMD-00-36, Oct. 29, 1999).

*Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination* (GAO/RCED-00-3, Oct. 27, 1999).



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