

HHS Fact Sheet

U.S. Department of Health and Human Services



www.hhs.gov/news

August 16, 2001

Contact: HHS Press Office
(202) 690-6343

HHS INITIATIVE PREPARES FOR POSSIBLE BIOTERRORISM THREAT

Overview: *While the exact risks are unknown, the use of biological weapons by terrorists potentially could result in life-threatening illness on a large scale. Even a lone terrorist could cause a major disease outbreak in the population - and, in the case of communicable disease, the outbreak could spread in successive waves of infection.*

Unlike explosions or chemical releases, a bioterrorist attack could be surreptitious and thus difficult and time-consuming to detect. Symptoms might not occur among victims for days or weeks, and those initially presenting themselves to physicians and clinics might be geographically dispersed. A strong public health network would be needed to piece together early reports and quickly determine what had happened. Once detected, the situation could overwhelm local health systems that are faced not only with the tasks of caring for mass casualties but also with the demands of even larger numbers of people requiring preventive care.

President Bush has named the Federal Emergency Management Agency to coordinate federal response efforts in the event of chemical, biological or nuclear terrorism. In a bioterrorism event, HHS would have special responsibilities, including detecting the disease, investigating the outbreak, and providing stockpiled drugs and emergency supplies in the large amounts needed. On July 10, 2001, Secretary Thompson named Scott Lillibridge, a physician who has coordinated the Centers for Disease Control and Prevention's bioterrorism response efforts, as his special advisor to lead the department's coordinated bioterrorism initiative.

In fiscal year 2001, HHS will invest \$297 million in anti-bioterrorism efforts. President Bush's fiscal year 2002 budget proposes an investment in the HHS anti-bioterrorism initiative of \$350 million, an 18 percent increase over fiscal year 2001 funding. HHS efforts are focused on five areas:

- improving the nation's public health surveillance network, to quickly detect and identify the biological agent that has been released;
- strengthening the capacities for medical response, especially at the local level;
- expanding the stockpile of pharmaceuticals for use if needed;
- expanding research on the disease agents that might be released, rapid methods for identifying biological agents, and improved treatments and vaccines; and
- preventing bioterrorism by regulation of the shipment of hazardous biological agents or toxins.

Background

There is little experience, especially in the United States, with the deliberate release of biological agents to cause major disease outbreaks. However, events of recent years have focused attention on the increasing possibility of such incidents, particularly to the possibility of terrorist incidents aimed at the civilian population.

Concern about deliberate use of disease agents presently focuses on anthrax (which can be spread by inhaled spores), as well as smallpox, pneumonic plague, tularemia, viral hemorrhagic fevers and botulism. While there generally are vaccines or treatments for these diseases, they do not exist in the quantities that would be needed and therefore must be stockpiled. Smallpox, while eliminated as a naturally occurring disease, could cause a chain reaction of person-to-person infection if ever released as a terrorist weapon. The existing smallpox vaccine supply is limited, and only supportive care would be available to those with the disease.

Challenges for Bioterrorism

In preparing for the possibility of bioterrorist incidents, HHS faces several challenges:

- **Silent Attack and the Need for Improved Public Health Network.** Unlike explosives or chemical releases, an attack involving biological agents could go undetected for days. Only when individuals present themselves to physicians or clinics with symptoms would any evidence of the attack appear, and even then the initial symptoms might not be recognized and accurately diagnosed. Furthermore, those presenting themselves with symptoms could be at great distances from the original site of exposure by the time symptoms occurred. In order to enhance our preparedness for and response to a bioterrorist attack, the United States needs an improved network of infectious disease surveillance, including improved communications,

U

upgraded laboratory facilities, advanced diagnostic techniques and expanded training of health care personnel.

- **Local Response Depends on National Leadership, Resources and Coordination.** The responsibility for responding to medical emergencies falls first and heaviest on local communities. Yet many of the special needs in responding to a bioterrorist attack (from the capacity to identify the problem to the availability of appropriate drugs) generally exceed the capacities of local systems. National response resources need to be prepared for use in cooperation with local and state officials and health personnel. Training for such unusual situations also needs to be developed and carried out with federal assistance. New working partnerships between public health, medical, public safety and intelligence agencies are needed.
- **Potential for Widespread Public Health Consequences.** Large numbers of people might be directly exposed to an agent released in a dense urban environment, and in some cases further spread of disease could occur person-to-person. In dealing with the consequences, appropriate measures for treatment and follow-up may need to be carried out on a massive scale, as would the distribution of drugs and emergency supplies from the stockpile, decontamination procedures and even the provision of appropriate mortuary services.

Current HHS Actions

HHS' five-year plan for combating bioterrorism includes a range of activities to strengthen and enhance the nation's preparedness for possible terrorist acts. The plan relies heavily on cooperation with state and local health agencies as well as local emergency medical response units. It also provides for an unprecedented vaccine and therapeutics "stockpile," including assurance of the effectiveness of such vaccines, antibiotics and emergency medical equipment. A "surge" production capacity has been developed in cooperation with drug manufacturers to address the needs for larger quantities of stockpiled materials. The plan also outlines accelerated research on the diseases, diagnostics, vaccines and treatments needed to help address the potential threat.

In his fiscal year 2002 budget, the President has requested \$350 million for HHS to prepare for and respond to the medical and public health consequences of a bioterrorist attack. Of this amount, \$182 million is for the Centers for Disease Control and Prevention (CDC), \$51 million is for the Office of Emergency Preparedness, and \$93 million is for research.

Disease Surveillance and Public Health Network: To better detect and respond to a wide range of infectious disease threats, including possible bioterrorist incidents, CDC is upgrading the nation's public health laboratory and epidemiological capacity. It is also expanding training and communications resources for state and local health agencies. This includes the capacity to detect outbreaks of illness that might have been caused by terrorists, improved laboratory identification and characterization of causal agents for disease outbreaks, and improved electronic communications among public health and other officials regarding outbreaks and responses to them.

Medical Consequence Management: HHS, through its Office of Emergency Preparedness (OEP), is expanding its efforts to develop medical response capabilities at local and national levels. In particular, OEP will increase the number of Metropolitan Medical Response Systems. So far, systems have been supported in 97 communities. Another 25 will be initiated in fiscal year 2002.

National Pharmaceutical Stockpile: The role of National Pharmaceutical Stockpile Program is to maintain a national repository of life-saving pharmaceuticals and medical materiel that will be delivered to the site of a bioterrorism event in order to reduce morbidity and mortality in civilian populations. The program has responsibility to identify, purchase, store, and manage pharmaceuticals and medical supplies that will assist state and local jurisdictions in their response to a chemical or biological terrorism event. The stockpile includes pharmaceuticals, intravenous supplies, airway supplies, emergency medications and bandages and dressings. Materials are intended to be available within 12 hours of an authorization to deploy from the national stockpiles. Pharmaceutical manufacturers may also be called upon to release inventories committed under prior agreement to the federal government

Research and Development: HHS is increasing support for research related to likely bioterrorism agents. An area of major emphasis at the National Institutes of Health will be the generation of genome sequence information on potential bioterrorism threats - especially the organisms that cause anthrax, tularemia and plague. The results of such genomics research, coupled with other biochemical and microbiological information, are expected to help in the development of rapid diagnostic methods, new or improved antibacterial and antiviral therapies, and new vaccines. In addition, NIH will support intensive work on a new smallpox vaccine.

Deterrence: HHS has the responsibility to track and monitor shipment of certain hazardous biological organisms and toxins. CDC will continue efforts toward ensuring that all laboratories that ship or receive these select agents are registered and in compliance with requirements.

###

Note: All HHS press releases, fact sheets and other press materials are available at <http://www.hhs.gov/news>.

U

Last revised: August 16, 2001



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)

Testimony on Combating Terrorism: Management of Medical Stockpiles by Robert F. Knouss, M.D.

Office of Emergency Preparedness
Public Health Service
U.S. Department of Health and Human Services

Before the House Committee on Government Reform, Subcommittee on National Security, Veterans' Affairs, and International Relations
February 23, 1999

[SEARCH](#)

[HOME](#)
[CONTACT US](#)

Mr. Chairman and Members of the Committee,

I am Dr. Robert Knouss, Director of the Department of Health and Human Services' (DHHS) Office of Emergency Preparedness (OEP). I appreciate the opportunity to appear before you once again to discuss our program's activities.

Last September, I appeared before this Committee and spoke about OEP and the National Disaster Medical System (NDMS), its teams and activities. Today, I am here to discuss the recently released General Accounting Office (GAO) report after an audit of the four specialized pharmaceutical caches used by our National Medical Response Teams (NMRTs), and the cache used by the Marine Corps' Chemical Biological Immediate Response Force.

Background and Purpose of the Pharmaceutical Caches

In Fiscal Year (FY) 1997, the Congress appropriated \$1.8 million to OEP for the creation of four stockpiles of specialized pharmaceuticals, and in FY 1999, an additional \$1.4 million was provided with the funds appropriated to the Centers for Disease Control and Prevention (CDC) to increase the stocks to be able to treat more victims. These stockpiles were designed to be deployed with our four specialized disaster teams in responding to a weapons of mass destruction (WMD) event and providing medical care to its victims. Three of the teams (California, Colorado and North Carolina) can be deployed anywhere in the country. The Washington, D.C. team does not deploy outside of the Washington, D.C. metropolitan area. The stockpiles contain specialized pharmaceuticals to treat up to 5,000 victims of a chemical exposure to nerve agents such as sarin and VX; vesicants, such as mustard gas; and pulmonary agents such as phosgene. In addition, each stockpile has medicines to protect the team members from cyanide poisoning and antibiotics to begin to provide prophylactic treatment to team members should they be exposed to a biological agent. Each stockpile will also accommodate treatment of the team for radiation exposure.

As you know, OEP is also working with metropolitan areas across the U.S. to create Metropolitan Medical Response Systems (MMRS). Part of the purpose of these systems is to ensure that each metropolitan area has specialized pharmaceuticals on hand to protect and treat responders and to be able to begin to treat WMD victims. We knew that an individual metropolitan area might not be able to afford to keep all the stores of pharmaceuticals on hand that it might need in the event of a WMD attack. We also knew that it would take up to 12 hours to deploy the National Pharmaceutical Stockpile that CDC is developing. Therefore, we designed our stockpiles to be able to deploy with our NMRTs. The three deployable teams and the associated stockpiles can be at an airport (commercial or military) and be ready to board within four hours of notification. The NMRT stockpiles are designed primarily to provide additional supplies to local areas that have depleted their own pharmaceutical resources in the initial hours after a chemical attack, when time is of the essence. The NMRT stockpiles have also been used to pre-position supplies for designated special events.

In FY 1997, when we began developing the NMRT stockpiles, we did not want to develop new and expensive systems, and we looked for systems that were already in place, on which we could build. The Department of Veterans Affairs (VA) is one of the four partners in the National Disaster Medical System (NDMS) and manages one of the largest pharmacy systems in the country. Consequently, we approached VA with our proposal for the purchase, management and deployment of the NMRT stockpiles. VA was able to purchase the pharmaceuticals and supplies through their purchasing systems, and store the stockpiles at

facilities in strategic locations near the NMRTs (Los Angeles, CA; Denver, CO; Winston-Salem, NC; and the Washington, D.C. metropolitan area).

GAO Report

The report recently issued by GAO raises important concerns about the manner in which these stockpiles were managed and the oversight provided by OEP. We have taken GAO's efforts and report seriously, and we are taking immediate steps to continue to ensure proper internal controls are in place and that we are in compliance with all regulations. Before commenting on the specific steps we are taking, however, I want to note that we have carefully reviewed the results of GAO's audit and do not believe that any of the issues cited degraded our ability to respond to a chemical attack should it have occurred over the last two years.

Based on the result of the GAO audit, however, we have signed a new interagency agreement with the VA that spells out each agency's responsibilities and activities, including:

- Assurance of appropriate storage and physical security of the stockpiles. The stockpiles will be in secured locations, with restricted personnel access. In addition, controlled substances will be ordered, received, stored and issued according to applicable DEA and OMB regulations.
- Strengthening of internal controls. OEP and VA personnel, with possible assistance and oversight from the HHS Inspector General's office, will conduct an initial 100 percent inventory and will be matched with inventory records. All out of date pharmaceuticals will be replaced, and we will assure that lot numbers are recorded correctly. Regular and no-notice audits will be conducted.
- Establishment of a schedule of regular communications. VA will provide inventory updates on a regular and recurring basis and will also provide reports on inventory replacements and changes. OEP will provide regular and recurring management oversight.

The FY 2001 President's budget includes resources for the stockpile management activities that the VA will now conduct and four our additional activities.

Ability to Respond

We certainly understand GAO's concerns that insufficient management and oversight controls do not provide any assurance that, even if the audit had been 100 percent correct on one day, there are no absolute assurances that the same would be true the next day, or at the time of deployment. However, we are concerned with GAO's implication that we would not have been able to respond effectively to a WMD incident. A "12 percent error rate" has to be put in the context of the type of items that were included in this calculation, and how the error rate was calculated. An excess of large gloves and an undercounting of medium size gloves is not a significant problem. And it is our understanding that an individual item could have produced up to three errors if it was over (or under) the count, if the lot number was recorded incorrectly, and if the expiration date was not the same as the inventory listing. Substitutions of an equivalent product also do not affect response capacity. To reiterate, we recognize the significant concern is not whether there is a 100 percent inventory accuracy, but whether the principles of quality control, quality assurance and inventory management have been utilized.

GAO has provided us with the spreadsheets from their audit of each cache. We have taken a serious look at the audit of each of the VA caches. We found that, for the most part, the errors occurred in the number of medical supplies, and that most of the errors were because of surplus quantities, not shortages. We focused our activities on the pharmaceuticals and controlled substances, and found that most of the missing pharmaceuticals at the time of the audit occurred at one location. Since being provided the audit results, we have been working with the VA to assure that these errors, regardless of level of significance, are corrected.

Security is a principal concern. As a result, we will be moving the location of one of our stockpiles so that it can be more readily monitored. In doing so, we want to be particularly careful, however, that we not increase the time that it would take to mobilize our team with its medical supplies and pharmaceuticals.

Further Actions

With the signature of the new agreement, we will accomplish the following:

- Have a more effective control environment - Requirements for stricter inventory control and monitoring, as well as for regular reporting and feedback, are included in the new agreement. In addition, VA officials have informed us that there are now clear lines of command and assignments for stockpile management. The new agreement includes the funding of additional staffing at the VA for close stockpile management.
- Properly record information and communicate with management - OEP will provide funds for additional staff and improved computerized inventory records at the VA to help ensure that the information is recorded properly and kept up to date. In addition, OEP and VA are instituting a monthly reporting system and periodic meetings with management.

- Ensure monitoring - VA staff is providing additional and regular on-site monitoring of the stockpiles. OEP staff or appropriate contractual staff, will conduct announced and no-notice inspections of each stockpile.
- Conduct risk assessments and implement control activities that are linked to the results of a mission risk assessment - The agreement provides that VA, with an OEP representative present, prepare a risk analysis of each location of storage. This analysis includes estimation of the risk's significance, assessment of the likelihood of its occurrence, decisions and recommendations on managing the risks and actions. Based on these analyses, OEP and VA will ensure appropriate risk management.

Conclusion

In conclusion, I want to reiterate that we are working very diligently within our own office and with the VA to correct the problems that GAO found, to do a 100 percent inventory, to ensure that current stocks and record keeping are accurate and up to date, and to develop and implement the proper management controls and oversight to ensure that the stockpiles are ready to deploy and that we are in compliance with all laws and regulations.

Mr. Chairman, this concludes my testimony. I will be pleased to answer any questions you may have.



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)
[Testimony](#)

[SEARCH](#)

[HOME](#)
[CONTACT US](#)

Testimony on Bioterrorism by Margaret A. Hamburg, M.D.

Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

Before the Senate Appropriations Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
March 16, 1999

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today. I am accompanied by colleagues who have responsibility for implementing various parts of our anti-bioterrorism initiative: James Hughes, M.D., Director of the National Center for Infectious Diseases, Centers for Disease Control and Prevention; Robert Knouss, M.D., Director of the Office of Emergency Preparedness, Office of the Assistant Secretary for Public Health and Science; John Taylor, Esq., Senior Advisor for Regulatory Policy, Food and Drug Administration; and Anthony Fauci, M.D., Director of the National Institute for Allergy and Infectious Diseases, National Institutes of Health. The Department of Health and Human Services (DHHS) welcomes your interest in our efforts to develop effective counter-measures for possible uses of biological weapons against the civilian population.

I will outline for you the overall strategic approach that DHHS is pursuing in our anti-bioterrorism activities - emphasizing our efforts to strengthen the public health infrastructure for infectious disease surveillance related to potential bioterrorism agents and our efforts to enhance capabilities for medical and public health response should a bioterrorist attack occur. Following that, my colleagues and I will be pleased to respond to questions.

I begin by noting that bioterrorism presents a special set of challenges to our emergency preparedness systems, public health organizations, and consequence management capability. Unlike a bomb or discrete chemical exposure, a terrorist incident involving a biological agent may not be detected or even suspected until people begin to present with serious illness. This may occur at considerable and varying distance from the site of initial exposure, both in terms of onset of disease (incubation periods can vary) and geographic location (e.g., if exposure occurs in a transportation terminal, people can spread out widely before becoming ill).

With a bioterrorist event, there is also the possibility of concentric, spreading circles of communicable disease exposure, extending significantly the damage caused by the agent released. This kind of threat will also dramatically increase the level of public fear and potential for major civil disruption.

Increasing the urgency of the need for our nation to prepare for the potential threat of bioterrorism is the fact that the agents most likely to be used in this type of attack are pathogens not commonly experienced in this country or routinely dealt with by our medical system. This has a number of significant implications: (1) the population generally has little or no immunity to the pathogen and hence is more vulnerable (e.g., no longer vaccinated against smallpox); (2) medical providers generally are not familiar with the diagnosis and treatment of these disorders (which they may even fail to initially recognize); and (3) routine scientific research into the pathogenesis and treatment of certain of these disease conditions has been at very low levels compared to other agents of infection because they have not been perceived to be high priority or because they require levels of biological containment that are not available at most research centers. For these reasons, a sound strategy for addressing bioterrorism will be quite different from one that targets other types of terrorist acts.

The DHHS initiative features activities in five distinct but related areas:

- Deterrence of biological terrorism
- Surveillance for unusual outbreaks of illness
- Medical and public health response

- Development of a national pharmaceutical stockpile
- Research and development

I will comment briefly on each.

Deterrence. The Centers for Disease Control and Prevention (CDC) has the responsibility mandated by the Antiterrorism and Effective Death Penalty Act of 1996 to regulate the shipment of certain hazardous biological organisms and toxins (hereinafter called "select agents"). Organizations such as research universities, pharmaceutical manufacturers, and microbiological archives often have occasion, as part of their routine work, to send or receive samples of dangerous pathogens or toxins. DHHS regulations (42 CFR 72.6) require that all facilities sending or receiving shipments of select agents register with the CDC, maintain records of such transfers, and otherwise document their compliance. CDC's administration of the select agent rule is part of the Administration's multi-agency effort, led by the Department of Justice, to combat terrorism.

CDC also fosters safe design and secure operation of laboratories that handle select agents. This involves consultation with laboratory officials to help ensure that new, renovated, or proposed facilities meet standard guidelines for the infectious organisms that will be handled. Development of guidelines and training materials for use by laboratory personnel and provision of technical assistance to states as requested regarding their inspection programs for BSL 3 facilities also are part of CDC's responsibilities..

Surveillance. Terrorist use of biological weapons against the civilian population is likely to be surreptitious. Absent an explosion, other immediate evidence of an attack, or notification of authorities by a perpetrator that an attack has been made (i.e., people have been exposed), the first responders will be health-care workers rather than fire or police personnel (as would be expected for a conventional emergency response scenario). The first indication that a silent attack has occurred probably will be an outbreak of some uncommon illness or an abrupt, significant increase in the incidence of commonly observed symptoms. How quickly the outbreak is detected, analyzed, understood, and addressed will determine the timeliness and effectiveness of the medical and public health response and hence the extent and severity of the impact upon the health and well-being of the affected community.

For example, most infectious agents have an incubation period measured in days or weeks. A silent release of a biological agent capable of producing a highly communicable disease, therefore, could afflict hundreds - if not thousands - of individuals over a wide geographic area during a period of several weeks before the need for a full medical and public health response could be identified and the response designed and mounted.

CDC is working to upgrade public health capability to counter bioterrorism through complementary, simultaneous improvements in the bioterrorism-related expertise, facilities, and procedures of state and local health departments and within the CDC itself. The emphasis areas are (a) preparedness planning by state and local health departments; (b) prompt reporting of cases of illness that might have been caused by terrorists; (c) epidemiological analysis of outbreaks to identify the source and mode of transmission; (d) laboratory identification and characterization of the agents causing the outbreaks; and (e) electronic communications among public health officials regarding occurrences of outbreaks and responses to them. CDC recently issued a competitive program announcement soliciting applications for cooperative-agreement awards whereby states and major metropolitan health departments can receive financial and technical assistance to effect desired improvements in one or more of the five emphasis areas. CDC will make these awards this summer.

Medical and Public Health Response. Much of the initial burden and responsibility for providing an effective response by medical and public health professionals to a terrorist attack of any kind rests with the local governments, with support from state and federal agencies. Local public health systems almost inevitably will be called on to provide protective and responsive measures for the affected populations, including:

- mass patient care -- including the establishment of auxiliary, temporary treatment facilities or procedures for the movement of overflow patients to other geographic areas for care;
- in the case of a bioterrorist event, mass immunization or prophylactic drug treatment for groups known to be exposed, groups who may have been exposed, and populations not already exposed but at risk of exposure from secondary transmission and/or the environment;
- mass fatality management to provide respectful and safe disposition of the deceased, including animals; and
- decontamination of the environment.

Presidential Decision Directive 62 designates DHHS as the lead federal agency to plan and prepare for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction. Within DHHS, this responsibility rests with the Office of Emergency Preparedness (OEP) within the Office of Public Health and Science.

OEP seeks to develop complementary medical response capabilities at local and national levels. It works closely with other agencies especially the relevant components of the Department of Defense (DOD), the

Department of Justice, the Department of Veterans Affairs, the Federal Emergency Management Agency, and others with a view toward ensuring that plans for managing the medical consequences of terrorist acts are well integrated with other emergency response systems. To date, the anti-terrorism focus across the federal government has been on the prospect of nuclear or chemical attacks. Future preparedness efforts must focus on the prospect of bioterrorism as well.

In particular, OEP contracts with local governments for the creation of Metropolitan Medical Response Systems (MMRSs) and, within these agreements, is placing new emphasis on preparedness for mass patient care and other consequences of biological terrorism. Also, OEP is working to strengthen its four National Medical Response Teams and the National Disaster Medical System overall with respect to the bioterrorism threat so that they can augment local capabilities as needed in the event of an attack. To date, OEP has contracted with 27 municipalities to develop MMRSs. Another 8 MMRSs are to be initiated this year; plans to fund 12 more with redirected Fiscal Year (FY) 1999 funds have been provided to the Subcommittee (bringing the total to 47); and the budget request for FY 2000 includes \$16.5 million for contracts with an additional 20 cities for MMRSs - bringing the total to 67. The long term goal is to establish MMRSs in all 120 metropolitan areas specified in The Response to Weapons of Mass Destruction Act of 1997.

National Pharmaceutical Stockpile. A release of biological, and some chemical, weapons of mass destruction will require rapid access to quantities of pharmaceutical antidotes, antibiotics and/or vaccines that will not be readily available in the locations in which they would be needed unless special stockpiles are created. Because no one can anticipate exactly where a terrorist will strike and each local government does not have the resources to create sufficient stockpiles on its own, special stockpiles must be created and maintained as a national resource.

The initial focus will be on acquiring antibiotics useful in treating anthrax, plague, and tularemia; enhancing the utility of the existing supply of smallpox vaccine; and developing a cache of drugs and equipment for countering chemical attacks. Once research and development have yielded improved vaccines against anthrax and smallpox and new antiviral drugs effective against smallpox, they will be included in the stockpile.

CDC has responsibility for developing the stockpile. Fifty one (51) million dollars has been appropriated for this purpose this fiscal year, and a comparable sum is requested for FY 2000.

Research and Development. Capability to detect and counter bioterrorism depends to a substantial degree on the state of relevant medical science and technology. Without rapid techniques for accurate identification of pathogens and assessment of their antibiotic sensitivity, planning for the medical and public health response will be compromised significantly. Without efficacious prophylactic and therapeutic agents, even the best planned responses are likely to fail. The current base of science and technology is strong in some areas (e.g., certain classes of anti-bacterial drugs) and weak in others (e.g., rapid diagnostics, anti-viral drugs, and vaccines). Strong, sustained research and development in relevant scientific disciplines is the only proven way to remedy such deficiencies in knowledge and technology.

The National Institutes of Health (NIH) is reinvigorating its research related to the pathogenesis of - and host immune responses to - infectious organisms likely to be used in terrorist acts - e.g., the organisms that cause anthrax, tularemia, and plague. This research would be greatly facilitated by the acquisition of genome sequence information on these and related pathogens. The results of such genomics research - coupled with other pathological, immunological, biochemical, and microbiological information - are expected to facilitate pursuit of a variety of critical goals including the development of rapid diagnostic methods for the most likely biological weapons, the development of antiviral therapies for smallpox and Ebola virus, and the development of new vaccines for anthrax, cholera, and smallpox. NIH also will undertake an array of basic and targeted studies oriented toward development of new or improved methods to diagnose chemical exposures and determine their effects upon the nervous system.

Building upon the rapid advances of recent years in the molecular and cell biology of infectious organisms, the Department has requested \$30 million in FY 2000 specifically for developing improved vaccines for the highest priority bioterrorism threats: anthrax and smallpox.

Other DHHS agencies are engaged in relevant research and development as well. CDC, as part of the surveillance initiative I described earlier, is expanding its in-house Rapid Toxic Screen project to develop methods for measuring, within 48 hours, toxicants in human blood or urine samples. The goal over the next three years is to devise methods to identify and measure 150 different toxins and to achieve an in-house analytic capacity of 200 samples per day. As new methods come on line, CDC will disseminate them to state and local laboratories as appropriate for incorporation into their analytic repertoires. Also, FDA proposes to expand its research on detection and characterization of toxins that might be used by terrorists.

Looking more generally at the entire civilian medical response to chemical and biological terrorism, DHHS contracted in May, 1997 with the National Academy of Sciences' Institute of Medicine (IOM) to provide specific recommendations for priority research and development activities to improve that response. The IOM's report, delivered this past January, examines a wide range of research and development needs - including not only the medical response areas described above but also topics such as environmental detection of chemical or biological agents, personal protective clothing and equipment, and decontamination. My colleagues and I have found this to be an excellent and helpful study; and the Office of Science and Technology within the Executive Office of the President is using the IOM report as its framework for assessing and coordinating counter-terrorism-related research and development throughout the Executive Branch.

Expedited Regulatory Review. The development of new or improved diagnostics, antibiotics, antivirals, and vaccines needed to combat bioterrorism must go hand in hand with efforts to streamline the regulatory process that new products must undergo successfully to be approved for marketing. FDA will work closely with sponsors and manufacturers to ensure effective and timely reviews of investigational new products. For example, NIH has created an Anthrax Vaccine Working Group, which brings together representatives of the NIH, FDA, and DOD to advance research and development relevant to developing a new anthrax vaccine. Also, FDA intends to accelerate the pace and increase the efficiency of its reviews by ensuring the availability of experts to guide sponsors through the regulatory process not only for new products but also for new uses of existing products.

In conclusion, Mr. Chairman, I believe that DHHS is off to a good start toward protecting this nation from those who would use biological weapons against the civilian population. Thanks to the leadership of President Clinton and the strong support of the Congress, the funding for the anti-bioterrorism initiative this fiscal year totals \$158 million. Moreover, the President's request for FY 2000 includes \$230 million to continue, expand, and strengthen the activities begun this year. The medical and public health communities clearly have the skill and the will needed for this task. We seek your help in ensuring that they also have the means.



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)
[Testimony](#)

[SEARCH](#)

[HOME](#)
[CONTACT US](#)

Statement on Bioterrorism by Jeffrey P. Koplan, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Before the Senate Subcommittee on Public Health Committee on Health, Education, Labor, and Pensions
March 25, 1999

I am Dr. Jeffrey P. Koplan, Director, Centers for Disease Control and Prevention (CDC). I am accompanied today by Dr. James M. Hughes, Director, National Center for Infectious Diseases, CDC. Thank you for the invitation to discuss the need to enhance the public health capacity in the United States to respond to the threat of bioterrorism. I will provide a brief discussion of the current situation and then I will describe the actions that CDC is taking to strengthen and modify our current public health laboratories and disease surveillance and control to ensure an effective response to acts of biological and chemical terrorism.

Vulnerability of the Civilian Population

In the past, an attack with a biological agent was considered very unlikely; however, now it seems entirely possible. Many experts believe that it is no longer a matter of "if" but "when" such an attack will occur. They point to the accessibility of information on how to prepare biologic weapons and to activities by groups such as Aum Shinrykyo, which, in addition to releasing nerve gas in Tokyo's subway, experimented with botulism and anthrax. In 1997, the FBI investigated a situation in Las Vegas in which an individual was in possession of the organism causing anthrax. Although he had an attenuated strain of anthrax used in an animal vaccine rather than a virulent strain, the incident provided another reminder of how easily a terrorist might cause serious illness and panic in a U.S. city.

An attack with a chemical agent is also increasingly likely. Such an attack might involve the release of a noxious gas, such as a nerve gas, phosgene, or lewisite, or an airborne chemical, such as hydrogen cyanide, chlorine, or pesticides, that can kill many people. Early in an investigation, it may not be obvious whether an outbreak is caused by an infectious agent or a chemical toxin; however, most chemical attacks will be localized, and their effects will be evident within a few minutes. An attack using a chemical agent will demand immediate reaction from emergency responders - fire departments, police, EMS, and emergency room staff - who will need adequate training and equipment. In contrast, when people are exposed to a pathogen like anthrax or smallpox, they will not know that they have been exposed, and they may not feel sick for some time. This delay between exposure and onset of illness, or incubation period, is characteristic of infectious diseases. The incubation period may range from several hours to a few weeks, depending on the exposure and pathogen.

The initial response to such a biological attack on civilians is likely to be made by the public health community rather than by the military or emergency responders. Thus, protection against terrorism requires investment in the public health system. This point is underscored in a report, commissioned by the Department of Health and Human Services Office of Emergency Preparedness and recently released by the Institute of Medicine and the National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, which stresses the need for long-term public health improvements in surveillance and epidemiology infrastructure. Copies of the report have been provided to the Subcommittee. The financial costs of these improvements will be relatively modest. For example, without these investments, it has been estimated that responding to an initially undetected and consequently uncontrolled anthrax attack that results in infecting 100,000 people could cost \$26 billion.

Public Health Leadership

As the nation's disease prevention and control agency, it is CDC's responsibility to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of a deliberate release of biological or chemical agents. This task is an integral part of CDC's overall mission to monitor the health of the U.S. population.

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan emphasizes the need to be prepared for the unexpected -- whether it be a naturally occurring influenza pandemic or the deliberate release of anthrax by a terrorist. Copies of this CDC plan have been provided to the Subcommittee previously.

Strengthening Public Health Readiness to Address Bioterrorism

Increased vigilance and preparedness for unexplained illnesses is an essential part of the public health effort to protect the American people against bioterrorism. Toward this end, CDC, working in collaboration with State and local health departments, many other public health partners, and other Federal agencies, has begun the effort to upgrade national public health capabilities to respond to biological and chemical terrorism.

Further, because terrorists may employ a wide range of biological and chemical agents, this country's infectious disease surveillance networks must have enhanced capacity to detect unusual events, unidentified agents, and unexplained illnesses. In addition, State and Federal epidemiologists must be trained to consider unusual or rare threat agents when a suspicious outbreak occurs and be prepared to address questions related to their transmission, treatment, and prevention.

Focus Areas For Public Health Action

In December 1998, CDC established the Bioterrorism Preparedness and Response Activity (BPRA), to lead an agency-wide effort to prepare for and respond to acts of terrorism that involve actual, threatened, or suspected uses of biological or chemical agents. BPRA is charged with the coordination of CDC's epidemiological and laboratory response following a suspected or actual attack and response to health threats from unknown biological or chemical agents.

Last month, in an effort to provide support and assistance to State and large metropolitan health departments in enhancing their ability to be prepared for and respond to a terrorist attack that involves a biological or chemical agent, CDC announced the availability of nearly \$41,000,000 in Public Health Preparedness and Response to Bioterrorism cooperative agreement funds. This announcement, along with other extramural and intramural strategies, focuses on strengthening four components of the public health infrastructure to improve the national capacity to address biological and chemical terrorism:

- **Detection of unusual events.** Because the initial detection of a biological or chemical terrorist attack will most likely occur at the local level, it is essential to educate and train members of the medical community -- both public and private -- who may be the first to examine and treat the victims. It is also necessary to upgrade the surveillance systems of State and local health departments, which will be relied upon to spot unusual patterns of disease occurrence and to identify any additional cases of illness as the disease spreads throughout the community and beyond.

To enable States and major cities to build core capacity to monitor and detect potential biologic and chemical threat agents, CDC will make up to 30 awards as a part of the Public Health Preparedness and Response to Bioterrorism cooperative agreement. CDC will also lead the development of new disease surveillance networks in hospitals and other health care facilities and will evaluate new surveillance mechanisms to improve the nation's ability to detect low incidences of unexplained illnesses.

- **Investigation and containment of outbreaks.** The initial response to an outbreak caused by an act of chemical and biological terrorism will take place at the local level. In the most likely scenario, CDC -- as well as DOD and security agencies -- will be alerted to a bioterrorist attack only after a State or local health department has recognized a cluster of cases that is highly unusual or of an unknown cause. For this reason, it is imperative that State and local health departments have sufficient resources to conduct epidemiologic investigations.

Through the cooperative agreement and other mechanisms, CDC will provide State and large metropolitan health departments with tools, training, and financial resources for local outbreak investigations, and help develop rapid public health response capacity at the local, State, and Federal levels. Additionally, in the event of a suspected or an actual attack, CDC will be prepared to assist State health departments in identifying threat agents and their modes of transmission, in instituting control measures, and in providing consultation on medical management.

CDC is also working to establish a National Pharmaceutical Stockpile which will ensure the availability of drugs, vaccines, prophylactic medicines, chemical antidotes, medical supplies, and equipment that might be needed in a medical response to a biological or chemical terrorist incident.

- **Laboratory diagnosis.** In the event of a biological or chemical terrorist attack, rapid diagnosis will

be critical, so that prevention and treatment measures can be implemented quickly. CDC will fund approximately 34 State and major metropolitan health departments under the cooperative agreement to improve capacity to diagnose biologic threat agents. At the same time, CDC will make up to four additional awards to enable selected State health laboratories to function as reference facilities for the identification of chemical threats. In addition to evaluating existing technology for identifying priority biological agents, CDC will develop a Rapid Toxic Screen that can assess exposure to 150 different chemical agents. CDC will develop guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of biologic and environmental samples. Working with other federal partners, CDC will develop a Rapid Assay and Technology Transfer laboratory to quickly identify pathogens and chemicals that might be used by terrorists and to serve as a triage laboratory.

Finally, CDC is working with public health partners to plan the development of a multi-level network of laboratories which will be used to provide the most immediate diagnosis of a biological agent in the event of a suspected terrorist attack. This network will ultimately include hospital laboratories, commercial reference laboratories, State and local health laboratories, and highly specialized Federal facilities. It will not only enhance public health capacity to address bioterrorism, but also contribute to the overall public health capacity to address naturally occurring infectious diseases.

- **Coordination and Communication.** In the event of an intentional release of a chemical or biological agent, rapid and secure communications will be especially crucial to ensure a prompt and coordinated response. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. In order to assure the most effective response to an attack, CDC will work closely with The FBI, which will take the lead in the criminal investigation of a terrorist attack, and with other government agencies, including the Food and Drug Administration (FDA), National Institutes of Health (NIH), DOD, and the Federal Emergency Management Agency.

In the event of a terrorist attack, we will need to ensure that the public is provided with accurate and timely information. An act of terrorism is likely to cause widespread panic, and on-going communication of accurate and up-to-date information will help calm public fears and limit collateral effects of the attack.

Internationally, global health security will be enhanced as CDC, in collaboration with the World Health Organization, responds throughout the world to reports of illnesses from unusual pathogens, suspected bioterrorism, and other outbreaks that might threaten the U.S. population.

Planning and Preparedness

CDC is working to ensure that all levels of the public health community -- Federal, State, and local -- are prepared to work in coordination with the medical and emergency response communities to address the public health consequences of biological and chemical terrorism. CDC will assist States and major cities in developing local public health bioterrorism preparedness plans that are well integrated into existing emergency response plans at the local, State, and Federal level. CDC is creating diagnostic and epidemiological performance standards for State and local health departments and will help States conduct drills and exercises to assess local readiness for bioterrorism.

In addition, CDC, NIH, DOD, and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism. For example, for several of the agents likely to be used as bio-weapons, we need to create rapid, simple, low-cost diagnostic kits that can be used in the field to test large numbers of people exposed to a biological or chemical agent within a short time frame. In some cases, new vaccines, antitoxins, or innovative drug treatments are also required. Moreover, we need to learn more about the pathogenesis and epidemiology of these rare diseases. We also have only limited knowledge about how artificial methods of dispersion may affect the infection rate or virulence of these diseases.

Disease Prevention

Disease experts at CDC are considering various strategies for preventing the spread of disease during and after bioterrorist attacks. Strategies under evaluation include: creating protocols for immunizing at-risk populations, isolating large numbers of exposed individuals, and reducing occupational exposures; assessing methods of safeguarding food and water from deliberate contamination; and exploring ways to improve linkages between animal and human disease surveillance networks since threat agents that affect both humans and animals may first be detected in animals.

CDC is enhancing its ongoing efforts to foster the safe design and operation of Biosafety Level 3 and 4 laboratories, which are required for handling highly dangerous pathogens. In addition, CDC is helping to limit access to potential terrorist agents by strengthening its capacity to administer the Select Agent Rule, *Additional Requirements for Facilities Transferring or Receiving Select Agents* (42 CFR Section 72.6), which regulates shipments of certain hazardous biological organisms and toxins.

Conclusions

In conclusion, the best public health method to protect, respond, and defend the health of civilians against chemical and biological terrorism is the development, organization, and enhancement of life-saving public health prevention tools. Such tools include expanded State public health laboratory capacity, increased surveillance and outbreak investigation capacity, and health communications and training at the local, State, and Federal levels. The tools we develop in response to bioterrorism threats are "dual use" tools. Not only will they ensure that we are prepared for man-made threats, but they also ensure that we will be able to recognize and control the naturally occurring emerging infectious diseases and the hazardous materials incidents of the late 20th century. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

Thank you very much for your attention. I will be happy to answer any questions you may have.

[Privacy Notice](#) | [FOIA](#) | [What's New](#) | [FAQs](#) | [Reading Room](#) | [Site Info](#)



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)
[Testimony](#)

[SEARCH](#)

[HOME](#)
[CONTACT US](#)

Statement on Bioterrorism by James M. Hughes, M.D.

Director, National Center for Infectious Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Before the Subcommittee on Technology, Terrorism, and Government Information,
Subcommittee on Youth Violence, Committee on the Judiciary
April 20, 1999

I am Dr. James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). Thank you for the invitation to discuss the need to enhance the public health capacity in the United States to respond to the threat of bioterrorism. I will provide a brief discussion of the current situation and then I will describe the actions that CDC is taking to strengthen and modify our current public health laboratories and disease surveillance and control to ensure an effective response to acts of biological and chemical terrorism.

Vulnerability of the Civilian Population

In the past, an attack with a biological agent was considered very unlikely; however, now it seems entirely possible. Many experts believe that it is no longer a matter of "if" but "when" such an attack will occur. They point to the accessibility of information on how to prepare biologic weapons and to activities by groups such as Aum Shinrykyo, which, in addition to releasing nerve gas in Tokyo's subway, experimented with botulism and anthrax. In 1997, the FBI investigated a situation in Las Vegas in which an individual was in possession of the organism causing anthrax. Although he had an attenuated strain of anthrax used in an animal vaccine rather than a virulent strain, the incident provided another reminder of how easily a terrorist might cause serious illness and panic in a U.S. city.

An attack with a chemical agent is also increasingly likely. Such an attack might involve the release of a noxious gas, such as a nerve gas, phosgene, or lewisite, or an airborne chemical, such as hydrogen cyanide, chlorine, or pesticides, that can kill many people. Early in an investigation, it may not be obvious whether an outbreak is caused by an infectious agent or a chemical toxin; however, most chemical attacks will be localized, and their effects will be evident within a few minutes. An attack using a chemical agent will demand immediate reaction from emergency responders - fire departments, police, EMS, and emergency room staff - who will need adequate training and equipment. In contrast, when people are exposed to a pathogen like anthrax or smallpox, they will not know that they have been exposed, and they may not feel sick for some time. This delay between exposure and onset of illness, or incubation period, is characteristic of infectious diseases. The incubation period may range from several hours to a few weeks, depending on the exposure and pathogen.

The initial response to such a biological attack on civilians is likely to be made by the public health community rather than by the military or emergency responders. Thus, protection against terrorism requires investment in the public health system. This point is underscored in a report, commissioned by the Department of Health and Human Services Office of Emergency Preparedness and recently released by the Institute of Medicine and the National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, which stresses the need for long-term public health improvements in surveillance and epidemiology infrastructure. Copies of the report have been provided to the Subcommittees. The financial costs of these improvements will be relatively modest. For example, without these investments, it has been estimated that responding to an initially undetected and consequently uncontrolled anthrax attack that results in infecting 100,000 people could cost \$26 billion.

Public Health Leadership

As the nation's disease prevention and control agency, it is CDC's responsibility to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of a deliberate release of biological or chemical agents. This task is an integral part of CDC's overall mission to monitor the health of the U.S. population.

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan emphasizes the need to be prepared for the unexpected -- whether it be a naturally occurring influenza pandemic or the deliberate release of anthrax by a terrorist. Copies of this CDC plan have been provided to the Subcommittee.

Strengthening Public Health Readiness to Address Bioterrorism

Increased vigilance and preparedness for unexplained illnesses is an essential part of the public health effort to protect the American people against bioterrorism. Toward this end, CDC, working in collaboration with State and local health departments, many other public health partners, and other Federal agencies, has begun the effort to upgrade national public health capabilities to respond to biological and chemical terrorism.

Further, because terrorists may employ a wide range of biological and chemical agents, this country's infectious disease surveillance networks must have enhanced capacity to detect unusual events, unidentified agents, and unexplained illnesses. In addition, State and Federal epidemiologists must be trained to consider unusual or rare threat agents when a suspicious outbreak occurs and be prepared to address questions related to their transmission, treatment, and prevention.

Focus Areas For Public Health Action

In December 1998, CDC established the Bioterrorism Preparedness and Response Activity (BPRA), to lead an agency-wide effort to prepare for and respond to acts of terrorism that involve actual, threatened, or suspected uses of biological or chemical agents. BPRA is charged with the coordination of CDC's epidemiological and laboratory response following a suspected or actual attack and response to health threats from unknown biological or chemical agents.

In February, in an effort to provide support and assistance to State and large metropolitan health departments in enhancing their ability to be prepared for and respond to a terrorist attack that involves a biological or chemical agent, CDC announced the availability of nearly \$41,000,000 in Public Health Preparedness and Response to Bioterrorism cooperative agreement funds. This announcement, along with other extramural and intramural strategies, focuses on strengthening four components of the public health infrastructure to improve the national capacity to address biological and chemical terrorism:

- **Detection of unusual events.** Because the initial detection of a biological or chemical terrorist attack will most likely occur at the local level, it is essential to educate and train members of the medical community -- both public and private -- who may be the first to examine and treat the victims. It is also necessary to upgrade the surveillance systems of State and local health departments, which will be relied upon to spot unusual patterns of disease occurrence and to identify any additional cases of illness as the disease spreads throughout the community and beyond.

To enable States and major cities to build core capacity to monitor and detect potential biologic and chemical threat agents, CDC will make up to 30 awards as a part of the Public Health Preparedness and Response to Bioterrorism cooperative agreement. CDC will also lead the development of new disease surveillance networks in hospitals and other health care facilities and will evaluate new surveillance mechanisms to improve the nation's ability to detect low incidences of unexplained illnesses.

- **Investigation and containment of outbreaks.** The initial response to an outbreak caused by an act of chemical and biological terrorism will take place at the local level. In the most likely scenario, CDC -- as well as DOD and security agencies -- will be alerted to a bioterrorist attack only after a State or local health department has recognized a cluster of cases that is highly unusual or of an unknown cause. For this reason, it is imperative that State and local health departments have sufficient resources to conduct epidemiologic investigations.

Through the cooperative agreement and other mechanisms, CDC will provide State and large metropolitan health departments with tools, training, and financial resources for local outbreak investigations, and help develop rapid public health response capacity at the local, State, and Federal levels. Additionally, in the event of a suspected or an actual attack, CDC will be prepared to assist State health departments in identifying threat agents and their modes of transmission, in instituting control measures, and in providing consultation on medical management.

CDC is also working to establish a National Pharmaceutical Stockpile which will ensure the availability of drugs, vaccines, prophylactic medicines, chemical antidotes, medical supplies, and equipment that might be needed in a medical response to a biological or chemical terrorist incident.

- **Laboratory diagnosis.** In the event of a biological or chemical terrorist attack, rapid diagnosis will

be critical, so that prevention and treatment measures can be implemented quickly. CDC will fund approximately 34 State and major metropolitan health departments under the cooperative agreement to improve capacity to diagnose biologic threat agents. At the same time, CDC will make up to four additional awards to enable selected State health laboratories to function as reference facilities for the identification of chemical threats. In addition to evaluating existing technology for identifying priority biological agents, CDC will develop a Rapid Toxic Screen that can assess exposure to 150 different chemical agents. CDC will develop guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of biologic and environmental samples. Working with other federal partners, CDC will develop a Rapid Assay and Technology Transfer laboratory to quickly identify pathogens and chemicals that might be used by terrorists and to serve as a triage laboratory.

Finally, CDC is working with public health partners to plan the development of a multi-level network of laboratories which will be used to provide the most immediate diagnosis of a biological agent in the event of a suspected terrorist attack. This network will ultimately include hospital laboratories, commercial reference laboratories, State and local health laboratories, and highly specialized Federal facilities. It will not only enhance public health capacity to address bioterrorism, but also contribute to the overall public health capacity to address naturally occurring infectious diseases.

- **Coordination and Communication.** In the event of an intentional release of a chemical or biological agent, rapid and secure communications will be especially crucial to ensure a prompt and coordinated response. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. In order to assure the most effective response to an attack, CDC will work closely with The FBI, which will take the lead in the criminal investigation of a terrorist attack, and with other government agencies, including the Food and Drug Administration (FDA), National Institutes of Health (NIH), DOD, and the Federal Emergency Management Agency.

In the event of a terrorist attack, we will need to ensure that the public is provided with accurate and timely information. An act of terrorism is likely to cause widespread panic, and on-going communication of accurate and up-to-date information will help calm public fears and limit collateral effects of the attack.

Internationally, global health security will be enhanced as CDC, in collaboration with the World Health Organization, responds throughout the world to reports of illnesses from unusual pathogens, suspected bioterrorism, and other outbreaks that might threaten the U.S. population.

Planning and Preparedness

CDC is working to ensure that all levels of the public health community -- Federal, State, and local -- are prepared to work in coordination with the medical and emergency response communities to address the public health consequences of biological and chemical terrorism. CDC will assist States and major cities in developing local public health bioterrorism preparedness plans that are well integrated into existing emergency response plans at the local, State, and Federal level. CDC is creating diagnostic and epidemiological performance standards for State and local health departments and will help States conduct drills and exercises to assess local readiness for bioterrorism.

In addition, CDC, NIH, DOD, and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism. For example, for several of the agents likely to be used as bio-weapons, we need to create rapid, simple, low-cost diagnostic kits that can be used in the field to test large numbers of people exposed to a biological or chemical agent within a short time frame. In some cases, new vaccines, antitoxins, or innovative drug treatments are also required. Moreover, we need to learn more about the pathogenesis and epidemiology of these rare diseases. We also have only limited knowledge about how artificial methods of dispersion may affect the infection rate or virulence of these diseases.

Disease Prevention

Disease experts at CDC are considering various strategies for preventing the spread of disease during and after bioterrorist attacks. Strategies under evaluation include: creating protocols for immunizing at-risk populations, isolating large numbers of exposed individuals, and reducing occupational exposures; assessing methods of safeguarding food and water from deliberate contamination; and exploring ways to improve linkages between animal and human disease surveillance networks since threat agents that affect both humans and animals may first be detected in animals.

CDC is enhancing its ongoing efforts to foster the safe design and operation of Biosafety Level 3 and 4 laboratories, which are required for handling highly dangerous pathogens.

Conclusions

In conclusion, the best public health method to protect, respond, and defend the health of civilians against chemical and biological terrorism is the development, organization, and enhancement of life-saving public

health prevention tools. Such tools include expanded State public health laboratory capacity, increased surveillance and outbreak investigation capacity, and health communications and training at the local, State, and Federal levels. The tools we develop in response to bioterrorism threats are "dual use" tools. Not only will they ensure that we are prepared for man-made threats, but they also ensure that we will be able to recognize and control the naturally occurring emerging infectious diseases and the hazardous materials incidents of the late 20th century. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

Thank you very much for your attention. I will be happy to answer any questions you may have.

[Privacy Notice](#) | [FOIA](#) | [What's New](#) | [FAQs](#) | [Reading Room](#) | [Site Info](#)



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)

Testimony on Bioterrorism by Margaret A. Hamburg, M.D.

Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

Before the Senate Committee on Health, Education, Labor, and Pensions, Public Health Subcommittee,
March 25, 1999

[SEARCH](#)
[HOME](#)
[CONTACT US](#)

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today.

The Department of Health and Human Services (DHHS) welcomes your interest in our efforts to develop effective counter-measures for possible uses of biological weapons against the civilian population.

I will outline for you the overall strategic approach that DHHS is pursuing in our anti-bioterrorism activities - emphasizing our efforts to strengthen the public health infrastructure for infectious disease surveillance related to potential bioterrorism agents and our efforts to enhance capabilities for medical and public health response should a bioterrorist attack occur.

I begin by noting that bioterrorism presents a set of non-trivial challenges to our emergency preparedness systems, public health organizations, and consequence management capability. Unlike an event involving explosives or chemicals, a terrorist incident involving a biological agent may not be discernable until people begin to present with serious illness. This may occur at considerable and varying distance from the site of initial exposure, both in terms of onset of disease (incubation periods can vary) and geographic location (e.g., if exposure occurs in a transportation terminus, people can spread out widely before becoming ill). If a bioterrorist event involves a communicable biological agent, there is also the possibility of ever-increasing, concentric circles of exposure, extending significantly the damage caused by the released agent. This kind of threat will also dramatically increase the level of public fear and potential for major civil disruption.

Terrorist attacks are intended to create some combination of illness, injury, suffering, death and economic loss all of which increase the likelihood of behavioral, psychological and social disorder. Bioterrorism, with its implication of death arriving imperceptibly through the air we breathe, poses a new constellation of threats to the resilient human mind and to the power of both large and small communities to survive intact. In addition to the potentially massive numbers of physical casualties or deaths, bioterrorism, by threat or in fact, will create a devastating number of psychological casualties. A bioterrorist event is different from all other forms of terrorism in its potential to precipitate mass behavior responses such as panic, civil disorder and pandemonium. This is especially true if the bioweapon used is a communicable agent that spreads disease in successive waves of transmission. We could expect a bioterrorist attack to seriously disrupt local and regional economic functioning over many weeks or months since the "damage" that is inflicted is not to material infrastructure but to the human infrastructure a kind of damage that takes considerably longer to repair.

What underscores the urgent need to prepare for the possibility of bioterrorism is the fact that the bioweapons most likely to be used are pathogens that are not routinely seen by health care providers. This has a number of significant implications: (1) the population generally has little or no immunity to the pathogen and hence is more vulnerable (e.g., no longer vaccinated against smallpox); (2) medical providers generally are not familiar with the diagnosis and treatment of these disorders (which they may even fail to initially recognize); and (3) routine scientific research into the pathogenesis and treatment of certain of these disease conditions has been at very low levels compared to other agents of infection because they have not been perceived to be high priority or because they require levels of biological containment that are not available at most research centers.

For these reasons, a sound strategy for addressing bioterrorism will be quite different from those that target other types of terrorist acts.

The DHHS initiative features activities in five distinct but related areas:

- Deterrence of biological terrorism
- Surveillance for unusual outbreaks of illness
- Medical and public health response
- Development of a national pharmaceutical stockpile
- Research and development

I will comment briefly on each.

Deterrence. Measures that will deter or prevent bioterrorism will be far and away the most cost effective means to counter such threats to public health and social order. Among the activities that need to be initiated are efforts to control access to and handling of dangerous pathogens, including proactive measures by the scientific community to monitor more closely the facilities and procedures surrounding the use of such biological agents.

The Centers for Disease Control and Prevention (CDC) has the responsibility mandated by the Antiterrorism and Effective Death Penalty Act of 1996 to regulate shipment of certain hazardous biological organisms and toxins (hereinafter called "select agents"). Organizations such as research universities, pharmaceutical manufacturers, and microbiological archives often have occasion, as part of their routine work, to send or receive samples of dangerous pathogens or toxins. DHHS regulations (42 CFR 72.6) require that all facilities sending or receiving shipments of select agents register with CDC, maintain records of such transfers, and otherwise document their compliance. CDC's administration of the select agent rule is part of the Executive Branch's multi-agency effort to combat terrorism.

CDC fosters safe design and secure operation of laboratories that handle select agents. This involves consultation with laboratory officials to help ensure that new, renovated, or proposed facilities meet standard guidelines for the infectious organisms that will be handled. Development of guidelines and training materials for use by laboratory personnel and provision of technical assistance to states as requested regarding their inspection programs for such facilities also are part of CDC's responsibilities.

Surveillance. Terrorist use of biological weapons against the civilian population is likely to be surreptitious. Absent an explosion, other immediate evidence of an attack, or notification of authorities by a perpetrator that an attack has been made (i.e., people have been exposed), the first responders will be health-care workers rather than fire or police personnel (as would be expected for a conventional emergency response scenario). The first indication that a silent attack has occurred probably will be an outbreak of some uncommon illness or an abrupt, significant increase in the incidence of commonly observed symptoms. How quickly the outbreak is detected, analyzed, understood, and addressed will determine the timeliness and effectiveness of the medical and public health response and hence the extent and severity of the impact upon the health and well-being of the affected community.

For example, most infectious agents have an incubation period measured in days or weeks. A silent release of a biological agent capable of producing a highly communicable disease, therefore, could afflict hundreds - if not thousands - of individuals over a wide geographic area during a period of several weeks before the need for a full medical and public health response could be identified and the response designed and mounted.

CDC is working to upgrade public health capability to counter bioterrorism through complementary, simultaneous improvements in the bioterrorism-related expertise, facilities, and procedures of state and local health departments and within the CDC itself. The emphasis areas are (a) preparedness planning by state and local health departments; (b) prompt detection of outbreaks of illness that might have been caused by terrorists; (c) investigation of outbreaks to identify the source and mode of transmission; (d) laboratory identification and characterization of the agents causing the outbreaks; and (e) electronic communications among public health officials regarding occurrences of outbreaks and responses to them. CDC recently issued a competitive program announcement soliciting applications for cooperative-agreement awards whereby states and major metropolitan health departments can receive financial and technical assistance to effect desired improvements in one or more of the five emphasis areas. The awards are to be made this year.

Medical and Public Health Response. Much of the initial burden and responsibility for providing an effective response by medical and public health professionals to a terrorist attack of any kind rests with the local governments, with supplemental support from state and federal agencies. Local public health systems almost inevitably will be called on to provide protective and responsive measures for the affected populations, including:

- mass patient care -- including the establishment of auxiliary, temporary treatment facilities or procedures for the movement of overflow patients to other geographic areas for care;
- in the case of a bioterrorist event, mass immunization or prophylactic drug treatment for groups known to be exposed, groups who may have been exposed, and populations not

already exposed but at risk of exposure from secondary transmission and/or the

environment;

- mass fatality management to provide respectful and safe disposition of the deceased, including animals;
- infection control; and
- assessment of the extent of contamination of the environment and identification of risk management steps to assure safe re-entry of the potentially contaminated areas.

Presidential Decision Directive 62 designates DHHS as the lead federal agency to plan and prepare for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction. Within DHHS, this responsibility rests with the Office of Emergency Preparedness (OEP) within the Office of Public Health and Science.

OEP seeks to develop complementary medical response capabilities at local and national levels. It works closely with other agencies especially the relevant components of the Departments of Defense (DOD) and Justice (DOJ) and the Federal Emergency Management Agency (FEMA) with a view toward ensuring that plans for managing the medical consequences of terrorist acts are well integrated with other emergency response systems. The almost exclusive anti-terrorism focus across the federal government to date has been on the prospect of nuclear or chemical attacks. Future preparedness efforts must focus on the prospect of bioterrorism as well.

In particular, OEP contracts with local governments for the creation of Metropolitan Medical Response Systems (MMRSs) and, within these agreements, is placing new emphasis on preparedness for mass patient care and other consequences of biological terrorism. To date, OEP has contracted with 27 municipalities to develop MMRSs; plans call for another 8 to be initiated in FY 1999. However, because the development of these Systems is considered to be a high priority, the Secretary intends to use her transfer authority, granted in Section 207 of P. L. 105-277, the Omnibus Consolidation and Emergency Supplemental Appropriations Act of 1999, to provide \$11 million to OEP to establish 12 additional MMRSs this year. These funds include monies to enhance city responses to bioterrorism for all 47 cities. Also, OEP is working to strengthen its four National Medical Response Teams and the National Disaster Medical System overall with respect to the bioterrorism threat so that they can augment local capabilities as needed in the event of an attack.

National Pharmaceutical Stockpile. A release of biological, and some chemical, weapons of mass destruction will require rapid access to quantities of pharmaceutical antidotes, antibiotics and/or vaccines that will not be readily available in the locations in which they would be needed unless special stockpiles are created. Because no one can anticipate exactly where a terrorist will strike and each local government does not have the resources to create sufficient stockpiles on its own, special stockpiles must be created and maintained as a national resource.

The initial focus will be on acquiring antibiotics useful in treating anthrax, plague, and tularemia; enhancing the utility of the existing supply of smallpox vaccine; and developing a cache of drugs and equipment for countering chemical attacks. Once research and development has yielded improved vaccines against anthrax and smallpox and new antiviral drugs effective against smallpox, they will be included in the stockpile.

CDC has responsibility for developing the stockpile. Fifty one (51) million dollars has been appropriated for this purpose this fiscal year, and a comparable sum is requested for FY 2000.

Research and Development. Capability to detect and counter bioterrorism depends to a substantial degree on the state of relevant medical science and technology. Without rapid techniques for accurate identification of pathogens and assessment of their antibiotic sensitivity, planning for the medical and public health response will be compromised significantly. Without efficacious prophylactic and therapeutic agents, even the best planned responses are likely to fail. The current base of science and technology is strong in some areas (e.g., certain classes of anti-bacterial drugs) and weak in others (e.g., rapid diagnostics, anti-viral drugs, and vaccines). Strong, sustained research and development in relevant scientific disciplines is the only proven way to remedy such deficiencies in knowledge and technology.

To assist the Department in identifying priorities for investments in research and development, the Institute of Medicine (IOM) recently completed, under contract with OEP, a report on R&D activities that would improve civilian medical response to the consequences of biological and chemical terrorism. Along with the Office of Science and Technology Policy, we believe that this report, which contains over 60 recommendations, provides a realistic road map for future research and development. Furthermore, it serves as a critical component of the Department's integrated long-term strategy for responding to and managing the medical and public health consequences of biological and chemical terrorism.

The National Institutes of Health (NIH) is reinvigorating its research related to the pathogenesis of - and host immune responses to - infectious organisms likely to be used in terrorist acts - e.g., the organisms that cause anthrax, tularemia, and plague, respectively. This research would be greatly facilitated by the acquisition of genome sequence information on these and related pathogens. The results of such genomic research - coupled with other pathological, immunological, biochemical, and microbiological information - are expected to facilitate pursuit of a variety of critical goals including the development of rapid diagnostic methods for the

most likely biological weapons, the development of antiviral therapies for smallpox and Ebola virus, and the development of new vaccines for anthrax, cholera, and smallpox. NIH also will undertake an array of basic and targeted studies oriented toward development of new or improved methods to diagnose chemical exposures and determine their effects upon the nervous system. In its FY 2000 budget, the Department has requested \$30 million specifically for developing improved vaccines for the highest priority bioterrorist threats: anthrax and smallpox.

Other DHHS agencies are engaged in relevant research and development as well. CDC, as part of the surveillance initiative I described earlier, is expanding its in-house Rapid Toxic Screen project to develop methods for measuring, within 48 hours, toxicants in human blood or urine samples. The goal over the next three years is to devise methods to identify and measure 150 different toxicants and to achieve an in-house analytic capacity of 200 samples per day. As new methods come on line, CDC will disseminate them to state and local laboratories as appropriate for incorporation into their analytic repertoires. Also, FDA proposes to expand its research on detection and characterization of toxins that might be used by terrorists.

Expedited Regulatory Review. The development of new or improved diagnostics, antibiotics, antivirals, and vaccines needed to combat bioterrorism must go hand in hand with efforts to streamline the regulatory process that new products must undergo successfully to be approved for marketing. FDA will work closely with sponsors and manufacturers to ensure effective and timely reviews of investigational new products. For example, NIH has created an Anthrax Vaccine Working Group, which brings together representatives of the NIH, FDA, and DOD, respectively, to facilitate identifying and advancing research and development efforts toward a new anthrax vaccine. Also, FDA intends to accelerate the pace and increase the efficiency of its reviews by ensuring the availability of experts to guide sponsors through the regulatory process not only for new products but also for new uses of existing products.

In conclusion, Mr. Chairman, I believe that DHHS has successfully launched its initiative to protect this nation and its people from those who would use biological weapons to inflict illness, death and chaos. We are grateful for the leadership of President and the strong support of the Congress in funding the anti-bioterrorism initiative this fiscal year at \$158 million. Moreover, the President's request for Fiscal Year 2000 of \$230 million will allow us to continue, expand, and strengthen the activities initiated this year. With recognition of bioterrorism as a real threat to the nation, we intend to mobilize our skills and resources to put in place the kind of infrastructure that will be necessary to contain and manage the consequences of a bioterrorist event, should one ever occur.



Assistant Secretary for Legislation (ASL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Mission](#)
[Divisions](#)
[Grants](#)
[Testimony](#)
[Other Links](#)
[ASL Home](#)
[Testimony](#)

[SEARCH](#)

[HOME](#)
[CONTACT US](#)

Statement on Medical Responses to Terrorist Attacks by Scott R. Lillibridge, M.D.

National Center for Infectious Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Before the House Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations
September 22, 1999

I am Scott Lillibridge, from the National Center for Infectious Disease, Centers for Disease Control and Prevention (CDC). Thank you for the invitation to discuss enhancing national public health capacity to respond to bioterrorism. I will describe the actions that CDC is taking as part of the DHHS Plan for Health and Medical Preparedness, to increase public health preparedness, enhance laboratory services, and expand disease surveillance to improve our Nation=s response to this important issue.

Vulnerability of the Civilian Population

In the past, an attack with a biological agent was considered very unlikely; however, now it seems entirely possible. Many experts believe that it is no longer a matter of *if* but *when* such an attack will occur. They point to the accessibility of information on how to prepare biologic weapons and to activities by groups such as Aum Shinrykyo, which, in addition to releasing nerve gas in Tokyo's subway, experimented with botulism and anthrax.

An attack with an agent such as smallpox could pose threats to large populations because of the potential for person-to-person transmission, enabling spread to other cities and states. Such a disease would quickly culminate in a nationwide emergency. International involvement would be sure to follow. The control of such an epidemic requires a coordinated effort of the entire public health community.

CDC has significant experience in responding to explosion and chemical related terrorism events and emergencies. Chemicals are plentiful and many of the world=s worst disasters have involved the release of industrial compounds. However, special risks are attendant with biological terrorism. For example, when people are exposed to a pathogen like plague or smallpox, they may not know that they have been exposed, and they may not feel sick for some time. This delay between exposure and onset of illness, or the incubation period, is characteristic of infectious diseases. The incubation period may range from several hours to a few weeks, depending on the exposure and pathogen. During this period, patients may continue to travel, visit family and friends, or attend public meetings at a time when they may be highly contagious. Consequently, a disease may be well established in the population before the first cases appear ill and require medical attention.

Public Health Leadership

As the Nation=s disease prevention and control agency, it is CDC=s responsibility to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of bioterrorism or any other deliberate attempt to harm our citizens. This task is an integral part of CDC=s overall mission to monitor the health of the U.S. population. This mission unfolds every day in various forms, such as outbreak response, concern for worker safety, and critical work in global health.

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC=s plan for combating today=s emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan emphasizes the need to be prepared for the unexpected -- whether it be a naturally occurring influenza pandemic or the deliberate release of anthrax by a terrorist. Copies of this CDC plan have been provided to the Subcommittee previously.

CDC is continuing to build on these efforts. An example of this is the strategic plan that CDC is developing with its partners to define the specific activities that will need to be conducted over the next several years to ensure that the country is prepared to respond to any threat or actual act of bioterrorism.

Strengthening Public Health Readiness to Address Bioterrorism

Unlike an explosion or a tornado, in a biological event, it is unlikely that a single localized place or cluster of people will be identified for traditional first responder activity. The initial responders to such a biological attack will most likely include county and city health officers, hospital staff, members of the outpatient medical community, and a wide range of response personnel in the public health system. Thus, protection against terrorism requires investment in the public health system. This point is underscored in a report, commissioned by the U.S. Department of Health and Human Services Office of Emergency Preparedness (OEP) and recently released by the Institute of Medicine and the National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, which stresses the need for long-term public health improvements in surveillance and epidemiology infrastructure.

Increased vigilance and preparedness for unexplained illnesses are an essential part of the public health effort to protect the American people against bioterrorism. Toward this end, CDC, working in collaboration with State and local health departments, many other public health partners, and other Federal agencies, has begun the effort to upgrade public health capabilities locally and nationally to respond to biological and chemical terrorism.

Areas For Public Health Action

As part of CDC's overall bioterrorism plan, in September 1999 CDC is providing approximately \$40,000,000 through cooperative agreements with State and large metropolitan health departments to enhance preparedness and response to a terrorist attack involving a biological or chemical agent. This program, along with other extramural and intramural strategies, focuses on strengthening components of the public health infrastructure to improve the national capacity to address biological and chemical terrorism:

- **Detection of unusual events - Public Health Surveillance.** Because the initial detection of bioterrorism will most likely occur at the local level after a period when patients have incubated the disease, it is essential to educate and train members of the medical community -- both public and private -- who may be the first to examine and treat the victims. State and Federal epidemiologists must be trained to consider unusual or rare threat agents when a suspicious outbreak occurs and must be prepared to address questions related to their transmission, treatment, and prevention. It is also necessary to upgrade the surveillance systems of State and local health departments, which will be relied upon to identify unusual patterns of disease occurrence and to locate any additional cases of illness as the disease spreads throughout the community and beyond.

CDC will promote the development of new disease surveillance networks which will better link critical health care facilities and components of the emergency medical system to public health agencies. CDC will also pilot and evaluate new surveillance systems to improve the nation's ability to detect low incidences of unexplained illnesses or track critical health resource utilization.

- **Investigation and containment of outbreaks.** In the response to an outbreak caused by an act of bioterrorism, the most likely scenario will be that CDC -- as well as DOD and security agencies -- will be alerted to the event only after State or local health officers, medical practitioners, or other workers in the health sector have identified and validated a cluster of cases that are highly unusual and potentially unexplained.

For this reason, it is imperative that State and local health departments have sufficient resources to conduct disease outbreak investigations. Through the cooperative agreements and other mechanisms, CDC will provide State and large metropolitan health departments with tools, training, and financial resources for local outbreak investigations, and help develop rapid public health response capacity at the State and local levels. Additionally, in the event of a suspected or an actual attack, CDC will assist in identifying threat agents and their modes of transmission, in instituting control measures, and in providing consultation on medical management.

To ensure the ready availability of drugs, vaccines, prophylactic medicines, chemical antidotes, medical supplies, and equipment that might be needed in a medical response to a biological or chemical terrorist incident, CDC is working to establish a National Pharmaceutical Stockpile, to be utilized when necessary and appropriate to contain the spread of disease in the outbreak.

- **Laboratory diagnosis.** In the event of a biological or chemical terrorist attack, rapid diagnosis will be critical, so that prevention and treatment measures can be implemented quickly. In fiscal year 1999, CDC is providing cooperative agreement assistance to State and major metropolitan health departments to improve capacity to diagnose biologic threat agents. In addition, CDC is making additional awards to enable selected State health laboratories to function as reference facilities for the identification of chemical threats. CDC will also evaluate existing rapid assay technology for

identifying critical biological agents and develop rapid toxic screening that can assess whether humans have been exposed up to 150 different chemical agents. CDC will develop guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of clinical samples.

Finally, CDC is working with public health partners such as the Association of Public Health Laboratories to implement a network of laboratories which will be used to provide the most immediate diagnosis of biological and chemical agents in the event of a suspected terrorist attack. This network will ultimately include hospital laboratories, commercial reference laboratories, State and local health laboratories, and highly specialized Federal facilities. It will not only enhance public health capacity to address bioterrorism, but also contribute to the overall public health capacity to address naturally occurring infectious diseases.

- **Coordination and Communication.** In order to assure the most effective response to a bioterrorism event, CDC works closely with Department of Justice, including the FBI and the National Domestic Preparedness Office. In addition, there is ongoing coordination with OEP, the Food and Drug Administration, the National Institutes of Health (NIH), the Department of Defense (DOD), the Federal Emergency Management Agency, and many other partners in this process.

Internationally, global health security will be enhanced as CDC, in collaboration with the World Health Organization, the Department of State, and various ministries of health, responds to reports of unexplained illnesses, unusual pathogens, and other outbreaks that might threaten the lives of U.S. citizens.

Strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. The Health Alert Network component of the CDC state and local preparedness initiative will provide a robust national electronic platform for communications, information access, delivery of targeted health alerts, and distance learning for use by public health officials working to detect and respond to bioterrorism and other unexplained health threats.

In the event of an intentional release of a chemical or biological agent, rapid and secure communications will be especially crucial to ensure a prompt and coordinated public health and medical response. Further, in the event of such an attack, we will need to ensure that the public is provided with accurate and timely information. An act of terrorism is likely to cause widespread panic, and on-going communication of accurate and up-to-date information will help calm public fears and limit collateral effects of the attack.

- **Preparedness and Planning.**

CDC is working to ensure that all levels of the public health community -- Federal, State, and local -- are prepared to work in coordination with the medical and emergency response communities to address the public health consequences of biological and chemical terrorism. CDC will assist in developing local public health bioterrorism preparedness plans that are well integrated into existing emergency response plans at the local, State, and Federal level. CDC is creating diagnostic and epidemiological performance standards for State and local health departments and will help States conduct drills, exercises, and laboratory readiness for bioterrorism.

CDC is working to assure that first responders are better prepared against biological and chemical exposures. CDC has significant experience in the areas of detector technology, personal protective equipment, including protective clothing and respirators, and the necessary training to work in hazardous environments. The challenge before us is to expand these capacities to better protect first responders from perils of biological and chemical terrorism.

In addition, CDC, NIH, DOD, and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism preparedness. The overall strategy for such research is coordinated through the Research and Development subgroup of the Interagency Weapons of Mass Destruction Preparedness Group. For example, for several of the agents identified as possible threats for bioterrorism, we need to create rapid, simple, low-cost diagnostic kits that can be used in the field to test large numbers of people exposed to a biological or chemical agent within a short time frame. In some cases, new or enhanced vaccines, antitoxins, or innovative drug treatments are also required. Moreover, we need to learn more about the pathogenesis and epidemiology of these rare diseases. We also have only limited knowledge about how artificial methods of dispersion may affect the infection rate or the harmful nature of these agents.

Disease experts at CDC are considering various strategies for preventing the spread of disease during and after bioterrorist attacks. Strategies under evaluation include creating protocols for immunizing at-risk populations, isolating large numbers of exposed individuals, and reducing occupational exposures; assessing methods of safeguarding food

and water from deliberate contamination; and exploring ways to improve linkages between animal and human disease surveillance networks since threat agents that affect both humans and animals may first be detected in animals.

CDC is enhancing its ongoing efforts to foster the safe design and operation of Biosafety Level 3 and 4 laboratories, which are required for handling highly dangerous pathogens. In addition, CDC is helping to limit access to potential terrorist agents by administering the Select Agent Rule, *Additional Requirements for Facilities Transferring or Receiving Select Agents* (42 CFR Section 72.6), which regulates shipments of certain hazardous biological organisms and toxins.

Conclusions

In conclusion, the best public health method to protect, respond to, and defend the health of our citizens against the adverse health effects of terrorism is the development, organization, and enhancement of life-saving public health tools. Expanded public health laboratory capacity, increased surveillance and outbreak response capacity, and health communications and training, with focused public health preparedness resources at the state and local level are necessary to ensure we will be able to respond when the alarm is sounded.

Thank you very much for your attention. I will be happy to answer any questions you may have.