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

The Department of Health and Human Services (HHS) welcomes your interest in our efforts to respond to terrorist events, including uses of biological weapons against the civilian population.

The Federal Emergency Management Agency (FEMA), as overall lead federal agency for consequence management efforts, has designated the Department of Health and Human Services (HHS) as the lead agency to coordinate medical assistance in national emergencies, be they natural disasters or acts of terrorism. When FEMA determines a federal response is warranted, this agency deploys medical personnel, equipment and drugs to assist victims of a major disaster, emergency or terrorist attack. Given our critical medical role in any biological, chemical, radiological or nuclear attack, I take HHS preparedness efforts most seriously.

As was announced yesterday by President Bush, FEMA will become the coordinating agency to ensure coordination of all anti-terrorism activities. My office will begin to work directly with FEMA to meet the threat of terrorism.

Bioterrorism presents unique challenges since it differs dramatically from other forms of terrorism and national emergencies. While explosions or chemical attacks cause immediate and visible casualties, an intentional release of a biological weapon would unfold over the course of days or weeks, culminating potentially in a major epidemic. Until sufficient numbers of people arrive in emergency rooms, doctors' offices and health clinics with similar illnesses, there may be no sign that a bioterrorist attack has taken place. Individuals with symptoms may be at considerable distance from the site of initial exposure, both in terms of onset of disease and geographic location. Moreover, the bioweapons most likely to be used are pathogens not routinely seen by health care providers. Medical providers generally are not familiar with the diagnosis and treatment of these disorders and may even fail initially to recognize symptoms. These scenarios underscore the importance of preparing for the possibility of bioterrorism.

What has HHS been doing to prepare for this kind of event? Our efforts include preparing the medical and public health response to mass casualty events, working to improve our infectious disease surveillance capabilities, managing and securing the National Pharmaceutical Stockpile and investing in necessary research and development to improve our capability to respond to

an emergency.

In order to advance an orderly and comprehensive approach to the many issues involved in such preparation, I will appoint a special assistant within the Immediate Office of the Secretary to lead the department's bioterrorism initiative. This person will report to me directly. I plan to call a national meeting of HHS agencies to evaluate the status of bioterrorism activities and report back to Congress on our efforts. In addition, the new special assistant will support the Surgeon General's efforts to revitalize the Public Health Service Commissioned Corps and its Readiness Force. Let me assure you that this is a top priority for me and for my entire department.

Because of the potential for widespread damage a bioterrorist attack could bring, I will focus on what I consider HHS's main priorities as the coordinator of medical assistance and the surveillance efforts CDC would undertake to identify the pathogen used.

Coordinating the Medical and Public Health Response to Mass Casualty Events

As you know, much of the initial burden and responsibility for providing an effective response by medical and public health professionals to a terrorist attack rests with local governments, which would receive supplemental support from state and federal agencies. However, if the disease outbreak reaches any significant magnitude, local resources will be overwhelmed and the federal government will be required to provide protective and responsive measures for the affected populations that may include any or all of the following:

1. 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;

1. in the case of a bioterrorist event, mass immunization or prophylactic drug treatment for groups known to be exposed, groups that may have been exposed and populations not

already exposed but at risk for exposure from secondary transmission and/or a contaminated environment;

1. deployment of material from the National Pharmaceutical Stockpile;

1. mass fatality management to provide respectful and safe disposition of the deceased, including animals;

1. infection control; and

1. assessment of the extent of contamination to the environment and identification of risk management steps to assure safe re-entry of the potentially contaminated areas.

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Within my agency, the Office of Emergency Preparedness (OEP) is the primary agency responding to requests for assistance and resources. OEP's primary function is to manage the National Disaster Medical System (NDMS) as well as the Public Health Service Commissioned Corps Readiness Force, which could be called into action depending upon the severity of

the event.

The National Disaster Medical System is a group of more than 7000 volunteer health professionals who can be deployed anywhere in the country to assist communities in which local response systems are overwhelmed or incapacitated. Organized into 44 Disaster Medical Response Teams, these volunteers would provide on-site medical triage, patient care and transport to medical facilities. Four National Medical Response Teams (NMRTs), which travel with their own caches of pharmaceuticals, have capabilities to detect illness-causing agents, decontaminate victims, provide medical care and remove victims from the scene. Three of the four NMRTs can be mobilized and deployed anywhere in the nation; the fourth is permanently stationed in the Washington, D.C. area. The NDMS also includes Disaster Mortuary Operations Response Teams that handle the disposition of the remains of victims of major disasters.

NDMS response teams can, upon request, be in an area to supplement local responders within 12 hours of a request. The system capability includes providing in-hospital care for up to 100,000 victims. Other activities that OEP has undertaken to help states and local communities develop their preparedness for mass casualties include but are not limited to:

1. development of competency standards for physicians, nurses and paramedics that focus on the emergency care and definitive treatment of mass casualties from nuclear, biological or chemical incidents;

1. guidelines for hospital mass casualty procedures that focus on in-hospital decontamination and medical practices for mass contaminated patients who arrive in hospital emergency rooms; and

1. mass casualty treatment protocol reviews/updates that will provide clinical guidelines for the treatment of patients exposed to a nuclear, biological or chemical weapon of mass destruction.

OEP also manages the development of local Metropolitan Medical Response Systems (MMRS), established in some 97 communities, as an additional resource to respond to mass casualties that could occur in such outbreaks. Through contractual relationships, the MMRS uses existing emergency response systems emergency management, medical and mental health providers, public health departments, law enforcement, fire departments, EMS and the National Guard to provide an integrated, unified response to a mass casualty event. By the end of this fiscal year, OEP will have contracted with 97 municipalities to develop MMRSs. The FY 2002 budget includes funding for an additional 25 MMRSs (for a total of 122).

MMRS contracts require the development of local capability for mass immunization/prophylaxis for the first 24 hours following an identified disease outbreak; distribution of materiel deployed to the local site from the National Pharmaceutical Stockpile; local capability for mass patient care, including procedures to augment existing care facilities; local medical staff trained to recognize disease symptoms so that they can initiate treatment; and local capability to manage the remains of the deceased.

A variety of planning, evaluation and demonstration projects involving MMRSs across the country have also been funded by OEP. One of them is in my home state of Wisconsin. The Milwaukee MMRS will coordinate, through the Wisconsin Department of Health, the development of a process to extend and integrate the concepts of MMRS development to rural and suburban communities. This project will also involve the Wisconsin Emergency Management Agency, the State Anti-Terrorism Work Group and the city of Madison.

Recognizing that preparedness rests in large measure on the knowledge, expertise and proficiency of those who must respond, OEP plans to initiate a number of training efforts, a few of which I will mention here. One is a pilot emergency medicine residency program focused on awareness and performance skills related to mass patient care that will be established in at least one accredited medical school. OEP proposes to undertake a parallel activity with nurses, i.e., development of a mass casualty nursing curriculum that will be tested in an accredited

nursing program.

These efforts and activities by OEP strengthen federal, state and local preparedness for terrorist attacks. As a first responder, HHS must continually assess its preparedness and develop better plans for implementation in case a terrorist act requires a comprehensive response. I plan to undertake a thorough review of our priorities in coming months and will keep members of the committee informed of my progress.

Improving Surveillance

If a terrorist used a biological or chemical weapon against the civilian population, how quickly the outbreak is detected, analyzed, understood and addressed would be the responsibility of state and local public health jurisdictions and the Centers for Disease Control and Prevention.

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The CDC has used fund provided by the past several congresses to begin the process of improving the expertise, facilities and procedures of state and local health departments and within CDC itself related to bioterrorism. CDC has established a Bioterrorism Preparedness and Response Program within its National Center for Infectious Diseases to direct and coordinate their activities. CDC has a dedicated anti-bioterrorism staff of more than 100 full-time professionals comprising expertise in epidemiology, surveillance and laboratory diagnostics.

Over the last two years, the agency has awarded more than $80 million in cooperative agreements to 50 states, one territory and four major metropolitan health departments to support (1) preparedness and readiness assessment; (2) epidemiology and surveillance; (3) laboratory capacity for biological or chemical agents; and (4) the Health Alert Network (a nationwide, integrated, electronic communications system).

The CDC has launched an effort to improve public health laboratories that likely would be called upon to identify a biological or chemical attack. The Laboratory Response Network (LRN), in collaboration with the Association of Public Health Laboratories, will help ensure that the highest level of containment and expertise in the identification of rare and lethal biological agents is available in an emergency event. The LRN also includes the Rapid Response and Advanced Technology Laboratory at CDC, which has the sole responsibility of providing rapid and accurate triage and subsequent analysis of biological agents, suspected of being

terrorist weapons.

The CDC is also working to provide coordinated communications in the public health system, between federal agencies and between public health officials and the public itself. To this end, CDC has launched several initiatives. It has developed the National Electronic Disease Surveillance System (NEDSS), which will collect health data automatically from a variety of sources on a real-time basis to assist in the ongoing analysis of trends and detection of emerging public health problems.

CDC has also instituted the *Epidemic Information Exchange (EPI-X)*, a secure, Web-based communications network that will enhance bioterrorism preparedness efforts by facilitating the sharing of preliminary information about disease outbreaks and other health events among officials across jurisdictions and provide experience in the use of a secure

communications system.

CDC supports the Health Alert Network (HAN), a nationwide system that, when completed, will distribute health advisories, prevention guidelines, distance learning, national disease surveillance information, laboratory findings and other information relevant to state and local readiness for handling disease outbreaks. HAN will provide high-speed Internet connections for local health officials; rapid communications with first responder agencies and others; transmission of surveillance, laboratory and other sensitive data; and on-line, Internet- and satellite-based distance learning. CDC has provided HAN funding and technical assistance to 37 state health agencies, three metropolitan health departments and three Centers for Public Health Preparedness.

Because of food is a likely medium for spreading infectious diseases, FDA as well as CDC are enhancing their surveillance activities with respect to diseases caused by foodborne pathogens. Through FoodNet, an active surveillance system for diseases caused by foodborne pathogens, FDA, CDC and the Department of Agriculture (USDA), in conjunction with state health departments, are able to conduct investigations to map out the epidemiology of illnesses caused by contaminated foods. PulseNet, a national network of public health laboratories created, administered and coordinated by CDC in collaboration with FDA and USDA, enables the comparison of bacteria isolated from patients from widespread locations, from foods and from food production facilities. This type of rapid comparison allows public health officials to connect what may appear to be unrelated clusters of illnesses, thus facilitating the identification of the source of an outbreak caused by international or accidental contamination of foods.

Managing and Securing the National Pharmaceutical Stockpile

The purpose of the National Pharmaceutical Stockpile (NPS) is to be able to rapidly respond to a domestic biological or chemical terrorist event with antibiotics, antidotes, vaccines and medical materiel to help save lives and prevent further spread of disease resulting from the terrorist threat agent. Operated by the CDC, the NPS Program would provide an initial, broad-based response within 12 hours of the federal authorization to deploy, followed by a prompt and more targeted response as dictated by the specific nature of the biological or chemical agent that is used. The first NPS "12-hour Push Package" was brought to operational status on December 27, 1999.

Since then, CDC has deployed six additional 12-hour Push Packages to various regions of the United States. One more Push Package awaits transport to its storage site. Each of these Push Packages is maintained in secure, climate-controlled facilities near a population center or at a transport hub from which they can be sent rapidly to any site in the country.

This fiscal year CDC will move into the next phase of its pharmaceutical response preparedness by finalizing contracts with pharmaceutical manufacturers and vendors for additional products that would be called for in case of a major event. Called Vendor Managed Inventory or "VMI," this portion of the NPS relies on products that are stored and managed by the manufacturers that produced them and/or the distributors through which they work to supply the nation's health care delivery system. VMI will be stored in facilities around the country where it can be efficiently rotated and from where it can be promptly transported. To the extent possible, pharmaceuticals in both the Push Packages and the VMI will be rotated so that the inventories always stay within their

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expiration dates or their extended shelf life. CDC has interim agreements with United Parcel Service and Federal Express Corporation to meet the transport needs of the NPS Program.

In order to ensure the quality of the products in the stockpile and the ability of the stockpile to deploy at a moment's notice, CDC will conduct periodic "no notice" inspections of facilities storing both the eight 12-hour Push Packages and the VMI and of the companies that are the NPS' cargo transport partners. FDA must also inspect drug and vaccine manufacturers whose products are stockpiled. In the spirit of vigilant oversight, CDC has mounted a program of training, exercises and technical assistance that will enhance the NPS Program's ability to receive, manage, repackage and distribute stockpile materiel on site. The Program, in cooperation with OEP, has engaged in an effort to develop a template for receipt, breakdown, repackaging and distribution of a Push Package. Because failure is not an option for the deployment of the stockpile, CDC must test its various components in advance. These exercises

will produce an assessment of how each system partner performs and what aspects of their performance might need to be strengthened.

Prevention

Measures that deter or prevent bioterrorism counter such threats to public health and social order. 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 (referred to as "select agents"). Organizations such as research universities, pharmaceutical manufacturers, public health laboratories and microbiological archives send or receive samples of dangerous pathogens or toxins under CDC regulation. All such facilities must register with CDC, maintain records and otherwise document compliance. As of April 2001, 230 laboratories have registered with CDC and thus certified to transfer select agents. To enhance the effectiveness of this regulation, CDC is providing training to public health officials in every state to assist them in accurately interpreting biosafety containment provisions and select agent procedures.

FDA is involved in the process of drug and vaccine development from the early stages of clinical trials through approval and post-approval. The agency is committed to assisting and expediting the development of, and access to, important new products for serious and life-threatening illnesses and conditions, including products that could be used to treat outbreaks caused by bioterrorist agents. To meet this objective, in October 1999 FDA proposed amending its regulations to allow approval of such drugs and biological products based on evidence of effectiveness derived from appropriate studies in animals, foregoing efficacy studies in humans given the ethical implications of such efforts.

Conclusion

This brief review of the broad array of activities my department has undertaken has been conducted in collaboration with our federal, state and local partners. The mutual and ongoing consultation, assistance and support HHS receives from FEMA, DOD, USDA, VA, State, Department of Justice, Department of Energy, the Environmental Protection Agency and the National Security Council are useful in identifying not only programmatic overlaps but also gaps in our preparedness efforts. These efforts also allow us to work toward integrating our respective initiatives into a government-wide framework. Our ongoing relationships with state and local governments have been reinforced in recent years as a result of the investments we have made in bioterrorism preparedness. Without their engagement in this undertaking, we would not be seeing the advances that have been made over the past three years.

To ensure that these advances continue, the special assistant I mentioned at the beginning of my remarks will coordinate all the planning described above. This individual will provide both executive leadership and organizational direction to this critically important effort.

Finally, Mr. Chairman, I am grateful for the strong support of the Congress in funding the anti-bioterrorism initiative for the past three consecutive years. With recognition of bioterrorism as a genuine 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 terrorist event, should one ever occur.

APPENDIX

CRITICAL BIOLOGICAL AGENTS

The U.S. Public Health system and primary healthcare providers must be prepared to address varied biological agents, including pathogens that are rarely seen in the United States. The critical agents are listed below in priority order:

Category A

High priority agents include organisms that pose a risk to national security because they can be easily disseminated or transmitted

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person-to-person; cause high mortality, with potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness. **Category A Agents:**

1. variola major (smallpox)
1. *Bacillus antrhacis* (anthrax)
1. *Yersinia pestis* (plague);
1. *Clostridium botulinum* toxin (botulism)
1. *Francisella tularensis* (tulararemia);
1. filoviruses,
1.
1. Ebola hemorrhagic fever; and
1. Marburg hemorrhagic fever; and
1.
1. arenaviruses,
1.
1. Lassa (Lassa fever)
1. Junin (Argentine hemorrhagic fever) and related viruses

Category B

Second highest priority agents include those that are moderate easy to disseminate; cause moderate morbidity and low mortality; and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

Category B Agents

1. *Coxiella burnetti* (Q fever)
1. *Brucella* species (brucellosis);
1. *Burkholderia mallei* (glanders)
1. alphaviruses,
1.
1. Venezuelan encephalomyelitis,
1. eastern and western equine encephalomyelitis;
1.
1. ricin toxin from *Ricinus communis* (castor beans);
1. epsilon toxin of *Clostridium perfringens*; and
1. *Staphylococcus* enterotoxin B

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A subset of List B agents includes pathogens that are food or waterborne. These pathogens include but are not limited to:

1. *Salmonella* species,
1. *Shigella dysenteriae,*
1. *Escherichia coli* O157:H7
1. *Vibrio cholerae*, and
1. *Cryptosporidium parvum.*

Category C

Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and potential for high morbidity and mortality and major health impact.

Category C Agents

1. Nipah virus,
1. hantaviruses,
1. tickborne hemorrhagic fever viruses
1. tickborne encephalitis viruses,
1. yellow fever, and
1. multidrug-resistant tuberculosis.