

Hearing on FEMA's Role in Managing Bioterrorist Attacks and the Impact of Public Health Concerns on Bioterrorism Preparedness

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Mr. Chairman, Distinguished Members of the Committee:

Thank you for the opportunity to appear before you to discuss the role of the Federal Emergency Response Agency (FEMA) in preparing the nation to respond effectively to possible acts of bioterrorism. My name is Tara O'Toole. I am a physician and public health professional and Deputy Director of the Johns Hopkins University Center for Civilian Biodefense Studies. From 1993-97 I served as Assistant Secretary of Energy for Environment Safety and Health. I have spent much of my professional life working to prevent and prepare to respond to industrial accidents, including accidents in the U.S. nuclear weapons complex.

Nothing in the realm of natural catastrophes or manmade disasters rivals the complex response problems that would follow a bioweapons attack against civilian populations. FEMA is one of government's organizational success stories. It has brought comfort and vital help to millions of people struggling to recover from earthquakes and hurricanes and floods and any number of other major calamities. Preparing to respond to a biological weapons attack, however, presents different issues, requires the engagement of different sets of responders and response organizations, and will depend on different institutional capacities than are evoked by natural disasters or acts of terrorism like the Oklahoma City bombing.

Today I will briefly describe the nature of a bioterrorist attack, outline what in my judgment are some of the major issues FEMA must confront in its role as coordinator of all Federal programs dealing with weapons of mass destruction consequence management, and suggest initial steps towards addressing some of these challenges.

I will emphasize three areas that are central to an effective response to a deliberate, bioterrorist-induced epidemic and which I and my colleagues at Johns Hopkins think are particularly problematic and in need of attention:

- Vulnerabilities within the "critical infrastructures" of sectors which are key to bioterrorism response – namely, the U.S. medical care system and public health agencies;
- The absence or insufficiency of essential vaccines and effective drugs to treat the major bioweapons agents;
- Decision makers' lack of familiarity with the principles of infectious disease control, public health practice, and the operational capacities and limitations of key sectors and organizations involved in bioterrorism response.

Some of these problems can be addressed, at least in part, by FEMA, whose exemplary record of managing complicated situations will stand it in good stead. Other problems integral to bioterrorism response are beyond the reach of any single agency. Some problems demand collaboration among several different organizations and some will only yield to the sustained and concerted attention of Congress and the Administration.

Biological weapons represent a strategic threat to the United States. In the words of Admiral Stansfield Turner, former Director, Central Intelligence Agency, only bioweapons and nuclear weapons have the potential to bring the United States “past the point of non-recovery”. [*Caging the Genie*] In coming years, the potency, diversity and accessibility of biological weapons will increase as biological science advances and the number of people knowledgeable in these fields increases. Ensuring the nation’s ability to respond to bioweapons attacks in ways that limit death and suffering while preserving U.S. strategic flexibility and fundamental American values and civil liberties are essential to bioterrorism response. An effective response capacity may also serve to deter such attacks.

The Nature of a Bioterrorist Attack and the Problems of Response

The consequence of a bioterrorist attack would be an epidemic. The “first responders” to such an event would be doctors, nurses and public health professionals in city and state health departments. A covert bioterrorist attack would likely come to attention gradually, as physicians became aware of an accumulation of inexplicable deaths among previously healthy people. The speed and accuracy with which doctors and laboratories reached correct diagnoses and reported their findings to public health authorities would directly affect the number of deaths. If the bioweapons used were a contagious disease – capable of being transmitted from one person to another – the ability to limit illness and death would depend critically on decisions made and actions taken in the hours and days immediately following discovery of the attack.

The early symptoms of most of the pathogens thought likely to be used as bioweapons resemble those of common illnesses. Once a bioterrorist attack is recognized and announced by the media, people all over the country are likely to fear that they or their families have been made ill by a deadly bioweapons and will seek medical care. It is quite possible, and indeed likely, that such a surge in patient demand will overwhelm local health care systems. Like all “dread” risks, a bioweapons attack would be silent, odorless and invisible. No one would know if they were infected until they became ill. People with other, naturally occurring illnesses might well fear they were victims of the attack. Large numbers of anxious people would be expected to flood into doctors’ offices and emergency departments.

Most medical laboratories could not rapidly distinguish those actually infected with a bioweapons agent from persons with other diseases – a situation that will deepen the stress on the health care system and complicate rational distribution of scarce vaccines and medicines. During the 1999 outbreak of West Nile Virus – which resulted in a total of 62 cases of illness – the U.S. laboratory capacity for diagnosing viral illnesses was tapped out.

Vulnerabilities in the U.S. Medical Care System

The U.S. healthcare system is operationally fragile and inelastic. The quest for financial efficiency within the health care sector coupled with the financial pressures imposed by managed care, rising drug prices, regulatory mandates, etc. have virtually eliminated hospital surge capacity. Nurses, medicines and equipment are all managed in accord with “just-in-time” models. Although a hospital may be certified to operate a certain number of unoccupied beds, the staff available to care for patients is limited. Shortages of nurses in particular are serious, widespread and expected to worsen. Were a bioterrorist attack to occur, we could expect that some health care workers would fail to come to work, worsening the already strained staffing situation in health care.

Even small increases in demand are enough to bring hospitals to the point of crisis. The mild and brief 1999 flu season caused cancellation of elective surgery and required three quarters of Los Angeles hospitals to re-route ambulances because emergency rooms were too full to accept additional patients. The number of days Maryland emergency rooms spent on bypass doubled every year for the past three years. [*USA Today*, Feb. 4, 2000, p.6A, “ER Conditions: Critical”] News reports in the past year have documented over- crowded emergency rooms and long waits for care in Boston, St. Louis,

Chicago, and New York. In the past decade, the U.S. lost over 1000 emergency rooms (they tend to be money-losers). At the same time, the number of people seeking care in emergency rooms rose by about 50%. [*Washington Post*, April 22, 2001, p. B1, “A State of Emergency”]. Following a fire in a high-rise apartment building, the Maryland’s Secretary of Health determined that the state – home to more than 60 hospitals, including two major academic medical centers – would be unable to handle an emergency that produced 100 patients needing ventilators.

The lack of surge capacity in American hospitals is such that few, if any, hospitals could handle a sudden influx of 100 patients needing advanced life-support care. In most locales, even the combined resources of all hospitals in a metropolitan area could not handle such a demand. No city in America, and no contiguous geographic region could handle 1000 patients suddenly needing advanced medical care.

The majority of hospitals currently lack models plans or templates that would guide institutional response during a bioterrorism crisis. Such templates need to be developed for different settings (large academic medical centers, community hospitals, rural facilities, etc.). Communitywide response plans that incorporate specific hospital capacities into a single coordinated response are also needed. Modern hospitals are autonomous organizations, which are unused to collaboration with other hospitals or institutions. Communications and data-sharing linkages that could connect hospitals and HMOs with local and state public health agencies are urgently needed.

Local and State Public Health Capacities

The operational capacity of state and local public health agencies to track the epidemic will have a critical bearing on FEMA’s ability to coordinate an effective response. Governmental decision-makers’ “situational awareness” will depend on public health data: how many are sick, where they are located, what the victims shared in common (and hence where or how the attack might have occurred), whether the number of afflicted is growing, whether there was more than one attack, projected numbers of deaths, etc. – all these questions depend on public health agencies’ ability to gather and analyze vital information. Yet state health agencies have been under funded and understaffed for decades, and have less potential surge capacity than do hospitals.

The Director of the Federal Centers for Disease Control and Prevention (CDC) noted last fall that many state health officials lack access to computers. Many local county health departments do not have access to the Internet. Since FY 2000, HHS has provided bioterrorism preparedness grants to state health departments. These funds are being used to create fundamental response capacities in areas such as disease surveillance and laboratory analysis. This is a critical program, but accounts for only \$40 million annually – a paltry amount given the importance of public health infrastructure to bioterrorism response and the urgent need to refurbish long neglected health departments.

CDC can supplement local health agencies to some degree. In 1999, CDC initiated the Office for Bioterrorism Preparedness and Response, which has made significant strides in supporting states’ efforts to identify and build critical epidemic response functions. HHS has made an effort to create expertise and response capacity in recent years, and Secretary Thompson’s recent appointment of a special assistant in charge of bioterrorism is a welcome step forward. But CDC’s own lack of surge capacity is not well appreciated. There are fewer than 150 officers in the CDC Epidemic Intelligence Service. Perhaps one or two thousand other CDC employees with some (however distant) field experience could be mobilized in a time of national crisis. The CDC Office of Bioterrorism Response and Preparedness has about 30 employees, but many of these are “matrixed” throughout the agency and have duties beyond bioterrorism issues.

HHS’ Office of Emergency Preparedness also has important responsibilities pertinent to bioterrorism response, notably the management of the Metropolitan Medical Response System (MMRS) which is part of the Federal government’s overall Domestic Preparedness Program. The role and function of the MMRS needs to be clarified. In some locales, the MMRS is reported to be working well, while the lack of engagement by the medical community and confusion about its functions hampers acceptance elsewhere. Whenever possible, preparations for bioterrorism response should be integrated into routine medical and public health functions. Given the urgent and competing demands levied upon the medical and public

health communities, the resources needed to build effective epidemic response capabilities must serve “dual uses”. Moreover, systems that are used only in rare emergencies seldom work as planned. For example, it should be possible, with planning and foresight, to construct for example, disease reporting systems that routinely track and help prevent medical errors and which can, in times of need, monitor epidemics.

The Need for More Effective Treatments and Vaccines

To date, Congress, the Administration and the media have focused primarily on organizational issues involved in bioterrorism response. Much attention has been directed towards questions of who (or what agency) is in charge, and how multi-agency functions should be coordinated and funded. Insufficient attention has been directed towards analyzing and preparing the concrete elements of the response itself. Epidemics are fundamentally different from other natural disasters and will demand very different responses than other types of “catastrophic terrorism”. The scant attention paid to vulnerabilities in critical infrastructures of medicine and public health reflects this lack of focus on the response itself.

Some of the most critical epidemic response tools must be developed and readied long before a bioweapons attack occurs. The most efficient and well-coordinated organizational response to a bioweapons attack cannot compensate for a lack of effective medicines. If we do not have effective vaccines or sufficient doses of vaccines on hand to stop the spread of contagious disease, disease containment strategies will be limited and could involve at least temporary suspension of some civil rights. We now have effective vaccines or drugs treatments for only 12 of the 50 most serious pathogens thought to be likely bioweapons agents. [George Poste, “Biotechnology: Future Promise and Peril” delivered at 2nd National Symposium on Medical and Public Health Consequences of Bioterrorism, Washington, DC, November 23, 2000.]

Just as the medical and public health systems do not have the ability to respond to rapid increases in demand, pharmaceutical and vaccine manufacturers also lack immediate surge capacity. HHS recently signed a contract with a private company to produce 40 million doses of smallpox vaccine by 2004; current supplies afford about 12-15 million doses. We would argue that 40 million doses is insufficient and that the country urgently needs a plan to produce vaccine on an emergent basis should it be needed.

Problems Associated with Decision Making and Epidemic Management

In May 2000, the Hopkins Center in collaboration with the ANSER Institute for Homeland Defense, the Center for Strategic and International Studies and the Oklahoma Memorial Institute for the Study of Terrorism held a bioterrorism exercise at Andrews Air Force Base. The scenario called for a mock National Security Council to react to a fictional, moderately sized smallpox attack. High-level former government officials took the role of NSC members. Former Senator Sam Nunn played the President; David Gergan played the National Security Advisor; Governor Frank Keating played himself, Frank Wisner was Secretary of State; James Woolsey played CIA Director; John White played Defense Secretary; Dr. Margaret Hamburg was HHS Secretary; the Attorney General was played by George Terwilliger; William Sessions was FBI Director; and Jerome Hauer played FEMA Director.

One of the striking observations of this exercise was the unfamiliarity of these distinguished and experienced professionals with the basic decisions and trade-offs associated with managing the response to the epidemic. As one participant, who had spent his life in high-level national security positions remarked, “the issues were so unfamiliar I had a hard time wrapping my mind around the problems. I didn’t know how to think about this.” Another participant noted that the relatively slow evolution of the epidemic masked the need for drastic action. Most of the participants wanted information on which to base decisions that would not be available within existing institutional capabilities – e.g., immediate estimates of the size and likely spread of disease, etc.

The uncertainties and unfamiliarity of epidemic management also were evident in the June 2000 TOPOFF exercise. Participants in that very useful exercise commented that the deliberate, consensus-based mode of decision making that is traditional within public health circles was dysfunctional in the setting of a fast-moving, lethal epidemic. Hospital leaders did not know who was in charge or whom to call for information or assistance. The law enforcement and public health realms

of the exercise seemed to operate independently. There were several “joint operations centers”. Different participants reported radically different notions of what decisions had been reached. Elected officials did not participate in TOPOFF so it is unclear if their presence would have improved decision processes or complicated them further.

In any case, a bioterrorism attack would represent a unique hybrid of a national security crisis and a public health emergency. Government is not experienced in dealing with the mix of issues that such a situation presents. The organizations involved in bioterrorism response follow different cultural styles, the individuals in leadership roles will likely not have worked together before, and top officials will be relying on the advice of experts they have never met, and making decisions about issues with which they are largely unfamiliar.

Suggestions for Improved Bioterrorism Response

- 1. Engage the Medical Community and Hospital Leaders in Planning for Bioterrorism Response:** FEMA’s leadership should immediately seek to engage leaders from the medical community, and from hospitals and hospital trade organizations in preparations for bioterrorism response. Without the participation of leaders from the medical community and hospital associations, efforts to prepare to deal with epidemic disease are destined to fail.

Congress and the Administration should allocate resources to allow hospitals to undertake meaningful planning for bioterrorism response. Such funds could perhaps best be disbursed in the form of competitive grants program. Planning for communitywide bioterrorism response should be expanded to include hospitals and other deliverers of medical services.

Over the past year and a half, my colleagues at Johns Hopkins and I have worked with the American Hospital Association and the Office of Emergency Preparedness within the Department of Health and Human Services to better understand why representatives from the medical community and hospital leaders have not been engaged in local and federal counter terrorism preparedness initiatives. There are two main reasons.

First, leaders in the Congress and the Executive branch have not persuaded hospital leaders that bioterrorism represents a serious national security threat or that the medical care system is expected to play a significant response role should an attack occur. Second, the government has not instituted any mandates or provided any incentives that would encourage hospitals to divert scarce and precious resources towards bioterrorism preparation and planning.

The profound financial pressures on the institutional infrastructure of the U.S. healthcare system are not well recognized. Thirty percent of all hospitals and half of academic medical centers are in the red. Hospitals and HMOs are not able to devote scarce resources to planning efforts unless the federal government makes it clear that such preparations are important and provides support for such endeavors.

- 2. Conduct Independent Analysis of Current Institutional Capabilities and Plans to Care for the Sick:** FEMA, in collaboration with HHS and the Congress should initiate an independent assessment of the response capacity of U.S. hospitals in the event of a bioterrorist attack. The capabilities, configuration and usefulness of the National Disaster Medical System (NDMS) and the Disaster Medical Assistance Teams (DMATs) in the wake of a bioterrorist attack should be investigated. A key component of the Federal Response Plan, the NDMS, was created decades ago to care for victims of a possible nuclear war in Europe, and many question its current viability in the current healthcare climate. The operational capabilities, availability and practical utility of using Veterans Administration resources and Defense Department assets are also in need of careful, independent examination.

Without clear analyses of patient care capacity, it is impossible to prepare coherent plans for bioterrorism response. If, as we believe, the U.S. health system possesses only very limited ability to meet sudden and sustained demands for care of the sick, then the nation will need to plan for extra-hospital treatment centers or at-home care. But the first step must be to analyze the true usefulness of current plans in the context of modern medical care and its inherent realities.

- 3. Establish a Substantial Research and Development Program for the Prevention and Treatment of Infectious Disease:** At present, the great advantage in bioweaponry belongs to the aggressor. But by leveraging existing investments already being made by the private sector, the U.S. government could spur the creation of new strategies for coping with bioweapons and infectious disease generally. Over the next few years, developments in the life sciences could create critically useful vaccines and medicines that could make bioweapons far less menacing and less likely to be used. Such advances might also provide tools that could prevent or cure some of the infectious diseases which account for half the deaths in developing countries and divert precious energy and resources away from their efforts to achieve self-sufficiency and prosperity.

Obviously, FEMA is not the proper agency to conduct a large scientific research program. But asking FEMA to coordinate bioterrorism response armed only with the vaccines and antimicrobial drugs currently available is tantamount to asking firefighters to battle a twelve-alarm blaze without water or foam. Little that FEMA does or can do will matter if we lack sufficient vaccines or adequate medicines to treat the sick and stop the spread of contagious disease. In some cases, effective treatments await new scientific breakthroughs that can only come from research. In other instances – the production of adequate supplies of smallpox vaccine, for example – what is needed is the will and organizational coherence to execute appropriate priorities.

- 4. Encourage, design, and assess the use of training programs, exercises and drills for bioterrorism responders, including high-level decision makers:** Well-designed bioterrorism response exercises provide an opportunity to test preparedness plans and precepts. Tabletop scenarios and more elaborate drills provide opportunities for collaboration among the diverse array of communities and individuals who would be involved in managing actual epidemics. Exercises can also serve as powerful teaching tools, conveying the problems associated with bioterrorism response with a vividness that mere documents cannot provide.

Many of those who would be key participants in responding to a bioterrorism are unfamiliar with the nature of epidemics, public health and disease containment principles, or the functional capacities and limitations of the agencies and institutions which would be called upon to respond to a deliberate epidemic.

Should a bioterrorism attack occur, it would be, in the words of one former official, “a watershed event in American history”, akin to Pearl Harbor. Such a moment is not the time for the country’s leaders to first learn of the limits of their public health authorities or to realize that life-saving vaccines are in short supply. As was demonstrated in TOPOFF, we have not yet created workable decision making processes in the context of epidemics. It is important that key officials come to recognize the gravity and nature of the bioweapons threat and begin to marshal the institutional strength necessary to counter this unfamiliar challenge.

FEMA should continue to sponsor federal exercises such as TOPOFF and should encourage similar drills on the state and regional level. Attention should be paid to the technical accuracy and plausibility of exercise scenarios and to identifying what approaches are most useful in conveying key lessons or uncovering problems. One of the major failings of past exercises is the absence of publicly accessible assessments and feedback of the exercises.

Conclusion

The United States Commission on National Security in the 21st Century noted in its September 1999 report that “the most serious threat to our security may consist of unannounced attacks on American cities by sub-national groups using genetically engineered pathogens.” Biological weapons, even in crude forms, have the potential to inflict horrible suffering and death. In this age of globalization, an attack on U.S. citizens could quickly become a worldwide epidemic.

FEMA and HHS both have critical roles to play in preparing the country to respond to a bioweapons attack, but creating an adequate response to the threat of biological weapons will require the attention and power of the Administration and the Congress as well as the active engagement of biological scientists, and medical and public health professionals. Controlling the growing power of the life sciences will be one of the main tasks of this generation. Ensuring that the knowledge and ability to manipulate the secrets of living organisms is not bent to deliberately destructive purposes will be among our most pressing obligations.