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Mr. Chairman and members of the Committee, thank you for the invitation to discuss the need to enhance our nation 's capacity to respond to the threat of biological terrorism. Your leadership and commitment in addressing this challenge comes at a critical time.

The tragic attacks last month have been a powerful reminder of our nation's vulnerability to terrorism, and have increased fears that we could face even more devastating assaults in the future, including the possible use of biological weapons.

Certainly, the events of recent days have underscored how seriously we must take this emerging threat. Whether an unsophisticated delivery system with a limited number of exposures, as we have seen in several American cities, or the potential of a more high-technology, mass casualty attack, the prospects are frightening. Today, no one is complacent about the possibility that a biological agent might be intentionally used to cause widespread panic, disease and death.

In this time of heightened anxiety and concern, our nation has a real opportunity and obligation—to make sure that we have in place the programs and policies necessary to better protect ourselves against this threat, and perhaps to prevent such an attack from occurring in the first place. While there are many challenges before us, we do know a great deal about what needs to be done and how to do it. I will address these issues in more detail later in my testimony, but I want to emphasize at the outset that improving the national response to bioterrorism must include several broad elements, such as:

Prevention. Every effort must be made to reduce the likelihood that dangerous pathogens will be acquired or used by those that want to do harm. This must include improving intelligence, limiting inappropriate access to certain biological agents and efforts to establish standards that will help prevent the development and spread of biological agents as weapons;

Strengthening public health. Rapid detection and response will depend on a well-

trained cadre of trained public health professionals to enhance disease surveillance and outbreak investigation, educated and alert health care providers, upgraded laboratories to support diagnosis, and improved communications across all levels of government, across agencies and

across the public and private sector.

Enhancing medical care capacity. We must improve treatment for victims of an attack by enhancing local and federal emergency medical response teams, training health professionals to diagnose and treat these diseases, developing strategies to improve the ability of hospitals to rapidly increase emergency capacity, and providing necessary drugs or vaccines where they are needed through a national pharmaceutical stockpile.

Research. A comprehensive research agenda will serve as the foundation of future preparedness. Perhaps most urgently, we need improved detectors/diagnostics, along with better vaccines and new medications.

Some of these activities are already underway, but need to be strengthened and extended; other programs and policies still need to be developed and implemented. This hearing represents an important forum to better define the agenda we must pursue to be a nation prepared.

DARK WINTER EXERCISE

I have been asked in my testimony to address "Dark Winter," a recent bioterrorism exercise which involved the intentional release of smallpox and the lessons learned. Although a simulation of a worst-case scenario, it powerfully conveyed the distinctive–and sobering–features of a potential bioterrorist attack and helped to spotlight many of the vulnerabilities that we must urgently and effectively address.

"Dark Winter" simulated a series of National Security Council (NSC) meetings dealing with a terrorist attack involving the covert release of smallpox in three American cities. The exercise was conducted by the Center for Strategic and International Studies, the Johns Hopkins Center for Civilian Biodefense Studies, and the ANSER Institute for Homeland Defense, under the leadership of John Hamre, Tara O'Toole and Randy Larsen, respectively. Many of the participants in "Dark Winter" had served previous Presidents in cabinet or sub-cabinet positions. Most knew how the NSC worked, and they were all individuals with considerable expertise and perspective in the security, law enforcement and health fields. I served as the Secretary of Health and Human Services.

In the opening minutes of "Dark Winter" we learned that cases of smallpox had just

been diagnosed by the Centers for Disease Control. Given the propensity of this disease to spread person-to-person, the 30% fatality rate of the disease, and the limited supply of smallpox vaccine, it was not surprising that we were soon dealing with an epidemic of devastating, if not catastrophic, potential.

In the 20th century, more than 300 million people died from smallpox – more than those killed in all wars of the century combined. Thanks to a massive and highly collaborative international campaign, smallpox as a naturally occurring disease was eradicated, and vaccination against the disease stopped. Consequently, each passing year has seen the birth of new generations of unvaccinated citizens, and a decrease in the potency of previous vaccinations among adults. So although the eradication of smallpox has saved thousands of lives, the end of vaccination against it has paradoxically left the world more vulnerable to the disease.

This fact would be of little consequence if we did not know that smallpox was made into a weapon by the Soviet Union, and that other nations or groups may have successfully acquired stocks of the virus.

Today, a single case of smallpox anywhere in the world would constitute a global medical concern. An example of the seriousness of this disease is the wave of smallpox that was touched off in Yugoslavia in 1972 by a single infected individual. The epidemic was stopped in its fourth wave by quarantines, aggressive police and military measures, and 18 million emergency vaccinations, this to protect a population of 21 million that was already highly vaccinated.

By comparison, in America today we have less than 15 million effective doses of vaccine to protect a population of 275 million that is highly vulnerable to the disease. The Yugoslavia crisis mushroomed from one case; the "Dark Winter" exercise began with 20 confirmed cases in Oklahoma City, 30 suspected cases spread out in Oklahoma, Georgia, and Pennsylvania, and many more individuals who were infected but not yet ill. Initially, we did not know the time, place or size of the release, so we had no way to judge the true magnitude of the crisis. We could easily predict, however, that it would get worse before it would get better.

Over a 24-hour period at Andrews Air Force Base, our NSC "war gamers" dealt with three weeks of simulated shock, stress and horror. We learned that on December 9, 2002, some dozen patients reported to the Oklahoma City Hospital with a strange illness confirmed quickly by the CDC to be smallpox. While we knew only about the Oklahoma cases the first day, we later learned the scope of the initial infections and the sites of three simultaneous attacks in shopping centers in Oklahoma, Georgia

and Pennsylvania. The initial infection quickly spread to five states and 3,000 victims, although at this point, most infected individuals had not displayed symptoms or gone to the hospital, so it was impossible to tell who or where they were.

The two primary tools for containing a smallpox epidemic are isolation of cases and vaccination of contacts. In accordance with this, a strategy was devised to include strict isolation of those with disease and a firewall of vaccine protection around those cases, but from the beginning, that strategy was limited by the large numbers of people initially infected, the rapid spread of the disease, and our limited supply of vaccine. Unfortunately, we had only enough vaccine for one out of every 23 Americans. (This remains the case in America today, although a contract is in place and is being accelerated to produce at least 40 million new doses by the end of 2002).

The Secretary of Defense demanded that all 2.3 million of U.S. military personnel be immediately vaccinated wherever they were in the world. In his wisdom, the President decided against this policy. Instead, we administered vaccine to U.S. military, including the National Guard, and security and medical service personnel who were on the front lines locally, and also those who were in areas of the world where a smallpox attack was more likely to occur.

So, on the first night of decision-making, we designed the vaccination strategy, and we ordered accelerated production of new stock. We even asked the Secretary of State to try to find surplus stock from other countries, but we were doubtful that they would comply with our request in the face of a smallpox epidemic that would in all likelihood become global.

On Day Six of the crisis, very little vaccine was left. The situation required that we consider measures considered draconian by modern standards, including enforced isolation, restrictions on travel, and providing food and other essential supplies to affected areas in the face of these restrictions. These problems were exacerbated by the fact that, by this point, we could no longer provide vaccine to essential providers.

On Day Twelve, when the war game ended, we were beginning the next stage of the epidemic – those who caught smallpox from the original 3,000 people who were infected in the initial terrorist attack. Epidemiologic models predicted that without effective intervention, every two to three weeks the number of cases would increase ten-fold.

At the conclusion of the exercise, the epidemic had spread to 25 states and 10 foreign countries. Civil disorder was erupting sporadically around the nation. Interstate commerce had ceased in large areas of the country. Financial markets had suspended trading. We were out of vaccine and were using isolation as the primary means of disease control.

For each of us around the table, the lessons learned were somewhat different, depending on our various backgrounds, experience and expectations. It was fascinating to see the differing perspectives that were brought to bear on the same fundamental sets of data and decision-points. At times, the old adage "what you see depends on where you sit" came to mind. Yet I think we all agreed that the exercise was indeed plausible - even conservative - in the framing of the scenario and the assumptions made about disease exposure, transmission and treatment. Certainly, we all left the room humbled by what we did not know and could not do, and convinced of the urgent need to better prepare our nation against this gruesome threat.

In my role as the Secretary of Health and Human Services, the perspective I brought to the table was that of someone who served first as a local health officer (New York City Health Commissioner) and then as a federal public health official (Assistant Secretary for Planning and Evaluation, Department of Health and Human Services). I felt first hand the devastation of terrorism as New York City's Health Commissioner when the World Trade Center was first bombed in 1993. Today, the horror of that event is dwarfed by the attacks of September 11th. Yet despite the incredible scale of these attacks, it is clear that an attack with a biological weapon has the potential to inflict even greater damage upon our country, both in terms of the extended timescale of the unfolding disaster and the numbers of people affected.

I should state that my bias is to approach the bioweapons issue in the broader context of infectious disease threats, both naturally occurring and intentionally caused. There is a continuum. A bioterrorist attack such as that depicted in "Dark Winter" would certainly represent the extreme end of that continuum, both in terms of its potentially catastrophic consequences for health and because of the disruption and panic that it would cause.

ISSUES RAISED BY DARK WINTER EXERCISE

"Dark Winter" raised many important issues and provided an opportunity to enhance awareness about the complexities of a bioterrorist attack. It served as a compelling illustration of just how much an attack caused by biological weapons would differ from conventional terrorism, military strikes or even attacks caused by other weapons of mass destruction.

It demonstrated how such an attack would unfold slowly - over days, weeks, months - as an infectious disease epidemic, with the potential to cause enormous suffering and death, as well as panic, destabilization and quite possibly civil disorder. There was little doubt that this would be a true public health emergency, for which our nation is ill-prepared to respond. Moreover, it showed how a bioterrorist attack would represent a national security crisis of enormous proportions, yet many of the traditional strategies to manage such an event would not apply. For example, identification of the perpetrator, as well as avenues for possible retaliation, might not be feasible. "Dark Winter" also underscored the interwined legal, ethical, political and logistical difficulties that attend contagious disease containment and control.

"Dark Winter" further demonstrated how poorly current organizational structures and capabilities fit with the management needs and operational requirements of an effective bioterrorism response. Responding to a bioterrorist attack will require new levels of partnership between public health and medicine, law enforcement and intelligence. However, these communities have little past experience working together and vast differences in their professional cultures, missions and needs. The "Dark Winter" scenario also underscored the pivotal role of the media, and how a productive partnership with media will be paramount in communicating important information to the public and reducing the potential for panic.

Another clear lesson that emerged from "Dark Winter" was that effective response will also require stronger working relationships across levels of government. While national leadership, guidance and support will be essential, it must be recognized that much of the initial crisis response and subsequent consequence management will unfold on the local level. "On-the-ground" local providers--public health and medical professionals, emergency response personnel, law enforcement officials and government and community leaders--will provide the foundation of the response and will deal with the problem from the moment the first cases emerge until the crisis is over.

The "Dark Winter" scenario also brought into bold relief the fact that management of such a crisis would almost certainly occur in the context of an already strained health care system and severe limitations on certain critical resources, including shortages of vaccine, hospital beds and isolation capacity.

CHALLENGES FOR THE FUTURE

As an exercise, "Dark Winter" was not designed to provide answers, but rather to raise critical questions and issues about our current preparedness to address the bioterrorist threat - Certainly it achieved that goal, but how do we begin to address these critical concerns? Building on lessons learned from "Dark Winter" from the perspective of public health and medicine, let me emphasize several key challenges as we move forward.

(1)Focus on the real threat/strengthen public health. In previous testimony before Congress, I have emphasized the need to convince policymakers and the public that the threat of bioterrorism is real. However, the recent cases of anthrax in Florida and New York City have made this point more forcefully than I ever could. However, even in the context of current events, I believe that a major challenge remains the need to get policymakers, legislators, and program planners to really comprehend that the threat of bioterrorism is fundamentally different than the other threats we face, such as "conventional" terrorism, or attack with a chemical or nuclear weapon.

Meaningful progress against this threat depends on understanding it in the context of an infectious and epidemic disease. It requires different investments and different partners. Until bioterrorism's true nature as an epidemic disease event is fully recognized, our nation's preparedness programs will continue to be inadequately designed: the wrong first responders will be trained and equipped; we will fail to fully build the critical infrastructure we need to detect and respond; the wrong research agendas will be developed; and we will never effectively grapple with the long-term consequence management needs that such an event would entail.

Unfortunately, if we look at our current preparedness efforts to date, necessary public health and medical care activities have been underdeveloped and underfunded. Of the roughly \$10 billion budget for counterterrorism efforts in FY 2001, only a very small percentage has supported activities that truly can be considered as core elements of a coherent program to address the bioterrorist threat. In the current environment, it is clear that very substantial new monies will be available, and we must ensure that a significant component of those resources are targeted to address these critical concerns.

(2) <u>Build on existing strategies</u>. Effective strategies must build on existing systems where possible, but build in flexibility. We do not want to develop an entire ancillary system for responding to the bioterrorist threat. Rather, we should strive to integrate our thinking and planning into the continuum of infectious disease threats and potential disasters that public health agencies are already charged to respond to. The

last thing we want is to find ourselves trying out a plan for the very first time in the midst of a crisis. Instead, we want to find the systems that work in routine activities and then identify what we need to do to amplify or modify them to be appropriately responsive for these more acute and catastrophic situations.

(3) <u>Support the health care system's capacity for mass casualty care</u>. Controlling disease and caring for the sick will require a deep engagement of the public health and medical community. There are currently many pressures on health care providers and the hospital community that limit their ability to prepare in some of the critical ways necessary for effective planning in the face of the bioterrorist threat. The enormous downsizing that has occurred, the competitive pressures to cut costs, the just-in-time pharmaceutical supplies and staffing approaches, and the limited capacity for certain specialty services such as respiratory isolation beds and burn units that may become critical in a biological or chemical terrorist attack, all need to be recognized and addressed.

We must be realistic about the potential costs that would be incurred by these institutions and individuals, as well as the enormous up-front investments needed if they are truly to prepare. And in many ways, if you are a health care institution today, making those preparatory investments is a high-risk undertaking. By preparing, you are also almost setting yourself up to incur a series of costs that may not be reimbursed after the crisis is over.

We know that we must find better ways to strategically support our health care institutions, both because of the implications of a bioterrorist attack but also because of the existing demands on the system, as evidenced this past year when a routine flu season overwhelmed hospital capacity in several cities.

There is an urgent need to develop programs that target dollars for health care disaster planning and relief, including training, templates for preparedness, and efforts to develop strategies in collaboration with other critical partners for providing ancillary hospital support in the event of a crisis. This could be done either through the army field hospital model or what was done in the 1918 pandemic flu, when armories, school gymnasiums and the like were taken over to provide medical care. In doing this, we need to support local and state planning efforts to assess community assets and capabilities, and we need to look at what federal supports can be brought to bear locally in a crisis.

(4) <u>Invest in research</u>. Today's investment in research and development will be the foundation of tomorrow's preparedness. A comprehensive research agenda should

be developed and pursued that extends across many important research domains. For example, our capability to detect and respond to a bioterrorist attack depends largely on the state of the relevant medical science and technology. Without rapid techniques for accurate identification of pathogens and assessment of their antibiotic sensitivities, planning for the medical and public health response will be significantly compromised. Without efficacious prophylactic and treatment agents, even the best planned responses are likely to fail. Biomedical research is needed to develop new tools for rapid diagnostics, as well as improved drugs and vaccines. At an even more basic level, we must invest in research to enhance the fundamental study of genomics, disease pathogenesis and the human immune response.

In addition to biomedical research, further research into such diverse concerns as defining appropriate personal protective gear or decontamination procedures under different circumstances will be important to our overall preparedness for a bioterrorist attack.

Research to support deeper understanding of the behavioral issues and psychosocial consequences of a catastrophic event of this kind is currently very limited but should be made a high priority. I believe that the importance of all of these areas has been underscored by our recent experience in responding to the mounting set of anthrax cases and exposures. These events have demonstrated critical gaps in our knowledge as well as deficiencies in our tools for detection, response and consequence management that we can and should swiftly address.

5) <u>Understanding the public response</u>. Sadly, the many fears, anxieties and uncertainties that have surrounded the current anthrax scare reinforce another major gap identified in current preparedness and planning efforts. This involves how to engage the public, and importantly, how to most effectively work with the public in the event of a crisis. The recent small-scale anthrax attacks, although they have sickened only a handful people, have given new insights into how complex these issues may be. Certainly, the specter of a silent, invisible killer such as an infectious agent evokes a different level of fear and panic than other disaster scenarios. Indeed, response to previous major disease epidemics—such as the outbreak of pneumonic plague in Seurat, India in 1994—suggests a level of panic and civil disruption on a far greater scale.

Anyone who has ever dealt with disaster response knows that how the needs of the public are handled from the very beginning is critical to the overall response. In the context of a biological event, this will no doubt be even more crucial. Managing the worried well may interfere with the ability to manage those truly sick or exposed. In fact, implementation of disease control measures may well depend on the

constructive recruitment of the public to behave in certain ways, such as avoiding congregate settings or following isolation orders. In the final analysis, clear communication and appropriate engagement of the public will be the key to preventing mass chaos and enabling disease control as well as critical infrastructure operations to move forward. Correspondingly, the needs and concerns of response personnel, including health care workers, must also be addressed. Again, prior experience with serious infectious disease outbreaks tells us that when this does not occur, essential frontline responders and key workers are just as likely as the public to panic, if not flee. The mass exodus of health care workers following onset of the Ebola epidemic in Kikwit, Zaire in the mid 1990s serves witness to this point.

(7). <u>Engage the media</u>. The media is key to efforts in a crisis to communicate important information to protect health and control disease, as well as to reduce the potential for panic. Over the past days, we have seen both the press and the public receive a crash course on anthrax. They have been fast learners, and for the most part, the media has done a credible and responsible job in communicating this important information. But there must be a clear plan for providing the news media with timely and accurate information. Furthermore, the credible and consistent voice of well-informed health officials is critical to this effort.

Stepping back, it is clear that the ability of the media to mobilize effectively in a crisis is greatly enhanced by a process of ongoing and continuing mutual communication and education in calmer times. We must strive for the development of a set of working relationships grounded in trust - trust that they will be provided with information in a timely and appropriate manner, and in turn, that they will use that information in a responsible, professional way.

No doubt there will always be tensions between the desire to get out a good story and an appreciation of the complexities, sensitivities and uncertainties inherent in such a crisis. But stonewalling the press or viewing them as the enemy is virtually guaranteed to make the situation worse.

(8) <u>Clarify legal authorities</u>. In planning for an effective response, an array of legal concerns need to be addressed. Issues include such basic ones as the declaration of emergency -- what are the existing authorities? Are they public health, or do they rest in other domains that will be relevant? What are the criteria for such a declaration? What are the authorities that still need to be established?

Other outstanding legal questions concern the ability to isolate, quarantine, or detain groups or individuals; the ability to mandate treatment or mandate work; restrictions

on travel and trade; the authority to seize community or private property such as hospitals, utilities, medicines, or vehicles; or the ability to compel production of certain goods. Also, questions concerning emergency use of pharmaceuticals or diagnostics that are not yet approved or labeled for certain uses need to be answered.

These questions involve many different levels of government, many different laws and authorities, and raise many complex and intertwined ethical, political and economic issues. In a systematic and coherent way, we must address this array of pressing issues and concerns. And not just what laws are in place or could be put in place, but then also what policies and procedures would be necessary to actually implement them.

(9) <u>Plan, prepare and practice</u>. Perhaps most fundamentally, "Dark Winter" signaled the need for more planning and preparation—across all the domains mentioned above and more. Planning can make a difference, but we cannot begin to prepare in the midst of a crisis. As "Dark Winter" unfolded, it was evident that a sense of desperation about what needed to be done arose, at least in part because the country had not produced sufficient vaccine; had not prepared top officials to cope with this new type of security crisis; had not invested adequately in the planning and exercises needed to implement a coordinated response; and had not educated the American people or developed strategies to constructively engage the media to educate people about what was happening and how to protect themselves.

Prior planning and preparation can greatly mitigate the death and suffering that would result from a serious bioweapons attack. As a nation, we need comprehensive, integrated planning for how we will address the threat of bioterrorism, focusing both on prevention and response. We need to define the relative roles and responsibilities of the different agencies involved, and identify the mechanisms by which the varying levels of government will interact and work together. We need true national leadership to address the bioweapons threat to our homeland. Planning efforts must be backed by the necessary resources and authority to translate planning into action. Moreover, we must practice what we plan. Preparations must be exercised, evaluated and understood by decision-makers if they are to prove useful in a time of crisis.

(10) <u>The importance of prevention</u>. The many intrinsic challenges involved in mounting an effective response to a bioterrorism attack - and the many casualties that will inevitably occur--should compel us to make a greater commitment to what can be accomplished to reduce the fundamental threat of their use. Clearly, measures that will deter or prevent bioterrorism will be the most cost effective means to

counter such threats to public health and social order - both in human and economic terms. Are there strategies to limit or prevent these often frightening microbes from getting into the hands

of those who might misuse them, and how do we reduce the likelihood that they would be misused?

On a policy level, such prevention efforts require a global approach, including the need to find ways to meaningfully strengthen and enforce the Biological Weapons Convention, as well as international scientific cooperation to create opportunities for scientists formerly engaged in bioweapons research to redirect their often considerable talents and energy into more constructive and open research arenas. For example, a number of scientific collaborations have begun in Russia in an attempt to address this goal.

We must also strengthen and expand efforts to control access to and handling of certain dangerous pathogens, including proactive measures by the scientific community to monitor more closely the facilities and procedures involved in the use of such biological agents.

THE NUCLEAR THREAT INITIATIVE—A New Foundation

Encouraging and supporting our government to deter, prevent, and defend against biological terrorism is a central part of our mission at the Nuclear Threat Initiative (NTI) – an organization founded by Ted Turner and guided by a distinguished board co-chaired by him and former Senator Sam Nunn. We are dedicated to reducing the global threat from biological, nuclear, and chemical weapons by increasing public awareness, encouraging dialogue, catalyzing action, and promoting new thinking about these dangers in this country and abroad.

We fully recognize that only our government can provide the leadership and resources to achieve our security and health priorities. But within that context, NTI is:

Seeking ways to reduce the threat from biological weapons and their consequences. Exploring ways to increase education, awareness and communication among public health experts, medical professionals, and scientists, as well as among policy makers and elected officials – to make sure more and more people understand the nature and scope of the biological weapons threat.

Considering ways to improve infectious disease surveillance around the globe -

including rapid and effective detection, investigation, and response. This is a fundamental defense against any infectious disease threat, whether it occurs naturally or is released deliberately.

Stimulating and supporting the scientific community in its efforts to limit inappropriate access to dangerous pathogens and to establish standards that will help prevent the development and spread of biological agents as weapons. And finally, NTI is searching for ways to help our government and the Russian government to facilitate the conversion of Russian bioweapons facilities and knowhow to peaceful purposes, to secure biomaterials for legitimate use or destruction, and to improve security of dangerous pathogens worldwide.

CONCLUSION

In conclusion, let me re-emphasize that a sound strategy for addressing bioterrorism will need to be quite different from those that target other types of terrorist acts. While a large-scale event most likely remains a relatively low probability event, the high consequence implications of bioterrorism place it in a special category that requires immediate and comprehensive action. Yet as we move forward to address this disturbing new threat, it is heartening to recognize that the investments we make to strengthen the public health infrastructure, to improve medical consequence management and to support fundamental and applied research, will also benefit our efforts to protect the health and safety of the public from naturally occurring disease.

To be effective, we will need to define new priorities, forge new partnerships, make new investments to build capacity and expertise, and support planning. We may never be truly prepared for some of the most catastrophic scenarios, but there is a great deal that can and should be done.

I look forward to working with you on these important issues and would be happy to answer any questions you may have.