STATEMENT OF
RICHARD A. FALKENRATH
SENIOR FELLOW
THE BROOKINGS INSTITUTION
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Introduction

Good morning, Mister Chairman, Senator Kennedy, and Members of the Committee. I am grateful for the opportunity to be here today to provide my views on the reauthorization of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), and biodefense and public health preparedness more generally. I am honored to be asked to assist your Committee as you discharge your vital oversight responsibilities.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was an extremely important bill. It was the first of several important steps taken by the United States in the area of biodefense after the terrorist attacks of September 11, 2001. The direction and authorizations contained within Title I of the Bioterrorism Act made sense at the time. Most of them still make sense today, but there are certain aspects in which I believe modifications are in order. I describe these recommendations in the testimony that follows.

I would like to commend the members of this committee for holding a hearing at this time. Biodefense and public health preparedness is not the crisis *de jour*. Yet biodefense and public health preparedness are profoundly important subjects: more important, in my judgment, than many of the security issues that have dominated the public debate in the last few months. As I know from first-hand experience, it is difficult for senior policymakers to devote their time and energy to matters of great importance but no immediate urgency.

I would also like to commend the American and international public health community. I am continually impressed by the beneficence and selfless dedication of the countless doctors, nurses, scientists, technicians, and other public servants who have devoted themselves to the fight against infectious disease. Here in the United States, we are particularly fortunate to have two individuals of highest possible caliber serving as our Director of the Centers for Disease Control (CDC) and our Director of the National Institute for Allergy and Infectious Disease (NIAID). I have some sense of the enormity of the challenges they and others still serving in government face. The testimony I have to offer today should in no way be taken as a critique of the performance of any individual government official at any level. Rather, the criticism I offer today is meant to be constructive and is directed at the overall U.S. strategy for dealing with catastrophic disease events.

For the record, my name is Richard A. Falkenrath and I am presently a senior fellow in Foreign Policy Studies at the Brookings Institution. I am also Managing Director of the

Civitas Group LLC, a strategic advisory and investment services firm serving the homeland security market, and a security analyst for the Cable News Network (CNN). Until May 2004, I was Deputy Assistant to the President and Deputy Homeland Security Advisor on the White House staff. Previously, I served as Special Assistant to the President and Senior Director for Policy and Plans within the Office of Homeland Security, and as Director for Proliferation Strategy on the National Security Council staff. Prior to government service, I was an Assistant Professor of Public Policy at the John F. Kennedy School of Government at Harvard University.

The Threat of Catastrophic Disease

I have studied many different threats to U.S. national security. As an undergraduate, I studied the Soviet maritime threat to the United States and its European allies. As a graduate student, I studied the Soviet conventional forces threat in central Europe. As a post-doctoral researcher, I co-authored a book on the threat of fissile material and nuclear weapons leaking out of the former Soviet Union's sprawling nuclear complex. As a Kennedy School professor, I co-authored another book on the threat of mass-casualty terrorism involving nuclear, biological, and chemical weapons. As a member of the National Security Council staff, I was a voracious consumer of intelligence on the extraordinarily wide variety of threats to the United States. After the terrorist attacks of September 11, 2001, I became one of the President's homeland security advisors; in this capacity, I scrutinized not only the never-ending stream of intelligence related to terrorist threats against U.S. interests, but also the less accessible body of information

related to America's underlying vulnerabilities – that is, to the plausible scenarios which present the greatest likelihood of the greatest harm to the nation. In previous testimony before the Senate Homeland Security and Government Affairs Committee, I have drawn attention to some of those vulnerabilities, notably those presented by toxic industrial chemicals.

My years of study and government service have led me to following conclusion. As the prospect of global thermonuclear war has faded away, the greatest remaining source of danger to U.S. national security in the 21st century – and to mankind as a whole – is disease.

I reach this conclusion in part because I define the catastrophic disease threat broadly, to include both natural and manmade disease outbreaks. The pathogens that cause disease range from the viruses that cause influenza, smallpox, West Nile, and SARS – to the bacteria that cause anthrax, cholera, plague, and tuberculosis – to the parasites that cause malaria and sleeping sickness. Some, like smallpox, are recorded in earliest human history; others, like the virus that causes SARS, have only recently become known to science. Like all living organisms, pathogens evolve to adapt to changes in their environment, which in most causes is another living organism – a human, a bird, a pig, or a mosquito, for instance – with an immune system that seeks to manage the host's microbial infections.

There are three basic categories of the catastrophic disease threat. The first are naturally occurring infectious diseases, such as influenza, yellow fever, and tuberculosis. Naturally occurring disease has profoundly influenced human history, as the scholar William McNeill explained in his brilliant 1976 book, *Plagues and Peoples*, and retains the capacity to do so again today despite revolutionary advances in public health methods and biomedical science. In the words of Nobel Laureate Joshua Lederberg:

> We are engaged in a type of race, enmeshing our ecologic circumstances with evolutionary changes in our predatory competitors. To our advantage, we have wonderful new technology; we have rising life expectancy curves. To our disadvantage, we have crowding; we have social, political, economic, and hygienic stratification. We have crowded together a hotbed of opportunity for infectious agents to spread over a significant part of the population. Affluent and mobile people are ready, willing, and able to carry afflictions all over the world within 24 hours' notice. This condensation, stratification, and mobility is unique, defining us as a very different species from what we were 100 years ago. We are enabled by a different set of technologies. But despite many potential defenses—vaccines, antibiotics, diagnostic tools—we are *intrinsically more vulnerable* than before, at least in terms of pandemic and communicable diseases.[1]

The greatest danger seems to develop when a pathogen shifts suddenly from an animal reservoir into an immunologically naive human environment (a process called zoonosis), as has happened in Asia and Turkey with the H5N1 influenza strain (and happened with the human immunodeficiency virus (HIV) in the late 1970s or early 1980s).

The second category of the catastrophic disease threat are naturally occurring disease-causing microorganisms that some state, non-state actor, or individual has deliberately

1. Joshua Lederberg, "Infectious Disease as an Evolutionary Paradigm," *Emerging Infectious Diseases*, Vol. 3, No. 4 (October-December 1997), at http://www.cdc.gov/ncidod/eid/vol3no4/lederber.htm [emphasis added].

acquired, produced, and then somehow disseminated against a susceptible population in order to cause harm; this is bioterrorism. In principle, virtually any disease-causing agent can be used as a weapon, but in practice certain characteristics – communicability, lethality, resistance to countermeasures, environmental resilience – make some agents far more attractive than others.[2] An essential element of the bioterrorism threat is what Richard Danzig, the former Secretary of the Navy and noted thinker on bioterrorism and biodefense, calls the "reload" problem.[3] Once a state or a terrorist has established an effective production process for a biological weapon, there are very few inherent limitations on the amount of biological weapon agent that can be produced. This is because microbes in proper settings reproduce and multiply on their own; time, therefore, is the main constrain on the amount of pathogenic agent a terrorist can deploy. The implications of this fact are profound and are responsible for putting bioterrorism in an altogether separate category from, for instance, nuclear terrorism. As Danzig warns us, bioterrorism needs to be thought of not as one or more discrete attacks but as a *campaign* that will continue until the attacker calls it off or its production process has been located and destroyed. (Nuclear terrorism, on the other hand, is far more likely to consist of only one or a few nuclear detonations due to limits established by the availability of fissile material).

2. The Centers for Disease Control list of "Category A" agents include anthrax (Bacillus anthracis); botulism (which is an acute intoxication rather than infectious disease, caused by clostridium botulinum); plague (Yersinia pestis); smallpox (variola major, which no longer exists in nature); tularemia (Francisella tularensis); and various viral hemorrhagic fevers (e.g., Ebola, Marburg], Lassa, Machupo). See http://www.bt.cdc.gov/agent/agentlist-category.asp#a.

3. Richard Danzig, Towards a Long-Term Strategy for Coping with the Risk of Bioterrorism. Washington, D.C.: The Defense Science Office, October 2005.

The third are disease-causing microorganisms that a state, non-state actor, or individual has genetically manipulated (or, conceivably, produced from scratch) for the purposes of improving their utility as a weapon, and then produced and disseminated against a susceptible population; this is bioterrorism involving a novel pathogen. As a result of revolutionary advances in genomics and microbiology, scientists can create new microorganisms that are more communicable, lethal, resistant to countermeasures, and/or resilient to the environment than naturally occurring pathogens. There is debate about the severity of the novel pathogen threat, but the potential dangers were graphically revealed in late 2000, when a team of Australian scientists inadvertently discovered that they could significantly increase the lethality (in rodents) of a relatively benign pox-virus by splicing the interleukin-4 gene into the virus.[4] This relatively simple genetic modification of an animal pathogen raised serious questions about the ease with which a bioterrorist could create novel pathogens that would be more dangerous than the likely naturally occurring biowarfare agents for use against human beings.

Infectious disease is, of course, a chronic problem throughout the world with particularly devastating manifestations in the developing world. My particular focus in this testimony is *catastrophic* disease events in any of the three categories outlined above. A catastrophic disease event is an extreme scenario may result when one or more of following three criteria apply.

4. Elizabeth Finkel**, "**Engineered Mouse Virus Spurs Bioweapon Fears," *Science*, Vol. 291, No. 5504 (January 26, 2001), p. 585.

- First, is the disease characterized by efficient human-to-human communicability and serious expected health effects due to inadequate immunological or likely medical response? The SARS outbreak did not meet this criterion because the disease was not particularly communicable. Efficient human-to-human transmission is most likely to be airborne, involving an invisible dispersion of infectious aerosol, since the other possible modes of transmission can more effectively countered through behavior change. Pandemic influenza is the disease most likely to satisfy this criterion in the near term.

- Second, is the outbreak the result of a wide-area release of a pathogenic agent deliberately and competently selected for the seriousness of its health effects, its resistance to available medical treatment, and/or its environmental resilience? The anthrax attacks of October 2001, as serious as they were, did not meet this criterion because of the relatively small amount of pathogenic agent used. A line- or point-release of 100 times as much agent of the same quality in a densely populated area would, however, in all likelihood satisfy this criterion and qualify as a catastrophic disease scenario.

- Third, is the fear created by the outbreak likely to trigger a public response of such scale or character that it damages the authorities' ability manage the initial outbreak and/or its follow-on waves, provokes civic unrest, impedes the provision of essential services, undermines public trust in government, damages the economy, or impairs the nation's ability to protect its strategic interests or fulfill its

global responsibilities? These effects seem most likely to result from shortages in vital, life-saving medical countermeasures to the disease in question. For instance, because of the "reload" problem noted above, an effective aerosolized anthrax attack in a confined area of the country is likely to create enormous demand for antibiotic prophylaxis across the entire country (until the perpetrator is identified and the anthrax production and weaponization facility destroyed). If this demand for antibiotic prophylaxis is satisfied, hundreds of thousands, if not millions, of healthy people could quickly consume nation's entire available supply of effective antibiotic – leaving the country acutely vulnerable to a follow-on attack.

A catastrophic disease event is admittedly an extreme scenario, residing at the very highest end of the threat spectrum. With respect to manmade threats – bioterrorism – I am not suggesting that such a scenario can be easily effectuated or is imminent. Nonetheless, I do not believe that the trends are in our favor. With every passing year, the latent technological potential of states and non-state actors to use disease effectively as a weapon rises inexorably. With respect to naturally occurring disease threats, no one can precisely estimate the likelihood, timing, or consequence of the appearance of a new human pathogen.[5] However, even the conservative World Health Organization concludes that "the world may be on the brink of another pandemic."[6] If this was along the lines of the relatively mild pandemic of 1957, it would likely result in 2

5. Again, in the words of Joshua Lederberg, "the outcome of encounters between mutually antagonistic organisms is intrinsically unpredictable. … Infectious agent outcomes range from mutual annihilation to mutual integration and resynthesis of a new species." Ibid.

6. http://www.who.int/csr/disease/influenza/pandemic10things/en/index.html

to 7.4 million deaths worldwide. A pandemic with the death rate of the 1918 Spanish flu – perhaps the most extreme human disease event in history – could result in several million fatalities in the United States and perhaps over one hundred million abroad.

In sum, when viewed in comparison to all other conceivable threats to U.S. national security, the catastrophic disease threat is and for the foreseeable future will remain the gravest danger we face. No state, no terrorist group, no ideology or system of government, no other tactic or target or category of weapons, no technological accident, and no other natural phenomenon, presents as terrifying a combination of likelihood, poor defenses and countermeasures, and consequence.

Achievements, Shortcomings, and Recommendations

Since the terrorist attacks of September 11, 2001, there is no area of national or homeland security in which the United States has made more progress than civilian biodefense, and no area in which the nation has further to go.

We have launched an extraordinary biodefense research program at the National Institutes of Health; improved our domestic and international epidemiological surveillance systems, including though the deployment of an effective atmospheric sampling system called BioWatch; and stockpiled enough smallpox vaccine for every American, as well as vast quantities of other pharmaceutical and emergency medical supplies that give us a dramatically better ability to manage the consequences of a certain categories of bioterrorist attack. No country in the world has attacked the

challenges for biodefense more aggressively or effectively as the United States, and in my opinion, no country in the world is better prepared for a bioterrorist attack.

There are, however, a number of serious shortcomings in our nation's current and likely future capacity to cope with most catastrophic disease scenarios. I will focus on four general areas: countermeasure availability; the National Response Plan; local, state, and federal responsibilities in response plan execution; and federal organization for biodefense and public health preparedness.

I. Medical Countermeasure Availability

The critical difference between pathogens and most other threats facing the United States is that disease is, in principle, treatable. The right vaccine administered with enough lead time can make a person immune to particular pathogen threats. Antibiotics administered quickly enough can cure a person of most bacterial threats, or at least those which have not acquired antibiotic resistance. Intensive care – respirators and other methods of treating the acute symptoms of a disease – can significantly improve an infected person's chance of survival.

The availability of appropriate medical countermeasures is, therefore, a critical element of the nation's overall biodefense and public-health preparedness. As noted earlier, the U.S. government has made some extraordinary strides in acquiring large stocks of

certain medical countermeasures that, in certain disease contingencies, will dramatically improve the nation's ability to cope with the crisis.

Two aspects of the U.S. strategy for acquiring biomedical countermeasures to pathogen threats seem to me to be essentially sound. The first is the multi-billion dollar NIAID biodefense research program. I believe this program is adequately funded, excellently led, has already yielded many important discoveries for reducing the catastrophic disease threat, and will continue to do so in the future. The second is the Department of Health and Human Service's program for procuring proven biomedical countermeasures against *known pathogen threats*, such as ordinary anthrax and smallpox. This effort has been funded through the $5.6 billion BioShield advance appropriation as well as the annual discretionary budget of the Department of Health and Human Services. Like most observers, I would like to see this HHS procurement move more swiftly, but in my estimation it is reasonably sized and directionally sound.

Nonetheless, I see four general problems in the area of pathogen countermeasure availability.

First, the pharmaceutical industry has not been effectively mobilized to the task. From the perspective of the largest pharmaceutical firms, their relatively modest commitment to anti-infective research, development, and production is economically understandable. There is in general less money to be made, and more risk incurred, from developing treatments for infectious disease than treatments of chronic disease and other ailments.

Governments, however, cannot shoulder the burden of countering pathogen threats alone, and so we must find a way to more effectively marshal the resources of the world's leading pharmaceutical firms.

Second, the clinical trial process for new biomedical countermeasures takes too long, often five years or more. It is, of course, necessary for drug researchers and manufacturers to demonstrate the efficacy as well as the safety of new drugs, and for the federal government to regulate this process. The finalization of the Food and Drug Administration's "animal rule" for clinical trials of countermeasures that cannot be tested on humans was step in the right direction, as was the emergency use authority conferred to the Secretary of Health and Human Services in the Bioterrorism Act of 2002 and BioShield Act of 2004. Even so, the revolutionary advances in the biological and computer sciences over the past decade should make it possible for the U.S. government to reduce significantly the length of time, and perhaps even the expense, of proving the efficacy and safety of all new disease countermeasures.

Third, the United States needs a discrete program dedicated to understanding and, to the extent possible, developing and acquiring countermeasures to *novel pathogens*. As noted earlier, the HHS procurement program for the Strategic National Stockpile focuses on against countermeasures against *known pathogen threats* – that is, the threat agents that appear on one of several official lists maintained by the Centers for Disease Control. At the moment, there is no government program focused on developing and acquiring countermeasures that will be effective against the threat

agents that do not exist or are not yet known. Given the long-term potential for the genetic manipulation of pathogens, the United States should invest in such a capability as part of the nation's overall biodefense effort. In its 2006 Quadrennial Defense Review, the Department of Defense has announced its plan to reallocate "more than $1.5 billion over the next five years to develop broad-spectrum medical countermeasures against advanced bio-terror threats, including genetically engineered intracellular bacterial pathogens and hemorrhagic fevers."[7] This important initiative, which has not yet begun, should be strongly supported by the Congress, authorized by statute (perhaps in the reauthorization of Title I of the Bioterrorism Act), and fully involve all other agencies with biodefense responsibilities. The location of the novel pathogen countermeasures program within the U.S. government matters less than that it exists in the first place and that it is organizationally separate from the government's program to procure countermeasures against known pathogens. This separation is important because novel pathogens are an over-the-horizon threat requiring innovative, advanced, high-risk countermeasure strategies that are not likely to prosper within a more conventional procurement bureaucracy.

Finally, the United States requires a domestic influenza vaccine production capacity to produce sufficient vaccine for the entire U.S. population within at most one year of the onset of a global pandemic. According to the estimates of the University of Minnesota's Center for Infectious Disease Research & Policy, the current domestic vaccine production capacity would allow only 37.5 million U.S. citizens, out of a total

7. Quadrennial Defense Review 2006, pp. 52-53.

population of 295 million, to be vaccinated during the first year of a pandemic.[8] The United States has plans to acquire 20 million doses of "pre-pandemic" vaccine – that is, a vaccine that was developed against the H5N1 strain that is currently endemic in avian populations but not yet communicable between humans. This pre-pandemic vaccine stockpile is clearly one critical strategy for ameliorating the expected vaccine shortage in the short run. Stockpiling "pre-pandemic" vaccine is not, however, a viable long-term strategy due to the uncertain efficacy of pre-pandemic vaccines against pandemic strains of the virus.

Currently, most of the world's vaccine production capacity islocated abroad, mainly in Europe, and relies on a relatively unreliable egg-based production technique with a rigid production timetable that can lead to months of unnecessary delay. CDC Director Julie Gerberding has testified that the "pandemic influenza vaccines produced in other countries will likely not be available to the US market as those governments may prohibit export of the vaccines produced in their countries until their domestic needs are met."[9] The implications are obvious: in the event of a global pandemic, thousands to hundreds of thousands of U.S. citizens will contract the disease, and some fraction of

8. "In the United States, domestic production was estimated at 50 million doses of trivalent vaccine during 2004. This would be equivalent to about 150 million doses of monovalent standard-dose, assuming 15 mcg HA per dose. … Two critical caveats need to be considered with these types of estimates: (1) it is not clear how many micrograms of antigen will be necessary to elicit an immune response to a pandemic strain and (2) two doses of vaccine will likely be needed to confer adequate protection. For example, recent data from a clinical trial of a candidate H5N1 vaccine demonstrated that volunteers required two doses of a 30-mcg vaccine to mount an adequate immune response to H5N1. If this is the case for a pandemic vaccine, then 60 mcg of antigen would be needed per person, which is four times higher than that needed per dose to confer protection with current annual influenza vaccines. An extrapolation of the current production capacity to this antigen requirement per person suggests that only 37.5 million people in the United States could be vaccinated during the first year of a pandemic (roughly 10% of the country's population)." See <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/biofacts/panflu.html#_Surveillance_Considerations>.

9. Testimony of Julie L. Gerberding, MD, MPH, before the Subcommittee on Health, Committee on Energy and Commerce U.S. House of Representatives, May 26, 2005 <http://www.cdc.gov/washington/testimony/in05262005.htm>

them will die, while the citizens of countries with more robust domestic vaccine production capacities – Australia, Canada, France, Germany, Italy, the Netherlands, Switzerland, and the United Kingdom – will acquire an effective vaccine and survive. Given the extreme public and political concern expressed over the security implications of Dubai Port World's intended acquisition of operating contacts for six container terminal facilities at six U.S. ports, the relative lack of concern over this far more significant foreign dependency is astonishing. As a matter of great national urgency, therefore, the United States should develop a large-scale, domestic-based vaccine production facility. I urge the Congress to include this mandate in its reauthorization of Title I of the Bioterrorism Act. If private-sector financing is unavailable or only partially available for this project, then it should be paid for from the general revenue. The total cost would be a small and an entirely justifiable fraction of total U.S. national security expenditures.

II. The National Response Plan

The National Response Plan (NRP) is not adequate for catastrophic disease contingencies. The plan assigns responsibility for Emergency Support Function #8, "Public Health and Medical Services," to the Department of Health and Human Services. The Biological Incident Annex to the NRP similarly assigns lead responsibility to the Department of Health and Human Services. The NRP's premise is that "state, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and

economic consequences of such an outbreak,"[10] and that HHS's role is to coordinate "the provision of Federal health and medical assistance to fulfill the requirements identified by the affected State, local, and tribal authorities."[11] This is a perfectly appropriate arrangement for ordinary emergencies, routine public health problems, and non-catastrophic disease contingencies. It is completely inappropriate and unrealistic for genuinely catastrophic disease contingencies, particularly those which will require the effective distribution of life-saving medicines to a fearful population over very large areas in very short periods of time. In such circumstances, we must assume that state, local, and private-sector health care capabilities become fully or partially incapacitated, and that the federal government will need to step in forcefully. A variety of recent full-field and tabletop exercises have supported this assumption.

The Department of Health and Human Services is the locus of most of the federal government's expertise on the science of disease and bioterrorism and should remain so. But HHS does not possess much capacity to conduct field operations. The Centers for Disease Control (CDC), an agency within HHS, has various operational capabilities at its headquarters in Atlanta and in the field, but these are, for the most part, optimized for routine public-health matters and epidemiological investigations. With its limited organic operational capabilities, the Department of Health and Human Services is simply not going to be able to meet the American people's expectation of the federal government in a truly catastrophic disease contingency such as a high lethal pandemic or major bioterrorist attack.

10. National Response Plan, p. 332.

11. National Response Plan, p. 160.

To address this problem, I believe that Homeland Security Presidential Directive 5 (HSPD-5 on “Management of Domestic Incidents”), HSPD-10 (”Biodefense for the 21st Century”), the National Response Plan, the National Strategy for Pandemic Influenza, the HHS Pandemic Influenza Plan, the CDC Smallpox Response Plan, the Defense Planning Guidance, and the DOD Contingency Planning Guidance should be amended to permit and, indeed, anticipate the assignment of ESF #8 to the Department of Defense in a catastrophic disease incident at the order of the President. The Department of Defense should be directed to plan and prepare for the assumption of the ESF #8 responsibilities -- to include the provision of essential health care, distribution of medical countermeasures, rationing of scarce essential supplies – and to anticipate the inability of state, local, and private-sector entities to perform the medical and logistical functions expected of them in the National Response Plan. In such a circumstance, the Department of Health and Human Services should be assigned responsibility for supporting the Department of Defense by providing necessary medical advice and personnel, thus essentially reversing the roles of the two departments in catastrophic disease situations. In ordinary emergencies, non-catastrophic disease scenarios, and catastrophic scenarios without a significant medical dimension, the Department of Heath and Human Services should retain responsibility for ESF #8. This can all be effectuated by Executive Order but given the significance of this change it would probably be prudent to authorize expressly in a statute such as the reauthorization of Title I of the Bioterrorism Act of 2002.

My reason for this recommended change is simple. Only the Department of Defense has the planning, logistics, and personnel resources needed to conduct nationwide medical relief operations in a full-scale catastrophic disease scenario.

III. Local, State, and Federal Responsibilities in Response Plan Execution

When Hurricane Katrina hit metropolitan New Orleans, we saw what could happen when state and local authorities lack appropriately robust contingency plans as well as the operational capability to implement those plans (which in some cases they did not even follow); when federal authorities assume incorrectly that state and local authorities will perform vital operational tasks in the early stages of the crisis; and when the federal authorities lack real-time situation awareness and effective mechanisms for interagency command, control, and coordination.

I believe that many, if not most, of the problems in the national response to Hurricane Katrina were unique to metropolitan New Orleans. Most other cities in the hurricane belt are above sea-level, and most other cities and states in this region have over the years demonstrated an ability to respond to major hurricanes more effectively than New Orleans and Louisiana did before, during, and after Katrina. This is not to excuse the many failures at the federal level, but instead to make a broader point about the nation's preparedness for the disease equivalent of a Category 5 hurricane – namely, to a catastrophic disease scenario such as the onset of pandemic influenza in the United States or a major, fully effective bioterrorist attack.

The federal government's strategy for responding to catastrophic disease scenarios relies very heavily on state and local authorities. The federal government expects states and localities to receive supplies from the vast federal stockpile of medical countermeasures – antibiotics, vaccines, and other pharmaceuticals as well as respirators and other essential medical supplies – for use at whatever treatment centers the state and local authorities plan to utilize or establish. The federal government expects state and local authorities to communicate with their citizens about when, where, and how they can receive necessary treatment. The federal government expects state and local authorities to ration scare medicines.[12] The federal government expects state and local authorities to develop plans for crowd control and security at medical treatment facilities and distribution centers, and to execute those plans in a crisis. The federal government expects state and local authorities to develop plans for "surge capacity" – that is, for the treatment of hundreds, thousands, or tens of thousands of people who may require medical attention and to execute those plans in a crisis. The federal government expects state and local authorities to work out appropriate operational, legal, and financial arrangements to support all these plans with private health-care and logistics providers.

12. On November 20, 2005, Secretary Leavitt even said on *Meet the Press* that, in the event of pandemic, the federal government will distribute its vital supplies of antiviral medicines and pre-pandemic vaccines – supplies which for the next few years will be insufficient for the entire U.S. population – to the states for further distribution to the citizens. This was also the approach employed by the Department of Health and Human Services during the unexpected shortfall of season influenza vaccine in 2004-2005 (see Monica Schoch-Spana, et al., "Influenza Vaccine Scarcity 2004-05: Implications for Biosecurity and Public Health Preparedness," *Biosecurity and Bioterrorism*, Vol 3, No. 3, 2005.

I am not sure that anyone in the country has an authoritative document that lays out all of these expectations. I do not think that any senior federal official has bluntly stated them in a public setting. In fact, I suspect that many responsible officials at the federal, state, and local level are not even aware that these are the expectations of state and local performance in the federal government's catastrophic disease response plans. I think that many people assume that, in the aftermath of a catastrophic disease outbreak, the federal government will come to the rescue of the affected communities, setting up its own treatment, isolation, and pharmaceutical or vaccine distribution system. This is not, so far as I am aware, the federal government's plan, and even if the federal government could perform this function (realistically, only the Department of Defense has capacity to perform such a task on a large scale, and even the Department of Defense could not undertake such an effort across the entire country), it would take weeks, if not months, to get up and running.

So far as I am aware, there is not a single state or city in the entire United States that is currently equipped to fulfill the federal government's expectations in the event of a catastrophic disease scenario.[13] The implications of this fact are deeply troubling.

This extraordinary national deficiency was first revealed during the first TOPOFF exercise in May 2000 at which I was an observer. It was revealed again during the May 2003 TOPOFF II exercise, in which I played a central role. And, in April 2005, it was revealed again in the TOPOFF III exercise at which I was again an observer. It has

13. This is despite the fact that the federal government has dispersed roughly $14.5 billion in biodefense spending through HHS between 2002 and 2005 (allocating about $5.5 billion to CDC specifically).

been revealed in a wide variety of smaller scale tabletop exercises and simulations. It has been candidly discussed at countless interagency meetings, some of which I participated in during my government service. The federal government, in other words, is fully on notice that a series of critical assumptions in its plans for responding to a major disease scenario – namely, those related to the effective and timely performance of a series of specific actions by state and local agencies and their associated private health-care and logistics providers – are incorrect. The implication is inescapable: the plans, if put to the severe test of a catastrophic disease scenario in the near future, will fail.

To deal with this problem, I believe that all federal homeland security assistance – that provided by DHS as well as HHS in the form of public health grants pursuant to Title I of the Bioterrorism Act of 2002 – should be made powerfully conditional. In particular, I believe that Congress should by statute give the President or his designee the authority and mandate to establish baseline requirements for state and local governments to conduct emergency medical operations and other essential homeland security functions. Every six months, Congress should require the secretaries of homeland security and health and human services to jointly certify to the President and the Congress that their requirements are or are not likely, with a high level of confidence, to be met by the state and local agencies in question. With respect to any state or local agency that the two secretaries certify as unlikely to fulfill their requirements in a crisis, the two secretaries shall be required to notify the President and the Congress of this fact. In addition, they should request that the Director of the Office of Management and

Budget freeze up to 100 percent of all federal grants, financial transfers, reimbursements, or in-kind assistance provided to the agencies in question indefinitely and until such time as the two secretaries determine the entity to be likely, with a high level of confidence, to be meet the appropriate requirements. At this time, the Director of the Office of Management and Budget will release the funds to the entity in question. Each freeze shall be individually reported to the Congress, which may at any time pass at Act requiring the release of the funds and resources in question.

The original public health-grant authorization in Title I, Section E, of the Bioterrorism Act of 2002 needs to be amend to impose some strong form of conditionality along the lines suggested here. Federal homeland security and public health grants should not be an entitlement but a part of a bargain that requires state and local agencies to fulfill their responsibilities under the Constitution, law, and national response plans.

IV. Federal Organization for Biodefense and Public Health Preparedness

During my service on the White House staff, I found biodefense and public health preparedness to be one of the most difficult areas in which to coordinate interagency policy and operations. The number of different departments, agencies, and offices within departments involved in biodefense and public health preparedness is astounding. The plain fact is that there is no executive branch official beneath the President is “in charge” of all relevant aspects of the federal government’s biodefense and public health preparedness program.

The President and most of the federal government look to the Department of Health and Human Services for intellectual leadership on biodefense and public health preparedness. But HHS is not a tightly integrated department and it pays attention only to certain aspects of the biodefense and public health preparedness challenge. Its three key agencies – CDC, NIAID, and FDA – are highly autonomous entities with their own appropriations and separate lines into the Congress and into the White House. These agencies possess deep subject matter expertise but, in my experience, have relatively limited interaction with other elements of the federal government and, at the working level, relatively little exposure to national security affairs. The Secretary of HHS has a very small staff, led by the Assistant Secretary for Public Health Emergency Preparedness established by Section 102 of the Bioterrorism Act of 2002, to advise and assist him on biodefense and public health preparedness, to run countermeasure procurement programs, and to manage the public health grants. I do not believe that the staffing and funding of this HHS staff element is commensurate with the expectations placed upon it.

The President's original legislative proposal for the Department of Homeland Security sought to give it a substantial role in biodefense and public health preparedness. This proposal was essentially rejected by the Congress, though the Homeland Security Act of 2002 did transfer a few biodefense-related assets and responsibilities to the new department. One of these was the Strategic National Stockpile, but this was transferred back to HHS in 2004 after much difficulty. Another was the Metropolitan

Medical Response System (MMRS), which oversees and helps support a variety of specialized medical response teams around the country. The MMRS is now located within FEMA; the advantages and disadvantages of this arrangement are not clear. DHS also runs the National Biodefense Analysis and Countermeasures Center at Fort Dietrich, Maryland. The most significant DHS responsibility for biodefense and public health preparedness relate to the Secretary of Homeland Security's role as the principal federal official in the management of all domestic incidents of national significance.

The Department of Defense also plays an important role in biodefense. There are three assistant secretary-level officials within the Office of the Secretary of Defense with significant biodefense responsibilities: the Assistant to the Secretary for Nuclear, Chemical, and Biological Defense Programs; the Assistant Secretary for Homeland Defense; and the Assistant Secretary for Health Affairs. There are countless research, development, and procurement programs in the Department of Defense related to biodefense, and the Northern Command engages in extensive planning and exercise related to domestic biodefense contingencies.

Most interagency policy and operational matters are managed out of the White House, mainly the biodefense directorate of the Homeland Security Council. Given the fragmentation of agency responsibilities, this White House staff function is indispensable.

Within this interagency setting, there are both substantially overlapping responsibilities and significant omissions. For instance, the Department of Homeland Security and the Department of Health and Human Services both make grants to state and local agencies to help improve their preparedness; there is little if any real coordination of these separately authorized, appropriated, and managed grant processes. HHS, DHS, and DOD all conduct research and development on a wide variety of biodefense technologies, with only the loosest coordination. Each of the three main departments tends to conduct exercises and develop plans in relative isolation from the others, leaving it to the White House staff to pull them together. A variety of different expectations and responsibilities apply to each of the three main departments in a crisis, which leads to both unnecessary duplication of some efforts and omission of others.

I have given a great deal of thought to how to improve the interagency coordination of biodefense policy and operations. It is tempting to simply declare one official to be "in charge." This, in my opinion, is unrealistic given the complex and interdisciplinary nature of the biodefense challenge and the distribution of statutory authorities and operational capabilities across multiple executive branch agencies and officers.

The only realistic option, in my judgment, is to strengthen to White House staff element in charge of interagency integration. Accordingly, I believe that the President should establish a Deputy National Security Advisor for Health Security, with appropriate support personnel, within the National Security Council staff, building on the existing biodefense directorate within the Homeland Security Council. I do not believe,

however, that this should be legislated as it pertains to the President's personal staff. At most, the reauthorization of Title I of the Bioterrorism Act of 2002 should offer a sense of the Congress that strong, continuous interagency leadership from the White House staff is essential given the statutorily grounded fragmentation of biodefense and public health preparedness across the executive branch.

I also believe that the Secretary of Health and Human Services requires a robust, large, and high qualified staff element to support him in discharging the extensive biodefense and public health preparedness responsibilities and to conduct intra-agency coordination and oversight. I do not have a precise number of the appropriate size of this staff, but I know it should be substantially larger than it is today. I further believe that it should be led by an Under Secretary, not an Assistant Secretary, and thus that Section 102 of the Bioterrorism Act of 2002 should be amended accordingly.

Conclusion

The Bioterrorism Act of 2002 has served the country well. It established the basic framework for the country's first serious effort to prepare itself for catastrophic disease contingencies. But, in the past four years, we have learned a great deal about this threat, as well as about how the department and agencies of the federal government are likely to respond to a catastrophic disease contingency. A great deal has been accomplished, but there is much more to do. In my opinion, our future efforts will be

even more successful and efficient if we modify certain core elements of our strategy for dealing with the catastrophic disease threat, as I have outlined in this testimony.

Thank you again for the privilege of appearing before you. I will try to answer any questions you may have.