Testimony
Committee on Homeland Security and Governmental Affairs
United States Senate

Safeguarding our Nation: HHS Readiness to Respond to a Biological or Other Emergency

Statement of
Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00am
Tuesday, October 18, 2011

Good morning Chairman Lieberman, Ranking Member Collins, and Members of the Committee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). Thank you for inviting me here today, on behalf of HHS, to testify on our nation's public health preparedness for a biological event.

Ten years ago, letters containing anthrax spores were mailed to several offices in Congress and the news media. While we were ill prepared at the time to face those attacks, we have made steady and significant progress over the past decade in our capabilities to prepare for and respond to such events. We have learned many lessons from subsequent events and continue to identify, improve and refine our capabilities. Thanks to investments made by Congress and the guidance that we continue to receive, we have made significant improvements in preparedness, response, and recovery at the federal, state, and local levels and have invested in a number of medical countermeasures to respond to a chemical, biological, radiological, or nuclear threat. State and local partners are more prepared than ever before, due to enhanced response capabilities, improved coordination, and enhanced awareness among the public health and medical communities. We have new legal and policy tools including statutes that created the Office of the ASPR to oversee a national program, and programs elsewhere that bolstered our nation's defenses against a chemical, biological, radiological, or nuclear (CBRN) event.

One of the biggest challenges we have encountered in the last decade is the lack of common national approaches and effective coordination among governments, health and response systems, and communities. The September 11, 2001 attacks in New York, Pennsylvania, and Washington D.C., and Hurricane Katrina offer particularly poignant examples of challenges and the imperative to improve. While there is still a lot of work ahead of us, we have made great strides in developing a unified national direction in strategy, policy, planning, and operations. Today, we have the National Response Framework and the National Recovery Framework to guide collective efforts to respond to and recover from disasters and emergencies, from the smallest incident to the largest catastrophe. In 2009, HHS released the National Health Security Strategy (NHSS), which refocuses the patchwork of disparate public health and medical preparedness, response, and recovery strategies to ensure that the nation is prepared for, protected from, and resilient in the face of health threats. The NHSS is the first strategy focused specifically on protecting people's health during an emergency, and has a vision built on resilient communities and strong, sustainable health and emergency response systems.

Our resilience depends on shared responsibility for preparedness across governments – from local communities to global partners, and includes all members of the public as full and equal partners in health security. Looking back, I'm encouraged by how far we have come and by how we are working together now in planning for the future. Challenges do however remain. The

threats to national security and public health are real and are constantly evolving. As science and technology create new opportunities for useful advances, they may also lead to new threats. As I testify today on our readiness, I will address both specific progress we've made over the past decade and the strategies we have in place to ensure that we continue to improve in advancing toward our goals.

In 2001, the use of anthrax spores in a biological attack killed five people, infected 17 others, threatened thousands more, and resulted in billions of dollars in costs—forcing us to re-think our approaches to preparedness for the CBRN threats that we face. Collectively, we recognized that we lacked basic capabilities and that a long-term concerted effort would be required to close the preparedness gap. Since that time we have also learned that investment alone is not enough—and in response we have established a common set of investment priorities and have fundamentally changed the way we manage our medical countermeasure enterprise. As Secretary Sebelius noted in 2010, "our nation must have the nimble, flexible capability to produce medical countermeasures rapidly in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional."

The nation owes a debt to the Congress in this context for providing critical authorities and appropriating billions of dollars for development and procurement of CBRN medical countermeasures that have been turned into real products by

the combined efforts of the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). This includes an unprecedented investment in pandemic influenza preparedness—what we often think of as a model approach in addressing a threat. I can say with certainty that we are now more prepared for the range of CBRN threats and other emerging infectious diseases, such as pandemic influenza, than at any point in our nation's history. For example, while prior to 2005 the country had lost its capability to domestically manufacture vaccines for the threat posed by a novel avian influenza, we have reversed the trend and are on the verge of having a fully approved manufacturing capability in partnership with Novartis for not just a brand new domestic manufacturing plant, but a completely novel and agile manufacturing process for this vaccine. Thanks to the foresight of Congress, the Project BioShield program, and the Public Health and Emergency Medical Countermeasures Enterprise (PHEMCE), we have products in the Strategic National Stockpile (SNS) for smallpox, anthrax, botulism, and radiological and nuclear threats. And, as we crossed the "valley of death" in advanced development, we have had substantial success with the medical countermeasure pipeline – including over 80 candidate products that if successful have the potential to transition to procurement contracts and inclusion in the SNS including. These include an entirely new class of antibiotics; anthrax vaccine and antitoxins; smallpox vaccine and antivirals; radiological and nuclear countermeasures including hematopoietic, radionuclide, pulmonary, cutaneous,

and gastrointestinal candidates; pandemic influenza countermeasures; and the first set of chemical antidotes. Furthermore, in demonstration of our end-to-end approach to development, we have successfully moved a product through all phases of the medical countermeasure pipeline—from discovery to procurement—and have begun manufacturing a new smallpox vaccine (Modified Vaccinia Ankara). We also developed and produced 186 million doses of 2009 H1N1 vaccine in record time for use in the U.S. and for international donation. However, there remain both complex scientific, financial, and marketplace challenges. In recognition of the need to do better, in December 2009, Secretary Sebelius requested a review of the medical countermeasures enterprise to ensure the nation has a forward-looking, 21st-century enterprise system upon which it can rely during an emergency or other public health event. In August 2010, HHS released the Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to meet Long-Range National Needs (MCM Review). The MCM Review focuses on "processes, policies, and infrastructure required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." Specifically, this review examined the steps involved and made recommendations regarding the research, development, and regulatory approval of medications, vaccines, and medical equipment and supplies for a public health emergency. As detailed in the 2011 Bipartisan WMD Terrorism Research Center's Bio-Response Report Card (WMD Report Card), medical countermeasure development and

procurement faces significant challenges due to the issues related to coordination of budget requests across our multiple agencies and availability of "sufficient, sustained funding." One recommendation included in the MCM Review was implementation of an integrated approach across the Department for investments in research, development, and procurement of medical countermeasures. FDA, NIH, ASPR, and CDC are currently working on a consolidated 5-year investment plan for such investments which will focus on many of the coordination issues regarding budget requests.

It is important to note that we are also working collaboratively with our interagency partners at the Department of Defense (DoD) to ensure appropriate synergy in our medical countermeasure activities and to avoid costly duplication of efforts, where possible.

The WMD Report Card also mentions HHS' efforts to build an advanced development and manufacturing facility to increase the national capacity for rapid manufacturing of pandemic influenza vaccines and other products during an emergency. I am pleased to inform you that HHS has contracts with multiple manufacturers to produce influenza vaccine annually. We have also entered into a contract supporting a cell-based approach to developing vaccine and have retrofitted other facilities to enhance domestic influenza vaccine manufacturing capacity.

Critical to our continued success is active and thoughtful partnership with the private sector. As you know, the federal government is often the only purchaser of essential preparedness products. In 2001, only a small sector of entrepreneurial companies ventured into the development and manufacturing of needed CBRN medical countermeasures. That remains true today. In response, the MCM Review includes two new initiatives. First, the Strategic investor (SI) is designed to support promising start-up companies with a full suite of testing, evaluation, product development, and manufacturing services, and the other is designed to provide meaningful financial incentives and rewards to private sector partners who succeed in developing the medical countermeasures we need. The Strategic Investor program is requested in the President's Budget, and we are working closely with the Congress to establish it in the reauthorization of the Pandemic and All-Hazards Preparedness Act. In addition, we have moved forward on the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program and we look to make awards early in 2012. Both programs offer an opportunity to leverage limited federal resources and incentivize new participation in this business sector, as well as look toward a process that can help this sector realize sustainability by creating products using platforms that can be applied to commercial and government needs. In addition, in 2008, we reviewed internal contracting processes and reorganized the line of reporting to reflect a more appropriate and efficient organizational structure consistent with comparable business models in the U.S. government. We established targets and timelines for contracting processes and aligned them

with a set of triggers. These actions and our close coordination with stakeholders helps to ensure that contract terms are clarified and requirements are better understood from the start. We are also using Broad Agency Announcements (BAA) to support investments in research and development of medical countermeasures. These BAAs have expedited review of proposals and contract awards immensely.

We know that leveraging our existing regulatory and scientific capabilities will ultimately lead to a more robust pipeline of products. The MCM Review prioritizes the translation of medical countermeasures concepts and research as well as enhances regulatory innovation, science, and capacity. Specifically, we need to ensure that the discoveries NIH supports through its investments in basic science are cultivated and available to be turned into products whose potential utility we may not yet appreciate. In addition, targeted investment is needed for regulatory science at FDA in order to increase their capability to respond to new technologies for which they are mandated to regulate, and to help them provide greater clarity to sponsors and manufacturers about the pathways to product approval.

In addition to these new tools and approaches, we established an enterprise-wide approach to management of the MCM portfolio. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) serves as the

overarching interagency convening body to coordinate the multiple efforts and programs that enable the nation to have the medical countermeasures needed to respond to CBRN and other emerging infectious disease threats. ASPR leads the PHEMCE, which brings together three primary HHS agencies—NIH, CDC, and FDA—along with four key interagency partners—Department of Homeland Security (DHS), DoD, Department of Veterans Affairs (VA), and Department of Agriculture (USDA). Working together, full-time, as an enterprise, these agencies and organizations are coordinating, exchanging information, and learning from each other daily to optimize preparedness and response for public health emergencies in connection with the creation, stockpiling and use of medical countermeasures. As a result of the 2010 MCM Review and based on development and procurement accomplishments, PHEMCE partners are now working to release an updated Public Health and Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats, expected in 2012. The current plan was developed in 2007 and has served as a playbook to guide research and procurement. The updated plan will continue to guide and coordinate investments across the spectrum of research, development, and procurement.

Beyond the realm of medical countermeasure development and procurement, HHS has a critical role in response operations. Since the tragic events of September 11, 2001, we have experienced a number of incidents impacting public health that have required a coordinated response to save lives. These

events—from hurricanes to emerging infectious diseases—each presented unique challenges. We have successfully captured the lessons learned from each operation and incorporated the concepts into subsequent planning and response operations. There continue to be a number of challenges, including reductions in state and local public health and medical resources and a continued need to more effectively coordinate with federal, state, local, tribal, non-profit, and private partners. In addition, we have recognized that new approaches are needed. These approaches must increase our focus on an all-hazards approach; improve our planning to ensure that funding is available when it is needed in an emergency; include conversations with the response community about crisis standards of care; and incorporate at-risk populations and behavioral health considerations into all aspects of our response planning.

Recently, we have seen tangible evidence of the value of our efforts and investments at the federal, state, and local level. The federal response enterprise is greatly strengthened, as evidenced by a robust National Disaster Medical System, expanded surveillance capabilities and deployable public health teams, and a Strategic National Stockpile with $4.4 billion worth of medical countermeasures at its disposal. Since 2001, HHS has expanded the Secretary's Operation Center (SOC) to ensure all public health and medical communications are coordinated and communicated to all stakeholders before, during, and after a public health incident. We are harnessing technologies to aid in response efforts, using electronic medical records to match demand with need,

geographic information systems to identify demographic characteristics of affected populations and available resources, and social media to communicate with new audiences and gain information on developing health trends.

Beyond these new technologies, there have been great improvements at the state and local levels including investments in hospital and community preparedness, establishing response plans for all-hazards, and conducting no-notice drills to test capabilities. A number of recent natural disasters were adequately managed at state and local levels; 10 years ago I am not confident this would have been the case. These incidents include the flooding in the Red River Valley and the tornadoes that touched down in Alabama and Missouri. In each incident, states were better able to respond and required little or no federal support. For example, Missouri purchased a mobile medical unit just before St. John's Regional Medical Center was destroyed by a tornado in May 2011. This mobile medical unit is still in use today providing the residents of Joplin essential medical care. However, this does not mean we can 'check the box' on adequate state and local response capability. The financial realities we all face challenge our public health and medical infrastructure and will further widen gaps in our laboratories, emergency rooms and public health departments. Two critical tools available to support investments in preparedness are the Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) cooperative agreement programs. HPP and PHEP support efforts at state and local public health and medical facilities to ensure that communities are prepared to respond

to public health emergencies. With HPP grants, we have made great strides in the ability of the predominantly private sector health care system to surge to provide medical care to large numbers of patients. In fact, more than 76 percent of hospitals participating in the HPP met 90 percent or more of all program measures for all-hazards preparedness in 2009. This is a significant accomplishment and clearly demonstrates participants' commitment to investing in preparedness. PHEP funding has fostered an increased level of preparedness throughout communities and contributed to state and local governments' decreased reliance on federal aid following disasters. We have made impressive strides as a nation in our state and local public health capabilities. There was a time in the not too distant past when getting internet access for a local health department was a challenge; the concept of sending blast fax communications was seen as a progressive and novel idea.

While we have made great strides in preparing state and local communities and public and private healthcare facilities, without continued support and funding for our public health and medical system, the infrastructure could begin to degrade and health outcomes may be affected. We are already witnessing a decline in the public health workforce as a result of fiscal constraints. As state and local capacity diminishes, we could see an increase in the call for federal assistance in response to disasters. This could result in longer recovery periods, higher response costs, and greater potential for loss of life.

As you know, I joined ASPR in 2009 and was immediately faced with a global public health emergency—a novel pandemic influenza virus. Due to the foresight and planning of the federal government and the Congress, we had developed an unprecedented level of preparedness for this emergency. At that time, we were three years into a five-year pandemic influenza plan and had allocated significant time, energy, funding, and resources in order to diversify domestic vaccine production and surge capacity; advance development of influenza vaccines manufactured in cell culture, antigen-sparing adjuvants, new antiviral drugs, and point-of-care clinical diagnostics; stockpile medical supplies and ventilators; and expand international surveillance, research, and scientific collaborations. In addition, we had successfully strengthened our national laboratory capacity to provide enhanced epidemiologic support quickly to detect emerging public health incidents. These are clear examples of prior investments paying off during real world events.

In each of our response efforts – from hurricanes and floods to earthquakes and infectious diseases – we have witnessed the importance of all-hazard planning. Since we are limited in our ability to forecast new and emerging threats, we are modifying response plans to ensure they are nimble, flexible, and adaptable to new challenges. All response operations require the commitment of resources as soon as possible to save lives. In today's budget environment, it is important to ensure resources are available to support a response as soon as a need arises. If we were to face another emerging infectious disease event similar to

the H1N1 pandemic, it is important to be able to quickly obligate funds to contracts to ensure adequate manufacturing of vaccine and antivirals to treat the population and limit spread. We are promoting a culture of budget preparedness across the federal, state, local and private sectors to ensure we are able to quickly and efficiently get resources where they are needed for the earliest critical response to a disaster.

We have always known that faster responses lead to better health outcomes. After our response to the Haiti earthquake we implemented actions to: streamline internal operations to ensure providers are adequately supported; provide needed services quickly and efficiently following disasters; and, ensure we have access to information that supports surveillance of the spread of illness. We have moved forward to improve the timeliness of information gathering and sharing, deployment times and distribution of countermeasures and other equipment and materiel. More recently, however, we have initiated systems to improve our responses before they even occur. In just this past year, FDA issued an emergency use authorization permitting pre- and post-event preparedness activities for mass distribution and dispensing of doxycycline in the event of an anthrax attack. This action will reduce the time it takes to provide a life-saving medical countermeasure to the end user in the event of an attack. We have also worked to strengthen the National Disaster Medical System (NDMS). NDMS is a federally coordinated system that augments the Nation's medical response capability. NDMS utilizes an Electronic Medical Record (EMR) system

that is able to standardized record keeping and promotes enhanced health surveillance during disasters. We are able to use the EMR system to better identify population needs, specifically in the area of pediatrics. The ability to identify the needs of the population, specifically the pediatric and at-risk population, will support a better and more focused response in the future.

It is critical that we include at-risk populations in all planning models and during the development and procurement of medical countermeasures. HHS has taken steps to ensure that at-risk individuals—children, pregnant women, senior citizens and other individuals who have special needs—are included in all planning scenarios, guidance documents, plans, and will be effectively treated in the event of a public health emergency. During the 2009 H1N1 pandemic, surveillance identified distinctly different risk groups—especially children and pregnant women—who quickly became, and remained, priority subgroups for prevention and mitigation measures, including vaccination and school closures. Identifying and monitoring this population was important in reducing the spread of illness. Finally, we include provisions for pediatric studies in every Project BioShield contract to support eventual licensure of products for this population.

So far I have addressed how we have improved and continue to improve enterprise management of our medical countermeasures and response efforts. As we move forward in those areas, we also need to be thinking about the foundations in thought that underpin all of our planning across preparedness,

response, and recovery—how to foster needed scientific research and build the evidence base for everything we do. One of the biggest challenges in preparedness and response has been the lack of a strong knowledge base to support decision-making, inform the public, and allow for rigorous assessments and continuous improvement in progressing toward our goals. One compelling example is from the 2010 Gulf oil spill. One of the public's primary concerns during this incident was, understandably, whether oil and dispersants would negatively affect their health and the health of their families and loved ones. We did not have adequate science or the best mechanisms in place to collect data during the response. Taking this as an important lesson learned, we have made significant progress. The NIH National Institute of Environmental and Health Sciences (NIEHS) has established studies and a research consortium with partners to address different health aspects of the oil spill and impacts on the affected communities, including looking at workers' exposure to oil and dispersants. HHS is also participating in a group of 17 federal agencies led by NOAA to create a single shared data repository and virtual workspace for federal agencies and the larger research community to access health data collected during the oil spill. The spill also offered an important reminder that nearly every emergency or disaster has a health impact or a need to communicate with affected communities about health concerns. Therefore, we are working to ensure that HHS and our partners are appropriately involved at the early stages of any national response.

As I conclude, it is important to recognize that despite the deaths of Osama bin Laden and Anwar Al-Awlaki, threats to the nation—and specifically to our public health—will continue. There continues to be real threats from the deliberate use of chemical, biological, radiological, or nuclear agents by hostile states or terrorists. In addition, the threat of natural disasters and emerging infectious diseases with the potential to cause widespread illness will always remain. We are actively working to improve based on the number of challenges and events we have faced. Looking forward, there are also improvements for which we need your support. I applaud Congress' wisdom in enacting the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006 that authorized my office and provided us needed authorities to enhance efforts to prepare for and respond to public health and medical incidents. As you work to reauthorize PAHPA, I encourage you to consider provisions that support getting the right resources, whether countermeasures or healthcare professionals, to where they are needed in an emergency; ensure adequate medical countermeasures are available for dispensing as soon as possible following the start of a public health incident; establish more efficient reimbursement for our partners following public health incidents; and reauthorize critical expiring authorities. We must continue investing in development of medical countermeasures, novel approaches to response operations, and our public health infrastructure. The reauthorization of PAHPA supports our work and will ensure we continue to have the tools necessary to respond.

Ultimately, all of our investments and efforts come down to the same goals – building a resilient nation and saving lives when disaster does occur. We have made great strides toward building a robust enterprise to quickly get medical countermeasures to people who need them, incorporating the clinical community into national preparedness systems and preparing clinicians to treat patients affected by emergencies, and collaborating with state and local partners to develop, exercise, and improve their response capabilities. I look forward to working with you to ensure that this progress and our strategies for the future continue to prepare the nation and save lives. Thank you for the opportunity to testify before you today. I am happy to answer any questions you may have at this time.