



**Testimony  
Subcommittee on Health  
Committee on Energy and Commerce  
United States House of Representatives**

***Bioterrorism, Controlled Substances and  
Public Health Issues***

*Statement of*

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Good morning Chairman Pitts, Ranking Member Pallone, and distinguished Members of the Subcommittee. I am pleased to be here today on behalf of the U.S Department of Health and Human Services (HHS) to testify on reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA; the Act). My name is Nicole Lurie and I serve as the HHS Assistant Secretary for Preparedness and Response. Today, I will discuss how critically important PAHPA is to our public health preparedness and the progress we have made since its enactment in 2006.

First, I would like to recognize the Congress, and especially the Energy and Commerce Committee, for its strong leadership in advancing the public health and preparedness of our Nation. PAHPA has supported our efforts to foster stronger, more resilient communities that are able to respond to, and recover from, public health emergencies. PAHPA established the foundation for a comprehensive preparedness for and response to emergencies. HHS has since built on these authorities to ensure the nation has the tools necessary to save lives.

### **The Pandemic and All-Hazards Preparedness Act Established a Formalized Approach to Public Health Preparedness**

PAHPA strengthened our country's foundation for public health preparedness by helping us address a variety of problems our nation encountered when preparing for, and responding to, disasters. As we have seen from recent emergencies

and disasters – including tornados, floods, an influenza pandemic, earthquakes, damage to a nuclear facility and a large oil spill – there is always an impact to the public’s health and medical care.

The Pandemic and All-Hazards Preparedness Act has been instrumental in supporting State and local preparedness and response efforts. Since the passage of the Act, HHS has implemented a number of initiatives to strengthen its preparedness and response activities.

The Pandemic and All-Hazards Preparedness Act designated the HHS Secretary as the lead federal official for public health and medical response to emergencies and incidents, and established my office, the Office of the Assistant Secretary for Preparedness and Response (ASPR). Under the Act, ASPR serves as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response and plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

Guided by the authorities in PAHPA, HHS established organizational priorities and enhanced its operations and response capabilities. Moreover, to carry out PAHPA authorities, ASPR’s mission was defined as leading the country in preparing for, responding to, and recovering from health effects of emergencies and disasters by supporting each community’s abilities to withstand adversity, to

strengthen our health and response systems, and to enhance national health security. The future of national public health and medical preparedness and response is a “whole community” approach. We work to build practices nationally that strengthen preparedness efforts implemented by local institutions including state and local government and private sector partners. We strive to create a fundamental body of knowledge for preparedness, response, and recovery and to encourage innovative efforts to build the nation’s capacity to stabilize and recover from an event. We are also working to ensure that our public and private sector partners are promoting a culture of budget preparedness to quickly and efficiently get resources where they are needed for the earliest, critical response to a disaster, and then for the longer recovery period.

### **The National Health Security Strategy Established a Common Strategic Framework to Align National Preparedness Efforts**

Since the enactment of PAHPA in 2006, HHS has had many significant accomplishments preparing for, and responding to, public health incidents. To help better align efforts internally; support and promote coordination efforts with federal, state, local, and private sector partners; and be efficient stewards of federal dollars, we released the National Health Security Strategy (NHSS) in December 2009 – a blueprint for preparedness and response. PAHPA required the completion of a NHSS as a first step in ensuring we have a fully integrated and coordinated strategy to address how various sectors of our medical and

public health systems will work together to respond to emergencies and save lives.

The principle at the heart of the strategy is to strengthen and promote resilient communities and health systems that coordinate and work together before, during, and after disasters. National health security is a shared responsibility – from individuals and families, to private industry, to every level of government. The NHSS also promotes building more resilient communities by including at-risk populations in planning all phases of our response. Supporting this strategy, HHS has taken steps to ensure that at-risk individuals – children, pregnant women, senior citizens, individuals with disabilities, and others who have access and functional needs – are included in all planning scenarios, guidance documents, and plans, and will be effectively treated in the event of a public health emergency. HHS also continues to focus on behavioral health as an integral part of building community resilience and enhancing response and recovery.

As required by PAHPA, the NHSS must be delivered to Congress every four years beginning in 2009. This schedule poses a challenge because it is not aligned with the schedule for agency strategic plans as established by the Government Performance and Results Act Modernization Act of 2010 (“GPRA Modernization Act of 2010,” P.L. 111-352). The next iteration of the agency strategic plan is due in 2014, while the NHSS plan is due in 2013.

Recognizing that we have learned a great deal about strategic planning processes in the past four years, we are interested in enhancing operational and long-term planning efforts while also streamlining requirements. In support of the principles of the NHSS, state and local jurisdictions have operational plans that describe operations during incidents caused by pandemic influenza or incidents from another hazard. The influenza plans – required by PAHPA – include a framework that guides communications and logistics, and coordinates general response efforts during pandemic influenza incidents. These pandemic plans have become part of a broader, all-hazards planning framework, with a required set of capabilities necessary to deal with many potential hazards, from a pandemic to an anthrax attack or a dirty bomb. At the time PAHPA was enacted, these plans were a relatively new concept – the original provision was to ensure that plans enhanced preparedness efforts for influenza. The focus on an all-hazards approach toward response capabilities enabled the development of stronger and more flexible plans. In addition, our experience has shown that a biennial reporting process generally is efficient and provides us an opportunity to integrate lessons from state and local plans from the prior year.

### **The Medical Countermeasure Review Established the Strategic and Operational Plan for HHS Countermeasure Preparedness**

To ensure the nation has adequate countermeasures available to respond quickly and efficiently following a chemical, biological, radiological, nuclear (CBRN), or other public health emergency, HHS released the Public Health

Emergency Medical Countermeasures Enterprise Review (MCM Review) in August 2010. This review articulated a vision for a nimble, flexible infrastructure to produce MCMs rapidly in the face of any attack or threat including a novel, previously unrecognized naturally occurring emerging infectious disease. The MCM Review took a ‘systems approach’ to MCM development. The Review identified “processes, policies, and activities required to conceptualize a product derived from a national requirement and take it through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling.” This ground-breaking review looked across the entire spectrum of product development, from early discovery through regulatory approval, and identified the chokepoints where product development was stalling or failing. Chokepoints create technical, business, and regulatory risks for small innovator companies that may lead to the failure of a product due to a funding shortage between the early stages of product development and the procurement of medical countermeasures. To address these chokepoints, the MCM Review recommended a set of interconnected strategies to further MCM development:

- The establishment of a Concept Acceleration Program at the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researcher, biotechnology companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products;

- The establishment of a private, not-for-profit corporation (Strategic Investor) that would rely on a variety of “venture-enabled” approaches to spur innovation and create a viable biodefense business sector by supporting companies that possess strategic technologies applicable to both commercial and government needs, but which might otherwise lack the necessary financial capital or business acumen to develop a commercially-viable, approved product;
- The establishment of U.S.-based Centers for Innovation in Advanced Development and Manufacturing; and
- An increased investment in regulatory sciences and review capabilities at the Food and Drug Administration (FDA) focused on medical countermeasures (MCMs) for chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats, such as pandemic influenza.

The Concept Acceleration Program (CAP) will leverage existing intramural and extramural research programs as well as applied and translational resources throughout the NIH, Centers for Disease Control and Prevention (CDC), FDA, and Department of Defense (DoD) to expedite the translation of promising concepts into candidate MCMs. We are committed to applying \$50M towards

CAP activities in FY11. Evaluations are in progress to identify CAP product candidates.

The Strategic Investor would spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, while mitigating the risk that biotechnology firms face. The Strategic Investor initiative would promote the transition of MCM development and procurement from a “one bug, one drug” approach to an enterprise capable of responding to any threat at any time. It is important to note that the Strategic Investor initiative is intended to work in concert with the BioShield program, not replace it.

In March, we published a request for proposals for the Centers for Innovation in Advanced Development and Manufacturing, which we will create to reduce risk, increase domestic manufacturing and surge capacity for MCM, and reduce total life-cycle costs through flexible manufacturing. These U.S.-based Centers are expected primarily to provide, on a routine basis, core services to commercial partners who collaborate with HHS’s Biomedical Advanced Research and Development Authority (BARDA). These services include advanced development and manufacturing capabilities and other technical services needed by the developers of medical countermeasures for MCMs to address national preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to manufacture influenza vaccine and other

biologics, as well as provide training opportunities for the pharmaceutical workforce.

Finally, advancing regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will help to accelerate MCM development and availability. Regulatory uncertainty is a major barrier to engaging MCM developers in the MCM Enterprise. FDA is addressing these challenges through its Medical Countermeasures Initiative (MCMi), which will promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures. The MCMi will also facilitate the timely access to medical countermeasures by establishing effective regulatory policies and mechanisms. The MCMi is designed to address key challenges in three areas: (1) enhancing the regulatory review process for the highest priority medical countermeasures and related technologies; (2) advancing regulatory science for medical countermeasure development; and (3) modernizing the regulatory and legal framework.

Flexibility can help address and help to solve unique scientific challenges posed by some MCMs. FDA benefits from flexibility to address the unique scientific challenges posed by MCM development, distribution, and use. FDA needs adequate time to receive and carefully consider input from stakeholders, including MCM sponsors, or conflict with the Medical Device User Fee and

Modernization Act/Prescription Drug User Fee Act obligations. We would be happy to discuss this further with you and your colleagues on the Committee.

HHS also prioritizes an enhanced approval and authorization process for stockpiled medical countermeasures to ensure products are dispensed as soon as possible following an event. One specific challenge is that the legal implications for using medical countermeasures whose expiration date has been extended under FDA's Shelf Life Extension Program (SLEP) is unclear. Another challenge is the inflexibility of issuing Emergency Use Authorization (EUA) of medical countermeasures prior to a CBRN event. Issuance of EUAs prior to an event could facilitate the prepositioning of products, minimizing delay in dispensing needed products if an event does occur. In addition, there is a lack of clarity that certain actions taken in preparing for or during an emergency will not violate the Federal Food, Drug, and Cosmetic Act (FDCA), including greater flexibility to mass dispense MCMs with instructions for emergency use. Clarifications on these issues could help ensure adequate medical countermeasures are available for dispensing as soon as possible, following the start of a public health incident.

### **PAHPA Helped Spur Development and Procurement of Medical Countermeasures**

The SRF is a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close

to, or have achieved, licensure. The SRF, as industry partners and other non-governmental stakeholders have continually asserted, is a market guarantee for medical countermeasure development and clearly demonstrates the U.S. Government's commitment to the procurement of security countermeasures. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the emergency use of unapproved products or the unapproved use of approved products, if certain standards are met.

Since its inception, we have drawn steadily on the use of Special Reserve Funds and have developed and procured:

- Anthrax therapeutics and vaccines;
- Heptavalent botulinum antitoxin;
- Smallpox vaccine for immunocompromised persons;
- Smallpox antiviral drug; and
- A number of MCM products intended for use after radiological or nuclear events.

Using its Advanced Research and Development (ARD) authority, HHS, through BARDA, bridges the “valley of death” – funding a gap that exists between the early stages of product development and the procurement of medical countermeasures under Project BioShield. Current priority investment areas include anthrax vaccines and treatments, broad-spectrum antimicrobial drugs, and treatments and diagnostics for illnesses associated with exposure to

radiation. In FY 2012, the President's Budget requests \$765M from Project BioShield balances to support these priorities.

Our ARD activities, combined with changes we have made since the MCM review, are beginning to bear fruit. We have seen a continued growth in interest in companies partnering with BARDA, and now have over 70 products in some stage of development. We have also implemented changes to our own business processes, and have succeeded in reducing our average contracting time. From 2009 to 2010, we reduced the average contracting time from 6.46 to 4.7 months. The SRF has succeeded—and remains important—in attracting biotechnology firms to develop needed medical countermeasures, but these firms have required substantial additional support for advanced research and development.

While the imminent threat of H1N1 influenza has subsided, avian influenza viruses continue to circulate, and critical work continues to prepare for the next influenza pandemic. One of the functions of the Centers for Innovation in Advanced Development and Manufacturing mentioned earlier, in addition to providing development and manufacturing of medical countermeasures to CBRN threats, will be to expand domestic pandemic influenza vaccine manufacturing surge capacity. HHS continues to develop flu antiviral drugs and vaccines and a more robust domestic vaccine manufacturing capability. We are focused on ensuring the nation has access to a safe and effective vaccine as soon as possible following the start of an influenza pandemic. We continue to implement

strategies for producing influenza vaccine more rapidly during an influenza pandemic, including the development and implementation of more rapid testing methods for vaccine release and the establishment of domestic recombinant and cell-based vaccine manufacturing capabilities. Supporting this effort, shortening the time frame for vaccine availability with new and faster product testing and next generation influenza vaccines made in the U.S. will achieve better products faster. I am pleased to inform you that we are already making great progress in these efforts.

### **HHS Has Significant Accomplishments since the Enactment of PAHPA**

We have accomplished much since the passage of PAHPA and were able to respond to a number of public health emergencies including:

- The first pandemic in 40 years;
- An earthquake in the western hemisphere's poorest country;
- An oil spill of national significance in the Gulf of Mexico;
- The 2011 Japan earthquake, tsunami, and associated radiological contamination event; and
- Other domestic events including food-borne outbreaks, E. coli, botulism, salmonella, hurricanes, floods, tornadoes, Avian influenza, West Nile virus, and ricin.

In addition, as I mentioned previously in my testimony, we were also successful in procuring and stockpiling medical countermeasures to protect against CBRN

threats, as well as against pandemic influenza and other emerging infectious diseases. All of the accomplishments were supported through the close collaboration of many at HHS including CDC, NIH, FDA, ASPR as well as the Centers for Medicare and Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of the Assistant Secretary for Health (OASH), and the Indian Health Service (IHS), just to name a few.

Since I was sworn in as the Assistant Secretary for Preparedness and Response, one thing has been clear - the investments we've made in the last decade have had a positive effect on our ability to respond to health effects of emergencies. In each response, HHS provided support to state, local, or international partners and in return learned valuable lessons to guide future response operations. We are working internally to strengthen and incorporate the lessons learned from these and other recent responses to ensure future response efforts are enhanced.

The earthquake in Japan and subsequent nuclear reactor crisis is an example of a catastrophic scenario that would present formidable public health and healthcare challenges to the U.S. should such an event occur here. We already knew the importance of deploying medical countermeasures as quickly as possible following an incident. However, as a result of this crisis, we are reexamining our policies, plans, and procedures to ensure that we can use and

deploy countermeasures as soon as possible following the start of a public health incident to help reduce morbidity and mortality.

Beyond medical countermeasures, many lessons learned during our 2009 H1N1 pandemic response will strengthen HHS's ability to respond to other emergency events. The 2009 H1N1 experience stressed the interdependence of the public health, pre- and post-hospital care, primary care, hospital care systems and community, education, and business organizations. It also confirmed the need for a "whole community" approach in planning and responding to a disaster, and confirmed that, going forward, we must address the entire healthcare community in our preparedness activities. Specifically during the 2009 H1N1 response, some state and local jurisdictions faced significant staff shortages as they dispensed vaccine to the general population. HHS is examining ways such staffing shortages could be limited and response could be enhanced.

Finally, after our response to the Haiti earthquake, we have taken actions to provide needed services quickly and efficiently following disasters and ensure we have access to information that supports surveillance of the spread of illness. I am pleased to inform you that we have been working to strengthen the National Disaster Medical System (NDMS). NDMS is a Federally-coordinated system closely linked to the Hospital Preparedness Cooperative Agreement program that augments the Nation's medical response capability. The primary purpose of the NDMS is to supplement an integrated National medical response capability for

assisting State and local authorities in dealing with the medical impacts of major peacetime disasters. One major element of this capability is the Definitive Care program which reimburses participating hospitals for medical services provided during emergencies. Currently, the process for making payments to these providers has resulted in some delays in payments. We are exploring ways in which this process can be improved, expediting reimbursement to these state and local providers. Supporting enhanced surveillance efforts, NDMS now uses an Electronic Medical Record (EMR) system that standardizes record keeping and promotes enhanced health surveillance during disasters. These and other enhancements we have made, enable us to better identify population needs as we respond, including in the area of pediatrics. These developments in identifying the needs of populations, specifically pediatric and at-risk populations, will support a better and more focused response in the future.

HHS has a number of programs and tools that aid state and local response and coordinate efforts during disasters. The ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including through planning for all-hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. We recently issued a report on the Hospital Preparedness Program that describes the achievements of our state partners in building healthcare preparedness across the nation, and illustrates how states

have used the capabilities developed and funded through the program in both large and small incidents. One specific accomplishment detailed in this report is that 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.

In addition to HPP, CDC's Public Health Emergency Preparedness (PHEP) cooperative agreements provide funding to enable state and local public health departments to have the capacities and capabilities to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. The PHEP program, which includes the Cities Readiness Initiative (CRI), has made great strides in just a few short years, building and sustaining preparedness and response capabilities, along with enhancing state/local public health infrastructure, which supports these preparedness and response capabilities. In fact, we've seen a lot of tangible evidence of program successes—we've heard from a number of states that they've been able to handle the health effects of events, including food-borne outbreaks, influenza, infectious diseases, as well as floods and tornados, without federal assistance as a result of investments and training made through the HPP and PHEP. To promote coordination and efficient use of resources, you may be pleased to learn that ASPR is leading an interagency effort to better align the

HPP and PHEP grant programs to ensure we are efficient with resources and that we eliminate duplicative or conflicting programmatic and administrative efforts for grantees. The core interagency partners critical to the success of this endeavor are ASPR, CDC, the Federal Emergency Management Agency (FEMA) and the Department of Transportation's (DoT's) National Highway Traffic Safety Administration (NHTSA). By streamlining grant mechanisms and maximizing the efficiency of grant management processes, we expect to improve preparedness outcomes and allow for more effective public health and medical care for State and local communities.

In addition, consistent with Presidential Policy Directive 8, we are working toward a framework for priority-setting, review, and reporting measures; development of a common pathway to focus dollars, measure outcomes, reduce duplication, and enhance return on investment and reporting; and enhanced data sharing for improved situational awareness during a response.

### **Other Important PAHPA Provisions**

PAHPA authorized a number of other programs that are set to expire at the end of 2011 include the following: Freedom of Information Act (FOIA) exemptions and Limited Antitrust exemptions; and authorization of appropriations for the Public Health Emergency Preparedness (PHEP), Hospital Preparedness Program

(HPP), the Medical Reserve Corps (MRC), the National Disaster Medical System (NDMS), and the Emergency System for the Advanced Registration of Volunteer Healthcare Personnel (ESAR-VHP).

BARDA, PHEP, HPP, MRC, NDMS, and ESAR-VHP are PAHPA programs that not only work well but also support resilient communities that are better prepared to respond to emergencies and other public health events. PAHPA's FOIA and Antitrust exemptions help ensure the HHS Secretary is able to continue to protect sensitive technical data and scientific information related to advanced research and development of MCMs and is able to convene meetings and consultations on critical medical countermeasure issues.

### **The Movement of Some Programs within HHS**

HHS programs have come a long way since the original PAHPA authorization, and we've made great strides in coordinating across HHS to achieve public health preparedness. Particularly in today's fiscal environment, we have been very aggressive in eliminating duplication and enhancing efficiencies by drawing on the expertise, capacity, and personnel of HHS partner agencies to make American communities more resilient.

Given our progress and continuing improvements to how we coordinate across HHS, we believe the current processes and systems in place are working. ASPR actively exercises policy direction for public health and medical preparedness

and response programs and activities. We will efficiently and effectively continue to build on the expertise and systems in place, incorporate lessons learned, and continuously improve collaborations with our agency partners on future responses.

### **Conclusion**

Our experiences since the passage of PAHPA have shown clearly that every part of the public health and medical community is critical to building resilience. We applaud Congress' wisdom in enacting PAHPA as the foundation for this approach, which is so critical to our preparedness. .

At this time I would be happy to address any questions you may have.