Testimony
Committee on Homeland Security
Subcommittee on Emerging Threats, Cybersecurity, and Science & Technology
United States House of Representatives

Pandemic Influenza: HHS Progress in National Preparedness Efforts

Statement of

Radm. William C. Vanderwagen, M.D.

Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
September 26, 2007

Chairman Langevin, Ranking Member McCaul, and distinguished Members of the Subcommittee, thank you for the opportunity to present the progress HHS has made in national preparedness for pandemic influenza. Over the past two years, with the $5.6 billion supplemental funding we received from Congress, we have worked closely with our International, Federal, state and local partners to advance our preparedness for pandemic influenza. While we all understand that preparedness is a process that is never completed, the advances I will highlight for you today demonstrate what can be accomplished when there is a shared vision and support for preparedness. The threat of a pandemic remains a real one, and I appreciate that in holding this hearing, you share our sense of urgency about our preparedness.

As you know, the President released the *National Strategy for Pandemic Influenza* in November 2005, followed by a detailed *Implementation Plan* from the Homeland Security Council (HSC) in May 2006. The HSC Implementation Plan assigned over 300 tasks across the Federal Government to improve our Nation's preparedness for pandemic influenza. HHS has made substantial progress in the nearly 200 action items assigned to our department, completing over 80% in one year. These gains are real and measurable, and they cover a broad range of preparedness, including enhancing our international laboratory networks, developing and releasing guidance on community-based measures to mitigate the effects of a pandemic, and expanding the Medical Reserve Corps program. We also released the HHS Pandemic Plan and HHS Implementation Plan, and those are available alongside additional information and planning resources at www.pandemicflu.gov. I will highlight for you specific accomplishments in three areas: State and Local Preparedness, Countermeasure Procurement and Advanced Development, and Federal Preparedness.

All of these accomplishments are consistent with the mission of my office, which Congress created in December 2006 through the Pandemic and All-Hazards Preparedness Act. The ASPR mission is to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and

disasters, and the vision we see is "A Nation Prepared." Within HHS, my office coordinates the preparedness and response enterprise, which focuses on the continuum of preparedness from research and development of medical countermeasures to response delivery platforms that support state and local responders in reaching our citizens during an incident.

Our preparedness for pandemic influenza involves a shared responsibility among our entire Department, our partners in the International community, the Federal interagency, state, local, tribal and territorial governments, the private sector, and, ultimately, individuals and families. In addition, we believe our planning for an influenza pandemic is part of an all-hazards approach. The gains we make in increased preparedness and response capability for pandemic influenza will help us across the spectrum of public health emergencies and disasters.

Enhanced State and Local Preparedness

By the end of this year, the Department will have awarded over $600 million in emergency supplemental funding through the Centers for Disease Control and Prevention (CDC) and ASPR to 62 awardees: 50 states, five U.S. territories, three Freely Associated States of the Pacific, New York City, Los Angeles County, Chicago, and the District of Columbia to upgrade state and local capacity in regard to pandemic influenza preparedness. The funding has occurred in three general phases:

Phase 1- $100 Million

Senior HHS officials, led by Secretary Leavitt, conducted Pandemic Influenza Preparedness Summits in every state to facilitate community-wide planning and to promote shared responsibility for pandemic preparedness. To assess gaps in pandemic preparedness and guide preparedness investments, CDC created an assessment tool for awardees to use in evaluating their own jurisdiction's current state of preparedness.

The awardees were required to submit: 1) a gap analysis; 2) a proposed approach to filling the identified gaps; and 3) an associated budget for the critical tasks necessary to address those gaps. High priority areas being addressed include:

- Exercising pandemic incident command systems,
- Linking animal and human surveillance systems,
- Augmenting laboratory capacity,
- Plans for vaccine and antiviral distribution, mortuary affairs, and continuity of essential functions

*Phase 2- $250 M*illion *($225* million*for four priority activities and $25* million*for competitive demonstration projects)*

Of the Phase 2 funds, $225 million were used for four priority activities: 1) work with jurisdictional colleagues in emergency management, community organizations and other agencies to develop a jurisdictional workplan to address gaps identified by the assessment process; 2) develop and exercise an antiviral drug distribution plan; 3) develop a pandemic exercise schedule to include – at a minimum -- medical surge, mass prophylaxis, non-pharmaceutical public health interventions and the antiviral drug distribution exercises; and 4) submit the jurisdictional pandemic influenza operational plan.

Three planning priorities were targeted — state/local exercises of key plans (mass vaccination using seasonal flu clinics, community containment, medical surge); developing antiviral distribution plans; and review of statewide pandemic influenza plans.

- 85% of the awardees used seasonal influenza vaccination clinics to exercise mass prophylaxis plans (Highlights - some state medical boards used Emergency Medical Technicians (EMTs) and paramedics to act as vaccinators to

reduce the burden on public health staff; some states used drive-through clinics to increase throughput and enforce social distancing.)

- 83% of the awardees participated in tabletop exercises of non-pharmaceutical interventions and plans to contain the spread of pandemic influenza. (Emphasis on school closing decisions and discouragement of large public gatherings; the majority of awardees responded that gaps in their existing plans were identified and that further planning refinements are necessary to produce viable and executable plans. Funding in Phase 3 will help address these gaps.)
- Over 50% of the awardees reported conducting exercises of antiviral distribution plans.
- The public health and medical components of this funding supplement have included two of the Target Capabilities identified as part of National Preparedness under Homeland Security Presidential Directive #8: Mass Prophylaxis and Medical Surge.
- 97% of the awardees have submitted pandemic influenza operational plans that involve interaction and partnership with law enforcement and emergency management (antiviral distribution), education, and business sectors (community mitigation and continuity of operations).

The remaining $25 million Phase 2 funds will be used to make pandemic influenza emergency supplemental awards based on performance. The funds will be awarded competitively to awardees that successfully propose a plan to develop, implement and evaluate pandemic influenza interventions. Proposals will be solicited for public health interventions for which there are few data, unclear consequences, or inconclusive effectiveness.

Phase 3- $250 Million Available.

CDC has awarded $175 million of Phase 3 funding to support awardees' efforts to fill

gaps identified in Phases 1 and 2. The awardees will be required to utilize the tools developed under the auspices of the Homeland Security Exercise Evaluation Program to create planning, training, and exercise evaluation programs. A total of $75 million will be awarded as supplements to the 62 entities that currently receive awards through the Hospital Preparedness Program (HPP) cooperative agreements. Applications are due in October 2007.

The HPP transferred from the HHS Health Resources and Services Administration (HRSA) to ASPR in March of this year as directed under the PAHPA. The Program has continued to focus on enhancing surge capacity. Priorities for Medical Surge that were evaluated as part of the state plan review are as follows:

- States have the ability to report available beds which is a requirement in the 2006 Hospital Preparedness Program Cooperative Agreement,
- Effective use of civilian volunteers as part of the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and Medical Reserve Corps (MRC) programs,
- Planning for Alternate Care Sites,
- Development of Health Care Coalitions that promote effective sharing of resources in surge situations – Will be funding 10 partnership demonstration projects for $18.1 million in FY 2007, and
- Plans for providing the highest possible standards of care in situations of scarce resources. ASPR partnered with the HHS Agency for Healthcare Research and Quality (AHRQ) in the development of a *Community Planning Guide on Mass Medical Care with Scarce Resources*. The guide includes a pandemic influenza case study.

The remainder of the Phase 3 funding has been allocated to the HPP program for upgrading state and local pandemic influenza preparedness capacities. This funding

will establish stockpiles of critical medical equipment and supplies, as well as be used to develop plans for maintenance, distribution and sharing of those resources. This funding may also be used to support the planning and development of alternate care sites (ACS) and medical surge exercises for pandemic influenza. Examples of allowable activities include:

- Stockpiles of ventilators, ancillary supplies and oxygen,
- Personal protective equipment (PPE) and infection control supplies,
- Alternate care sites – staffing, operational plans and exercises,
- Mass fatality plans and equipment and supplies, and
- Medical surge exercises.

Countermeasure Procurement and Advanced Development

HHS has also made tremendous progress in addressing the Pandemic influenza medical countermeasure goals that emanate from the HSC Implementation Plan. These goals are listed on the table below.

Vaccine Goal #1	To establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 million persons: H5N1 stockpiles (40 million doses)
Vaccine Goal #2	To provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration: pandemic vaccine (600 milliondoses)
Antivirals Goal #1	To provide influenza antiviral drug stockpiles for treatment of pandemic illness for 25% of U.S. population who we estimate will become clinically ill during a pandemic (75 million treatment courses[1])
Antivirals Goal #2	To provide influenza antiviral drug stockpiled for strategic limited containment at the onset of a pandemic (6 million treatment courses)
Diagnostics Goal #1	To develop new high throughput laboratory and Point of Care influenza diagnostics for pandemic virus detection

[1] This figure assumes a severe, 1918-like pandemic.

- *Advanced Development:*
    - *Cell-based vaccines.* Current influenza vaccines are based on influenza virus grown in fertilized chicken eggs. In an effort to modernize influenza vaccine manufacturing for greater flexibility and less vulnerability, and to increase domestic manufacturing capacity with the potential for surge production, six contracts were awarded in 2005-06 for $1.1 billion to develop seasonal and pandemic cell-based influenza vaccines towards U.S.-licensure. In 2007 three manufacturers will begin late stage pivotal clinical evaluation of their cell-based influenza vaccines with sights set on Biologics License Application (BLA) submissions to FDA in 2008. Further, one manufacturer has already broken ground on new state-of-the art cell-based influenza vaccine manufacturing facilities in North Carolina with completion scheduled in 2010. The ultimate goal here is to strengthen the U.S. domestic manufacturing system and to ensure adequate U.S.-based production capability.

    - *Antigen-sparing vaccines.* To stretch the domestic pre-pandemic influenza vaccine manufacturing capacity further and to provide vaccines with broad cross-protective immunity, three contracts were awarded in January 2007 for $133 million to develop antigen-sparing pandemic influenza vaccines towards U.S.-licensure. These H5N1 vaccine candidates formulated with new adjuvants show great promise in mid-stage clinical evaluation with expectations that one or more will be submitted as BLAs in 2008 for licensure. An adjuvant is a vaccine additive that amplifies the immune response. HHS is coordinating studies with a number of manufacturers to determine whether these adjuvants can be used safely and effectively with H5N1 vaccine antigens currently in the stockpile that have been produced by different manufacturers – a key step toward expansion of the pre-pandemic vaccine stockpile supply.

- *Next generation vaccines.* Our investments in cell culture technology mentioned above will expand production capability. Because of the time vaccine production takes (20-23 weeks from identification of the pandemic virus), we are also investing in next generation vaccines with shorter production timelines. To provide pandemic vaccine earlier after the onset of a pandemic, a synopsis for a contract solicitation was issued in August 2007 to seek proposals for advanced development of next generation recombinant influenza vaccines over the next 3-5 years with the goal of accelerating the development of new vaccine technologies that will greatly shorten vaccine production timelines in a pandemic.

- *Antivirals*. Until recently, there was little incentive for manufacturers to develop new approaches to treat influenza. Currently, we have only two classes of antiviral drugs that are effective against influenza. Only one of those classes of drugs, the neuraminidase inhibitors (oseltamivir [Tamiflu®] and zanamivir [Relenza®]), is being actively stockpiled because of the development of resistance to the older class of antiviral drugs. As our options are limited, we need new antiviral candidates in case clinically significant resistance to our current stockpile of antiviral drugs develops. To promote the advanced development of new influenza antiviral drugs towards U.S.-licensure, a contract was awarded in January 2007 for $102 million to develop peramivir, a neuraminidase inhibitor that may be administered in life-threatening influenza illnesses. This drug is in mid-stage clinical evaluation presently. In 2008 more influenza antiviral drug candidates will emerge in the pipeline that may be ready for advanced development and eligible for funding. We need new antiviral candidates should the viruses become resistant to the currently available antivirals.

- *Diagnostics.* To provide healthcare professionals with a means to distinguish pandemic influenza viruses from other respiratory pathogens including seasonal influenza viruses, four contracts for $12 million were awarded in November 2006 for development of rapid point-of-care diagnostic devices. By the end of 2007, two of these devices will be evaluated independently for further clinical development with expectations of licensure submissions in 2009. Solicitations to award contracts for development of high throughput laboratory and single-use home diagnostics for pandemic influenza are also expected to be issued by the end of 2007.

- *Ventilators.* To close the enormous gap in the availability of ventilators, which will be essential to treat severely-ill patients during an influenza pandemic, a Blue-Ribbon Panel will be assembled this fall to establish the product requirements for a next generation affordable, mobile ventilator. A contract solicitation will be issued early in 2008 for the advanced development of next generation ventilators.

- *Federal Stockpile Acquisitions.*
  - *Vaccines*. To establish pre-pandemic vaccine stockpiles, multiple contracts have been awarded for over $900 million between 2004 and 2007 to U.S.-licensed influenza vaccine manufacturers to develop and produce at commercial scale using licensed manufacturing processes and facilities for egg-based inactivated split H5N1 vaccines against multiple virus clades. These stockpiling efforts led to the U.S. licensure of the first H5N1 vaccine in April 2007. To date 15 million vaccine single antigen doses have been manufactured as bulk vaccine product, and 11 million more doses will be manufactured this fall for a total of 26 million by the end of 2007. I should note, however, that while pre-pandemic vaccine stockpiles are based on our best assumptions of what virus strains are

likely to present during a pandemic, they may not closely match the virus that actually arrives. Finally, Secretary Leavitt issued a Pandemic Response Emergency Preparedness Act declaration in January 2007 to provide comprehensive liability immunity for manufacturers and administrators of H5N1 influenza vaccines.

- *Antiviral Drugs.* The Pandemic Influenza Plan seeks to ensure the availability of antiviral treatment courses for 25 percent of the U.S. population or 81 million treatment courses. To meet the federal stockpile goal of 50 million treatment courses of influenza antiviral drugs for treatment during a pandemic, 37.5 million treatment courses of U.S.-licensed neuraminidase inhibitors were purchased in 2006-07 and delivered to the Strategic National Stockpile (SNS). The U.S. now has domestic manufacturing capabilities for these drugs. The remaining 12.5 million treatment courses will be purchased in FY08 upon approval of the pending appropriation request. To assist States in meeting their collective pandemic stockpile goal of 31 million treatment courses of influenza antiviral drugs, $170 million was allocated to subsidize state purchases made using a federal contract with manufacturers of antiviral drugs. To date the States have purchased 15.1 million treatment courses of influenza antivirals for their stockpiles and are expected to reach the overall goal by July 2008.

- *Ventilators.* The SNS will purchase 2000 new ventilators in 2007 for distribution during a pandemic or as required in other all hazards incidents and states can invest in ventilator procurements through the investments being managed through the HPP program.

- *Syringes*. The SNS will purchase in excess of 20 million syringe/needle units in 2007 for usage with pre-pandemic influenza vaccines.

- *Infrastructure Building.*
  - *Vaccines.* To utilize existing facilities for pandemic influenza vaccine manufacturing, two contracts were awarded in May 2007 for $133 million for retrofitting existing domestic biological manufacturing facilities for production of egg-based influenza vaccines and providing warm base operations for up to five years. A contract solicitation for proposals to establish new domestic cell-based influenza vaccine manufacturing facilities is also expected in 2008 with manufacturing capacity requirements of at least 150 milliondoses of pandemic vaccine within six months.

While we have been making great strides with procurement and advanced development we have also drafted guidance on how to maximize these investments. We believe it's important to work with stakeholders in order to finalize that guidance, and that preparedness is best achieved not just by focusing on producing additional products, but by assuring that they are deployed and used optimally. This requires leadership in developing guidance and promoting preparedness, consultation with those who have a critical role in implementation (including states and professional societies), and understanding and overcoming any barriers to achieving success.

Federal Preparedness Planning

For the past six months, ASPR has been a lead partner in the development of a U.S. Government-wide Pandemic Influenza Strategic Plan, which describes what steps Federal Departments will take to respond to the emergence of a novel influenza virus abroad and here in the homeland. This strategic planning process further codifies the HHS public health and medical responsibility to mitigate illness and reduce deaths

during a pandemic through the provision of medical countermeasures and materiel, community mitigation guidance, necessary laboratory and surveillance tools, and some of the nation's finest public health and medical emergency response personnel.

The Department's operational plan for pandemic influenza response details how HHS will fulfill its important responsibilities and how ASPR will coordinate the deployment and utilization of HHS assets and expertise. This plan, or playbook as we call it, will be further refined in the coming months to ensure a seamless integration with the U.S. Government-wide Plan. Further, HHS Operating Divisions including the CDC are developing their own detailed operational plans that are aligned with the Department's plan to enable a cohesive Departmental preparedness approach. A goal for next year is to work with states to develop regional playbooks that will continue to promote integrated planning across all tiers of government.

HHS held a number of exercises to test the operational plans I have described. ASPR hosted Department-wide exercises with senior leadership to test how we will leverage the full scope of HHS resources and capabilities in response to pandemic influenza. ASPR has pre-identified six Senior Federal Officials to work in coordination with the pre-designated Pandemic Influenza Principal Federal Officials, and our Senior Federal Officials are engaged in State-sponsored exercises taking place in their regions. In addition, CDC launched an extensive exercise program to identify planning gaps and stretch the limits of their assumptions and response strategies.

The last two exercises have included state participation to promote seamless preparedness integration across the different tiers of response. The state participants were actively involved in the planning meetings leading up to the conduct of both of these CDC-sponsored exercises.

- April 25-27, 2007: coordinated activities with State Emergency Operations Centers (EOCs) and State Health Department EOCs from three states (Arkansas, Florida and Ohio).

- August 14-16: CDC Pan Flu Surge exercise, where representatives from five states (Arkansas, Florida, Georgia, Michigan and Ohio) served in our Exercise Control Group to replicate the activities of their states and those of other states that were not actively represented.

The CDC's Division of Strategic National Stockpile (DSNS) also conducted a number of exercises. For example:

- *Operation Wild Canary*, a full scale exercise executed in partnership with the State of Iowa. The purpose of the exercise was to test antiviral distribution from the federal stockpile down to the local treatment facility. During the exercise the DSNS deployed training material exactly replicating Iowa's pro-rata allocation of antiviral drugs to the state receipt, stage, and store site in Des Moines. From there the state sent antiviral drugs on a pre-established allocation to distribution hubs throughout the state. Local treatment facilities then received their antiviral allocation from the distribution hubs.

Some examples of state and local promising practices in pandemic influenza activities include:

- <u>Maine</u>
    - Formed pandemic influenza workgroups on all levels including:
        - Statewide Steering Committee including public constituents
        - County Pandemic Influenza Planning Groups including public constituents and association and governmental members at the county and local level.

- Intergovernmental Pandemic Influenza Planning Committee including the Departments of Agriculture and Inland Fisheries, the Maine Emergency Management Agency, and Maine Emergency Medical Services.

- Wisconsin

The state has significantly improved planning for treatment centers resources and personnel. As a result of pandemic influenza planning the state has a better understanding of their treatment facilities' capabilities, as well as an accurate location and point of contacts for each treatment facility, which has helped to improve their overall level of preparedness.

- Atlanta, Georgia and Los Angeles County, California

- Both cities are working with the Business Executives for National Security (BENS) to engage local corporations in preparedness planning.
- In an upcoming exercise drill, the L.A. Business Force/Homeland Security Advisory Council will be the first private-sector representative ever included in a security exercise at the vital Port of Los Angeles/Long Beach, the gateway for 40 percent of all U.S. trade.

Thank you for the opportunity to present the progress HHS has made in national preparedness for pandemic influenza. With your leadership and support, we have made substantial progress. The threat remains real, and we have much left to do to ensure that we meet our mission of a Nation prepared for a potential influenza pandemic.

This concludes my testimony. I will be happy to answer any questions.