

**BEYOND THE CHECKLIST: ADDRESSING
SHORTFALLS IN NATIONAL PANDEMIC
INFLUENZA PREPAREDNESS**

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGING
THREATS, CYBERSECURITY AND
SCIENCE AND TECHNOLOGY

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**BEYOND THE CHECKLIST: ADDRESSING
SHORTFALLS IN NATIONAL PANDEMIC
INFLUENZA PREPAREDNESS**

wednesday, September 26, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY
AND SCIENCE AND TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to call, at 10:11 a.m., in Room 311, Cannon House Office Building, Hon. James Langevin [chairman of the subcommittee] presiding.

Present: Representatives Langevin, Pascrell, and McCaul.

Mr. LANGEVIN. [Presiding.] The Committee on Homeland Security will come to order. The committee is meeting today to receive testimony on Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness.

Good morning. I would like to take this opportunity to thank the witnesses on both our panels for appearing today.

And I would especially like to thank and welcome Dr. Tony Cirillo from my home state of Rhode Island, who will be participating in the second panel this morning.

Let me just say I appreciate your willingness to help Congress understand the devastating nature of pandemic influenza and to work with us in determining what resources are necessary to help prepare the nation before a pandemic occurs.

Today we will explore what it takes to prepare for and respond to an influenza pandemic that would affect every sector of society and every person in the world.

Planning is problematic to begin with because it is so difficult to fathom both the potential casualties and the impact of such a pandemic.

Even when we focus just on our own country, the projected numbers are still staggering—200,000 dead, 2 million ill, all sectors and every aspect of the infrastructure negatively impacted.

Though this is a problem that we will not be able to control through standard disease management practices, we can and must rise to the challenge. Make no mistake about it—we are due for a severe influenza pandemic at some point for a variety of reasons.

The influenza viruses that could result in a pandemic are increasing in virulence. Record numbers of humans are now living in close proximity to current and potential animal carriers.

Rapid transit moves people and cargo at increasingly faster rates, fostering the movement and transfer of diseases. Influenza viruses are already mutating faster than we could have imagined, and the toll that avian influenza is taking on other countries is already devastating.

The impact this disease could have on the security of our homeland is indeed worrisome, which is why awareness and preparedness are critical.

Increased emphasis on pandemic planning and preparedness for the United States in recent years has resulted in the generation of the National Strategy for Pandemic Influenza, released in November 2005, and its Implementation Plan, released in May 2006.

Some departments and agencies within the executive branch have also created their own strategies to distribute resources and guidance throughout the country at all levels of government and to the private sector based on their strategies and the National Strategy itself.

Although these are positive steps, one thing is clear. The nation is still not ready for an influenza pandemic to occur here or overseas.

Today we will discuss the insufficiencies of the National Strategy and its Implementation Plan and hopefully find ways to improve upon our current strategies.

The Implementation Plan for the National Strategy is composed of hundreds of separate actions forming a checklist with some 324 items.

Although checklists are good tools for getting things accomplished, we can sometimes make checking things off more important than actually achieving the goals and objectives we set out for ourselves in the first place.

Our nation's leaders are not seeing the big picture. Instead, they are driving our departments and agencies to focus so much effort on checking boxes that there is barely time left to actually combat a potential pandemic.

We need to address the shortfalls in our national pandemic influenza preparedness and get beyond the checklist.

Our effort seems to have gotten stuck at the federal level but it is time to shift our resources to the states, territories, tribes and localities.

State, territorial, tribal and local entities have found themselves preparing for a pandemic without adequate funding, necessary resources, strategy-driven guidance or strong leadership.

When pandemic influenza hits this country, our public health professionals and health care practitioners will be fighting to save lives and the federal government will be assisting in those efforts. We need to cater to them, not the checklist.

Today we will also examine the interactions among the members of the executive branch, especially the Department of Homeland Security and the Department of Health and Human Services as they co-lead activities to manage an influenza pandemic when it does strike our nation.

Unfortunately, there is little evidence that either agency knows what their roles and responsibilities would be during an actual event.

And I very much fear another Hurricane Katrina situation, where delays in identifying principal federal officials resulted in a significant problem and unnecessary losses of life. We cannot afford for this to ever happen again.

We must therefore work the uncertainties out today so that we can properly deal with these situations tomorrow. I very much appreciate the efforts put forward by our federal and non-federal colleagues in the private and public sectors, and thank you all for being here this morning.

With that, the chair now recognizes the ranking member of the subcommittee, the gentleman from Texas, Mr. McCaul, for the purpose of an opening statement.

PREPARED OPENING STATEMENT OF THE HONORABLE JAMES R. LANGEVIN, CHAIRMAN,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND
TECHNOLOGY

Good morning, I'd like to thank the witnesses on both of our panels for appearing today, and I would especially like to thank Dr. Tony Cirillo from my home state of Rhode Island who will be participating on the second panel. I appreciate your willingness to help Congress understand the devastating nature of pandemic influenza—and to work with us in determining what resources are necessary to help prepare the Nation before a pandemic occurs.

Today we will explore what it takes to prepare for, and respond to, an influenza pandemic that would affect every sector of society, and every person in the world. Planning is problematic to begin with, because it is so difficult to fathom both the potential casualties and the impact of such a pandemic. Even when we focus just on our own country, the projected numbers are still staggering—200,000 dead, 2 million ill, all sectors and every aspect of the infrastructure negatively impacted. Though this is a problem that we will not be able to control through standard disease management practices, we can and must rise to the challenge. Make no mistake about it, we are due for a severe influenza pandemic.

The influenza viruses that could result in a pandemic are increasing in virulence. Record numbers of humans are now living in proximity to current and potential animal carriers. Rapid transit moves people and cargo at increasingly faster rates, fostering the movement and transfer of diseases. Influenza viruses are already mutating faster than we could have imagined, and the toll that avian influenza is taking on other countries is already devastating.

The impact this disease could have on the security of our homeland is indeed worrisome, which is why awareness and preparedness is critical. Increased emphasis on pandemic planning and preparedness for the United States in recent years has resulted in the generation of the National Strategy for Pandemic Influenza (released in November 2005) and its Implementation Plan (released in May 2006). Some Departments and agencies within the Executive Branch have also created their own strategies, and distributed resources and guidance throughout the country, at all levels of government, and to the private sector—based on their strategies and the National Strategy itself. Although these are positive steps, one thing is clear: the Nation is still not ready for an influenza pandemic to occur here or overseas.

Today we will discuss the insufficiencies in the National Strategy and its Implementation Plan, and hopefully find ways to improve upon our current strategies. The Implementation Plan for the National Strategy is composed of hundreds of separate actions—forming a checklist with 324 items. Although checklists are good tools for getting things accomplished, we can sometimes make checking things off more important than actually achieving the goals and objectives we set for ourselves in the first place.

Our Nation's leaders are not seeing the big picture—instead, they are driving our Departments and agencies to focus so much effort on checking boxes that there is barely time left to actually combat a potential pandemic. We need to address the shortfalls in our National Pandemic Influenza Preparedness, and get beyond the checklist. Our efforts States, Territories, Tribes, and Localities. State, territorial, tribal, and local entities have found themselves preparing for a pandemic without:

- Adequate funding,
- Necessary resource,
- Strategy-driven guidance, or
- Strong leadership.

When pandemic influenza hits this country, our public health professionals and health care practitioners will be fighting to save lives, and the Federal government will be assisting in those efforts. We need to cater to *them*, not the checklist. Today we'll also examine the interactions among the members of the Executive branch—especially the Department of Homeland Security and the Department of Health and Human Service as they co-lead activities to manage an influenza pandemic when it does strike our nation.

Unfortunately, there is little evidence that either agency knows what their roles and responsibilities would be during an event. I very much fear another Hurricane Katrina situation, where delays in identifying principal federal officials resulted in the significant problems and unnecessary losses of life. We cannot afford for this to happen again. We must therefore work the uncertainties out today so we can properly deal with these situations tomorrow. I very much appreciate the efforts put forward by our Federal and non-federal colleagues, in the private and public sectors, and thank you for being here this morning.

Mr. MCCAUL. I thank the chairman.

I would like to welcome our distinguished panel of witnesses here today, and in particular Dr. David Lakey from my home town of Austin, Texas, who will be on the second panel here today.

In the 109th Congress this committee held hearings and a series of briefings which examined the National Strategy for Pandemic Influenza and its Implementation Plan.

Today we are more than a year after the Implementation Plan was released, and we ask whether we are more prepared today than we were then to deal with the potential onset of a pandemic.

I hope the answer is yes, that we are more prepared. I think the answer is yes, but there is certainly more to be done.

Never before has the human population anticipated and prepared for a pandemic. We cannot be certain that our efforts are enough or if they are even realistic. But we do know that we are long overdue for an outbreak of influenza.

The 20th century witnessed three separate pandemics that cost hundreds of thousands of lives, and we understand that the efforts we make now to prepare for a pandemic, whether it is caused by the H5N1 strain or some other unidentified strain, will shape the scope of that pandemic and may save countless lives.

The release of the National Strategy and the Implementation Plan were certainly, in my view, a step in the right direction.

I agree that pandemic preparedness efforts should go beyond merely checking the box for the action items in the plan and that a comprehensive and flexible approach should be adopted.

I don't want us to overlook the significant accomplishments, however, that the federal government has made in its efforts to plan for a pandemic. We are working with our international partners to limit the spread of H5N1 overseas in hopes that it will not reach the United States.

We are expanding our vaccine development capability and stockpiling antiviral drugs which will be critical at the onset of the pandemic.

Plans have been made to increase surge capacity at medical facilities and to continue the operations of government and private sector business during high rates of absenteeism.

But we must not be complacent. It is important that the relevant players clarify and test their leadership roles and responsibilities for a pandemic situation.

It is also important that others involved in the pandemic planning process, including state and local governments, understand their roles.

And while the media coverage of this issue has certainly waned, the threat posed by the emergence of pandemic influenza to homeland security has not.

I am happy to see that this committee is continuing its examination of pandemic preparedness in this Congress.

And I want to thank you, Mr. Chairman, for holding this hearing, and I yield back.

Mr. LANGEVIN. I thank the gentleman.

This is obviously a very busy day on the Hill. We will have members coming in and out and several markups going on.

But other members of the committee are reminded that under committee rules, opening statements may be submitted for the record.

And I now welcome the first panel of witnesses. Our first witness, Ms. Bernice Steinhardt, is the Director of Strategic Studies at the United States Government Accountability Office.

Our second witness is Dr. Tilman Jolly. Dr. Jolly is the associate chief medical officer for medical readiness in the Office of Health Affairs at the Department of Homeland Security.

And our third witness is Dr. Craig Vanderwagen, Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. Dr. Vanderwagen was the senior federal health official in the response to Hurricane Katrina and Rita.

We thank all three of our witnesses for their service to the nation and for being here today. We look forward to your testimony.

Without objection, the witnesses' full statements will be inserted in the record.

And I now ask each witness to summarize his or her statement for 5 minutes, beginning with Ms. Steinhardt.

Welcome.

STATEMENT OF BERNICE STEINHARDT, DIRECTOR, STRATEGIC ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE

Ms. STEINHARDT. Thank you very much, Mr. Chairman and Mr. McCaul. We really appreciate the opportunity to be here today to talk about our recent report on planning for potential pandemic influenza in the United States.

Fortunately, the administration has taken an active approach in preparing a national pandemic Strategy and Implementation Plan. But we found that much more needs to be done to make sure that federal leadership roles are clear and that the plan is viable and can be effectively implemented.

Let me turn to leadership roles first. The plan assigns shared leadership roles to the Secretaries of Health and Human Services and Homeland Security, the first for medical response in a pandemic and the DHS secretary for overall incident management and response.

But given that a severe pandemic would entail not only a medical response but would also have to focus on sustaining critical infrastructure and the economy, it is not clear when in a pandemic

the HHS Secretary would have the lead and when the DHS Secretary would have the lead.

And these two are far from the only leadership positions. Under the Post-Katrina Reform Act, which was enacted subsequent to the pandemic Strategy and Plan, the FEMA administrator has now been designated the Principal Domestic Emergency Management Advisor to the President.

And also after the pandemic Plan was prepared, the DHS Secretary pre-designated a national Principal Federal Official, or a PFO, and created five pandemic regions, each with a regional PFO and a Federal Coordinating Officer, or FCO, all of them responsible to some extent for coordinating federal planning, exercise and support.

Not only is this leadership structure complex and potentially confusing, it has never been tested.

As this committee well understands, as your remarks indicated, Mr. Chairman, one of the major lessons the country learned from Katrina was that plans and assumptions have to be understood, they have to be tested and the lessons learned incorporated into plans before emergencies occur.

Yet the only national pandemic exercise to date was a Cabinet-level tabletop simulation in December 2005, well before the national Implementation Plan was released and the leadership structure created.

I want to turn now to our assessment of the national pandemic Strategy and Plan. Although the Plan did a good job in defining the problem and discussing constraints and challenges, it is missing some significant elements. I want to highlight just a few here.

For one thing, the plan does not identify what it will cost to carry out. Obviously, our ability to do all that the plan outlines is going to be affected by our ability to pay for it.

Not everything is going to be easily addressed through existing mechanisms and could, in fact, place considerable stress on existing resources.

We are also concerned that despite the fact that states, local and tribal entities will be on the front lines of the pandemic, these stakeholders were not directly involved in developing the Strategy and Plan.

And lastly, we noted that there is no provision in the plan for monitoring and reporting on progress and for updating the plan to reflect lessons learned from exercises or changes in leadership responsibilities or other policy decisions.

To address these gaps, we outline several steps. First, we recommended that the HHS and DHS Secretaries work together to develop and conduct rigorous testing, training and exercises for pandemic influenza.

We also recommended that the Homeland Security Council establish a specific process and time frame for updating the plan, one that involves key non-federal stakeholders and fills in other gaps that we identified.

I would note that HHS and DHS agreed with our recommendations, but the Homeland Security Council did not respond or offer comments on the report.

I want to say, in closing, that these gaps are not trivial or simply procedural. When a pandemic actually occurs, the effectiveness of actions that are taken at the outset are going to be of critical importance in helping to limit the spread of the disease.

While we recognize that our understanding of the virus is still evolving, it is important to take these steps now before a disaster strikes.

With that, I will conclude my remarks and I look forward to your questions. Thank you.

[The statement of Ms. Steinhardt follows:]

PREPARED STATEMENT OF BERNICE STEINHARDT

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear here today to discuss the federal government's efforts to prepare for and respond to a possible influenza pandemic. An influenza pandemic is a real and significant threat facing the United States and the world. Although the timing and severity of the next pandemic is unpredictable, there is widespread agreement that a pandemic will occur at some point. Unlike incidents that are discretely bounded in space or time (such as a storm or a terrorist attack), a pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and could pass through communities of all sizes across the nation and the world simultaneously.

Today, I will discuss (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic, (2) our assessment of the National Strategy for a Pandemic Influenza (Strategy) and the Implementation Plan for the National Strategy for a Pandemic Influenza (Plan), and (3) opportunities to increase the clarity of federal leadership roles and responsibilities and improve pandemic planning.

This statement is based on our August 14, 2007, report, requested by the Ranking Member, Senate Budget Committee; the Chairman and Ranking Member, House Committee on Oversight and Government Reform; and the Chairman, House Committee on Homeland Security.¹ Our objectives in that report were to address the extent to which (1) federal leadership roles and responsibilities for preparing for and responding to a pandemic are clearly defined and documented and (2) the Strategy and the Plan address the characteristics of an effective national strategy; we conducted our work in accordance with generally accepted government auditing standards. We analyzed relevant documents, interviewed cognizant federal officials, and assessed the Strategy and Plan to determine the extent to which they jointly addressed the six desirable characteristics of an effective national strategy that we developed and used in previous work.² While national strategies necessarily vary in content, the six characteristics we identified apply to all such planning documents and can help ensure that they are effective management tools.

In summary, although the administration has taken an active approach to this potential disaster by developing a Strategy and Plan, and has undertaken a number of other efforts, much more needs to be done to ensure that the Plan is more viable and can be effectively implemented in the event of an influenza pandemic.

- Key federal leadership roles and responsibilities for preparing for and responding to a pandemic continue to evolve and will require further clarification and testing before the relationships of the many leadership positions are well understood. Most of these leadership roles involve shared responsibilities, and it is not clear how these would work in practice. Because initial actions may help limit the spread of an influenza virus, the effective exercise of shared leadership roles and responsibilities could have substantial consequences. However, only one national, multisector pandemic-related exercise has been held, and that was prior to issuance of the Plan.
- The Strategy and Plan do not fully address the characteristics of an effective national strategy and contain gaps that could hinder the ability of key stakeholders to effectively execute their responsibilities. In addition to the fact that

¹GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Leadership Roles and an Effective National Strategy*, GAO-07-781 (Washington, D.C.: Aug. 14, 2007).

²See GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004); *Rebuilding Iraq: More Comprehensive National Strategy Needed to Help Achieve U.S. Goals*, GAO-06-788 (Washington, D.C.: July 11, 2006); and *Financial Literacy and Education Commission: Further Progress Needed to Ensure an Effective National Strategy*, GAO-07-100 (Washington, D.C.: Dec. 4, 2006).

the Strategy and Plan do not clarify how responsible officials will share leadership responsibilities, they do not include a description of the resources required to implement the Plan, and consequently do not provide a picture of priorities or how adjustments might be made in view of resource constraints. Additionally, state and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the Plan, and the linkage of the Strategy and Plan with other key plans is unclear.

The gaps in the Strategy and Plan are particularly troubling because they can affect the usefulness of these planning documents for those with key roles to play and, with no mechanisms for future updates or progress assessments, limit opportunities for congressional decision makers and the public to assess the extent of progress being made or to consider what areas or actions may need additional attention.

We made two recommendations in our August 2007 report to address these concerns.

- We recommended that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza to ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges. Once the leadership roles have been clarified through testing, training and exercising, the Secretaries of Homeland Security and Health and Human Services should ensure that these roles and responsibilities are clearly understood by nonfederal partners.
- Our report also recommended that the Homeland Security Council (HSC) establish a specific process and time frame for updating the Plan. This process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The next update of the Plan could be improved by addressing the gaps we identified.

The Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) concurred with the first recommendation. The HSC did not comment on the draft report or our recommendation.

Background

To address the potential threat of an influenza pandemic, the President and his HSC issued two planning documents. The Strategy was issued in November 2005 and is intended to provide a high-level overview of the approach that the federal government will take to prepare for and respond to an influenza pandemic. It also articulates expectations for nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities.

The Plan was issued in May 2006 and is intended to lay out broad implementation requirements and responsibilities among the appropriate federal agencies and clearly define expectations for nonfederal entities. The Plan includes 324 action items related to these requirements, responsibilities, and expectations and most of them are to be completed before or by May 2009. It is intended to support the broad framework and goals articulated in the Strategy by outlining specific steps that federal departments and agencies should take to achieve these goals. It also describes expectations regarding preparedness and response efforts of state and local governments, tribal entities, the private sector, global partners, and individuals. The Plan's chapters cover categories of actions that are intended to address major considerations raised by a pandemic, including protecting human and animal health; transportation and borders; and international, security, and institutional considerations.

Federal Leadership Roles Are Unclear, Evolving, and Untested

Several federal leadership roles involve shared responsibilities for preparing for and responding to an influenza pandemic, including the Secretaries of Health and Human Services and Homeland Security, the Administrator of the Federal Emergency Management Agency (FEMA), a national Principal Federal Official (PFO), and regional PFOs and Federal Coordinating Officers (FCO). Many of these leadership roles and responsibilities have not been tested under pandemic scenarios, leaving unclear how all of these new and developing relationships would work.

Federal Leadership Roles and Responsibilities Are Unclear and Evolving

The Strategy and Plan do not clarify the specific leadership roles and responsibilities for a pandemic. Instead, they restate the existing leadership roles and responsibilities, particularly for the Secretaries of Homeland Security and Health and Human Services, prescribed in the National Response Plan (NRP)—an all-hazards plan for emergencies ranging from hurricanes to wildfires to terrorist attacks. How-

ever, the leadership roles and responsibilities prescribed under the NRP need to operate somewhat differently because of the characteristics of a pandemic that distinguish it from other emergency incidents. For example, because a pandemic influenza is likely to occur in successive waves, planning has to consider how to sustain response mechanisms for several months to over a year—issues that are not clearly addressed in the Plan.

In addition, the distributed nature of a pandemic, as well as the sheer burden of disease across the nation, means that the support states, localities, and tribal entities can expect from the federal government would be limited in comparison to the aid it mobilizes for geographically and temporarily bounded disasters like earthquakes and hurricanes. Consequently, legal authorities, roles and responsibilities, and lines of authority at all levels of government must be clearly defined, effectively communicated, and well understood to facilitate rapid and effective decision making. This is also important for public and private sector organizations and international partners so everyone can better understand what is expected of them before and during a pandemic.

The Strategy and Plan state that the Secretary of Health and Human Services is responsible for leading the medical response in a pandemic, while the Secretary of Homeland Security is responsible for overall domestic incident management and federal coordination. However, since a pandemic extends well beyond health and medical boundaries, to include sustaining critical infrastructure, private sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations, it is not clear when, in a pandemic, the Secretary of Health and Human Services would be in the lead and when the Secretary of Homeland Security would lead.

A pandemic could threaten our critical infrastructure, such as the capability to deliver electricity or food, by removing essential personnel from the workplace for weeks or months. The extent to which this would be considered a medical response with the Secretary of Health and Human Services in the lead, or when it would be under the Secretary of Homeland Security's leadership as part of his/her responsibility for ensuring that critical infrastructure is protected, is unclear. According to HHS officials we interviewed, resolving this ambiguity will depend on several factors, including how the outbreak occurs and the severity of the pandemic. Although DHS and HHS officials emphasize that they are working together on a frequent basis, these roles and responsibilities have not been thoroughly tested and exercised.

Moreover, under the Post-Katrina Emergency Management Reform Act of 2006 (referred to as the Post-Katrina Reform Act in this testimony), the FEMA Administrator was designated the principal domestic emergency management advisor to the President, the HSC, and the Secretary of Homeland Security, adding further complexity to the leadership structure in the case of a pandemic.³ The act also gives the Administrator responsibility for carrying out a national exercise program to test and evaluate national preparedness for responding to all-hazards, including an influenza pandemic.

Other evolving federal leadership roles include those of PFOs and FCOs. To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary of Homeland Security predesignated a national PFO and established five pandemic regions each with a regional PFO and FCO. PFOs are responsible for facilitating federal domestic incident planning and coordination, and FCOs are responsible for coordinating federal resources support in a presidentially declared major disaster or emergency. However, the relationship of these roles to each other as well as with other leadership roles in a pandemic is unclear.

U.S. Coast Guard and FEMA officials we met with recognized that planning for and responding to a pandemic would require different operational leadership roles and responsibilities than for most other emergencies. For example, a FEMA official said that given the number of people who would be involved in responding to a pandemic, collaboration between HHS, DHS, and FEMA would need to be greater than for any other past emergencies. Officials are starting to build on these relationships. For example, some of the federal officials with leadership roles for an influenza pandemic met during the week of March 19, 2007, to continue to identify issues and begin developing solutions. One of the participants told us that although additional coordination meetings are needed, it may be challenging since there is no dedicated funding for the staff working on pandemic issues to participate in these and other related meetings.

It is also unclear whether the newly established national and regional positions for a pandemic will further clarify leadership roles in light of existing and newly

³Pub. L. No. 109–295, Title VI.

emerging plans and issues. For example, in 2006, DHS made revisions to the NRP and released a Supplement to the Catastrophic Incident Annex—both designed to further clarify federal roles and responsibilities and relationships among federal, state, and local governments and responders. However, we reported in February 2007 that these revisions had not been tested and there was little information available on the extent to which these and other actions DHS was taking to improve readiness were operational.⁴ We also reported in May 2007 that FEMA has predesignated five teams of FCOs and PFOs in the Gulf Coast and eastern seaboard states at risk of hurricanes. However, there is still some question among state and local first responders about the need for both positions and how they will work together in disaster response.⁵

More recently, DHS reviewed the NRP and its supplemental documents. One of the issues this review intended to address was clarifying roles and responsibilities of key structures, positions, and levels of government, including the role of the PFO and that position's current lack of operational authority over the FCO during an emergency. On September 10, 2007, DHS released a draft National Response Framework to replace the NRP, for public comment. Comments on the framework are due October 11, 2007, and comments on the supplemental documents, such as revised Emergency Support Function specifications, are due by November 9, 2007.

Exercising and Testing of Plans Is Crucial in Ensuring Capacity

Disaster planning, including for a pandemic influenza, needs to be tested and refined with a rigorous and robust exercise program to expose weaknesses in plans and allow planners to refine them. Exercises—particularly for the type and magnitude of emergency incidents such as a severe influenza pandemic for which there is little actual experience—are essential for developing skills and identifying what works well and what needs further improvement. Our prior work examining the preparation for and response to Hurricane Katrina highlighted the importance of realistic exercises to test and refine assumptions, capabilities, and operational procedures, and build upon strengths.⁶

While pandemic influenza scenarios have been used to exercise specific response elements, such as the distribution of stockpiled medications at specific locations or jurisdictions, no national exercises have tested the new federal leadership structure for pandemic influenza.⁷ The only national multisector pandemic exercise to date was a tabletop simulation conducted by members of the cabinet in December 2005. This tabletop exercise was prior to the release of the Plan in May 2006, the establishment of a national PFO and regional PFO and FCO positions for a pandemic, and enactment of the Post-Katrina Reform Act.

Gaps in the National Strategy and Plan Limit Their Usefulness

Our work found that the Strategy and Plan do not address all of the characteristics of an effective national strategy as identified in our prior work. While national strategies necessarily vary in content, the six characteristics we identified apply to all such planning documents and can help ensure that they are effective management tools. Gaps and deficiencies in these documents are particularly troubling in that a pandemic represents a complex challenge that will require the full understanding and collaboration of a multitude of entities and individuals. The extent to which these documents, that are to provide an overall framework to ensure preparedness and response to a pandemic influenza, fail to adequately address key areas could have critical impact on whether the public and key stakeholders have a clear understanding and can effectively execute their roles and responsibilities.

Specifically, we found that the documents fully address only one of the six characteristics of an effective national strategy—problem definition and risk assessment—because they identified the potential problems associated with a pandemic as well as potential threats, challenges, and vulnerabilities. The Strategy and Plan did not address one characteristic—resources, investments, and risk management—because they did not discuss the financial resources and investments needed to implement the actions called for and therefore, do not provide a picture of priorities or how adjustments might be made in view of resource constraints. They partially addressed the four remaining characteristics, as shown in table 1.

⁴GAO, *Homeland Security: Management and Programmatic Challenges Facing the Department of Homeland Security*, GAO-07-398T (Washington, D.C.: Feb. 6, 2007).

⁵GAO, *Homeland Security: Observations on DHS and FEMA Efforts to Prepare for and Respond to Major and Catastrophic Disasters and Address Related Recommendations and Legislation*, GAO-07-835T (Washington, D.C.: May 15, 2007).

⁶GAO, *Hurricane Katrina: GAO's Preliminary Observations Regarding Preparedness, Response, and Recovery*, GAO-06-442T (Washington, D.C.: Mar. 8, 2006).

⁷Congressional Research Service, *Pandemic Influenza: Domestic Preparedness Efforts*, RL 33145 (Washington, D.C.: Feb. 20, 2007).

Table 1: Extent to Which the Strategy and Plan Address GAO's Desirable Characteristics of an Effective National Strategy

Desirable characteristic	Addresses	Partially addresses	Does not address
Clear purpose, scope, and methodology		X	
Problem definition and risk assessment	X		
Goals, subordinate objectives, activities, and performance measures		X	
Resources, investments, and risk management			X
Organizational roles, responsibilities, and coordination		X	
Integration and implementation		X	

Source: GAO analysis of the National Strategy for Pandemic Influenza and Implementation Plan for the National Strategy for Pandemic Influenza.

More specifically, the following are highlights of some of the gaps in the Strategy and Plan.

- *The Strategy and Plan do not address resources, investments, and risk management.* Developing and sustaining the capabilities stipulated in the Plan would require the effective use of federal, state, and local funds. Given that funding needs may not be readily addressed through existing mechanisms and could stress existing government and private resources, it is critical for the Plan to lay out funding requirements. For example, one of the primary objectives of domestic vaccine production capacity is for manufacturers to produce enough vaccine for the entire U.S. population within 6 months. However, the Plan states that production capacity would depend on the availability of future appropriations. Despite the fact that the production of enough vaccine for the population would be critical if a pandemic were to occur, the Plan does not provide even a rough estimate of how much the vaccine could cost for consideration in future appropriations.
 - *State and local jurisdictions were not directly involved in developing the Strategy and Plan.* Neither the Strategy nor Plan described the involvement of key stakeholders, such as state, local, and tribal entities, in their development, even though these stakeholders would be on the front lines in a pandemic and the Plan identifies actions they should complete. Officials told us that state, local, and tribal entities were not directly involved in reviewing and commenting on the Plan, but the drafters of the Plan were generally aware of their concerns.
 - *Relationships and priorities among action items are not always clear.* While some action items depend on other action items, these linkages are not always apparent in the Plan. An HHS official who helped draft the Plan acknowledged that while an effort was made to ensure linkages among action items, there may be gaps in the linkages among interdependent action items within and across the Plan's chapters that focused on such issues as human health, animal health, and transportation and borders considerations.
- In addition, we found that the Plan does not establish priorities among its 324 action items, which becomes especially important as agencies and other parties strive to effectively manage scarce resources and ensure that the most important steps are accomplished.
- *Performance measures are focused on activities that are not always linked to results.* Most of the Plan's performance measures are focused on activities such as disseminating guidance, but the measures are not always clearly linked with intended results. This lack of linkages to outcomes and results makes it difficult to ascertain whether progress has in fact been made toward achieving the national goals and objectives described in the Strategy and Plan.
 - *The linkage of the Strategy and Plan with other key plans is unclear.* Although the Strategy states that it is consistent with the National Security

Strategy and the National Strategy for Homeland Security, it does not state how it is consistent or describe the relationships with these two strategies. In addition, the Plan does not specifically address how the Strategy, Plan, or other related pandemic plans should be integrated with the goals, objectives, and activities of the national initiatives already in place, such as the interim National Preparedness Goal.

Further, the Strategy and Plan do not provide sufficient detail about how the Strategy, action items in the Plan, and a proposed set of agency plans are to be integrated with other national strategies and frameworks. For example, the Plan contains 39 action items that are response related (i.e., specific actions are to be taken within a prescribed number of hours or days after an outbreak). However, these action items are interspersed among the 324 action items, and the Plan does not describe the linkages of these response-related action items with the NRP or other response related plans.

- *The Plan does not contain a process for monitoring and reporting on progress.* While most of the action items have deadlines for completion, ranging from 3 months to 3 years, the Plan does not identify a process to monitor and report on the progress of the action items nor does it include a schedule for reporting progress. According to agency officials, the HSC is monitoring executive branch agencies' efforts to complete the action items. However, there is no specific documentation describing this process or institutionalizing it. This is important since some of the action items are not expected to be completed during this administration. Also, a similar monitoring process for those actions items for which nonfederal entities have the lead responsibility does not appear to exist. Additionally, there is no explicit timeline for the HSC to report on the overall progress and thus, when progress is reported is left to the HSC's discretion.

- *The Plan does not describe an overall framework for accountability and oversight.* While the plan contains broad information on roles and responsibilities and describes coordination mechanisms for responding to a pandemic, it does not, as noted earlier, clarify how responsible officials would share leadership responsibilities. In addition, it does not describe an overall accountability and oversight framework. Agency officials told us that they had identified individuals to act as overall coordinators to monitor the action items for which their agencies have lead responsibility and provide periodic progress reports to the HSC. However, we could not identify a similar oversight mechanism for the action items that fall to state and local governments or the private sector. This is a concern since some action items, particularly those that are to be completed by state, local, and tribal governments or the private sector, do not identify an entity accountable for carrying out the action.

- *Procedures and time frames for updating and revising the Plan were not established.* The Plan does not describe a mechanism for updating it to reflect policy decisions, such as clarifications in leadership roles and responsibilities and other lessons learned from exercises, or to incorporate other needed changes. Although the Plan was developed as initial guidance and was intended to be updated and expanded over time, officials in several agencies told us that specific processes or time frames for updating and revising it have not been established.

Opportunities Exist To Clarify Federal Leadership Roles and Improve Pandemic Planning

A pandemic poses some unique challenges and would be unlike other emergencies given the likelihood of its duration and geographic coverage. Initial actions may help limit the spread of an influenza virus, reflecting the importance of a swift and effective response. Therefore, the effective exercise of shared leadership roles and implementation of pandemic plans could have substantial consequences, both in the short and long term.

Since no national pandemic exercises of federal leadership roles and responsibilities have been conducted since the release of the Plan in May 2006, and key leadership roles continue to evolve, rigorous testing, training, and exercising is needed. Exercises test whether leadership roles and responsibilities, as well as procedures and processes, are clear and well-understood by key stakeholders. Additionally, they help identify weaknesses and allow for corrective action to be taken before an actual emergency occurs. Consequently, in our August 2007 report, we recommended that the Secretaries of Homeland Security and Health and Human Services work together to develop and conduct rigorous testing, training, and exercises for pandemic influenza to ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges. Once the leadership roles have been clarified through testing, training, and exercising, the Secretaries of Homeland Security and Health

and Human Services should ensure that these roles and responsibilities are clearly understood by state, local, and tribal governments; the private and nonprofit sectors; and the international community. DHS and HHS concurred with the recommendation, and DHS stated that it is taking action on many of the shortfalls identified in the report.

The Strategy and Plan are important because they broadly describe the federal government's approach and planned actions to prepare for and respond to a pandemic and also set expectations for states and communities, the private sector, and global partners. The extent to which the Strategy and Plan fail to adequately address key areas could have a critical impact on whether key stakeholders and the public have a clear understanding of their roles and responsibilities. However, gaps in the Strategy and Plan limit their usefulness as a management tool for ensuring accountability and achieving results. The plan is silent on when information will be reported or when it will be updated. Although the HSC publicly reported on the status of action items in December 2006 and July 2007, it is unclear when the next report will be issued or how much information will be released. This lack of transparency makes it difficult to inform a national dialogue on the progress made to date or what further steps are needed. It also inhibits congressional oversight of strategies, funding priorities, and critical efforts to enhance the nation's level of preparedness.

Therefore, in our August 2007 report we recommended that the HSC establish a specific process and time frame for updating the Plan. We stated that this process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. Further, we stated that the Plan could be improved by including the following information in the next update: (1) resources and investments needed to complete the action items and where they should be targeted, (2) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (3) clearer linkages with other strategies and plans, and (4) clearer descriptions of relationships or priorities among actions items and greater use of outcome-focused performance measures. The HSC did not comment on the draft report.

Mr. Chairman and Members of the Subcommittee, this completes my statement. I would be pleased to respond to any questions that you might have.

Mr. LANGEVIN. Thank you for your statement.

I would now recognize Dr. Jolly to summarize his statement for 5 minutes.

Welcome.

**STATEMENT OF DR. B. TILMAN JOLLY, ASSOCIATE CHIEF
MEDICAL OFFICER, MEDICAL READINESS, OFFICE OF
HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY**

Dr. JOLLY. Thank you, Mr. Chairman, Ranking Member McCaul and members of the subcommittee. Thank you for the opportunity to testify before the subcommittee to discuss the progress of the National Strategy for Pandemic Influenza and its Implementation Plan.

Before I begin, I would like to take this opportunity to thank you and members of the full committee on behalf of Secretary Chertoff for your continued willingness to work alongside the Department to provide leadership in protecting and ensuring the security of our homeland.

I would also like to thank our partners at the Department of Health and Human Services and others with whom we work every day.

Pandemic influenza is unique. It is likely to come in waves, passing through communities of all sizes across the nation and the world simultaneously. The pandemic may last as long as 18 months.

An unmitigated pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity.

Further, an influenza pandemic could have major impacts on society and the economy, including our nation's critical infrastructure and key resources based on illness and related absenteeism.

DHS has been and remains actively engaged with its federal, state, local, territorial, tribal and private sector partners to prepare our nation and the international community for an influenza pandemic.

As outlined in the Implementation Plan, DHS is responsible for the coordination of the overall domestic federal response during an influenza pandemic, including implementing policies that facilitate compliance with recommended social distancing measures, developing a common operating picture for all federal departments and agencies, and ensuring the integrity of the nation's infrastructure, domestic security, and entry and exit screening for influenza at the borders.

In working with our partners, such as HHS, the State Department and USDA, DHS has developed and implemented a number of initiatives and outreach to support continuity of operations planning for all levels of government and private-sector entities.

I will highlight a few noteworthy accomplishments and responsibilities under the Implementation Plan particular to DHS. DHS produced and released the Pandemic Influenza Preparedness, Response and Recovery Guide for Critical Infrastructure and Key Resources.

The guide has served to support business and other private sector pandemic planning by complementing and enhancing, not replacing, their existing continuity planning efforts.

With that in mind, DHS and its partners developed the guide to assist businesses whose existing continuity plans generally do not include strategies to protect human health during emergencies like a pandemic.

As a next step, DHS is currently leading the development of specific guides for each of the 17 critical infrastructure and key resource sectors using the security partnership model.

In coordination with other federal departments and agencies, DHS is developing a coordinated government-wide planning forum. An initial analysis of the response requirements for federal support has been completed.

From this analysis, a national plan defining the federal concept for coordinating response and recovery operations during a pandemic has been developed and will be undergoing interagency review.

Utilizing this planning process, a coordinated federal border management plan has been developed and is currently also in review. This process included a wide range of partners.

DHS has also conducted or participated in federal and state interagency pandemic influenza exercises and workshops and forums with critical infrastructure key resources owners and operators.

Consistent with his role under Homeland Security Presidential Directive 5, Secretary Chertoff pre-designated Vice Admiral Vivien Crea, the Vice Commandant of the U.S. Coast Guard, as the national Principal Federal Official, or PFO, for pandemic influenza, and has pre-designated five regional PFOs and 10 deputy PFOs.

Likewise, our partners have pre-designated infrastructure liaisons, Federal Coordinating Officers, senior officials for health as well as defense coordinating officers.

Vice Admiral Crea and the regional PFOs have participated in multiagency training and coordination sessions regarding preparedness duties.

Additionally, the PFO teams have begun outreach both nationally and in their regions in advance of the more formalized exercise program which is being developed by DHS.

On an ongoing basis, DHS participates in interagency working groups to develop guidance, including community mitigation strategies, medical countermeasures, vaccine prioritization and risk communication strategies.

In closing, significant progress has been made in national preparedness for pandemic influenza. In fact, September is National Preparedness Month, which encourages all Americans to prepare for emergencies and take necessary actions for all hazards.

DHS looks forward to continuing its partnership with the federal interagency, state, local, tribal, territorial and private sector stakeholders to complete the work of pandemic preparedness and to further the nation's ability to prepare for, respond to and recover from all hazards.

Thank you again for the opportunity to testify on behalf of the Department of Homeland Security on these issues of critical importance to our nation's security and well-being. I would be happy to answer any questions you might have.

[The statement of Dr. Jolly follows:]

PREPARED STATEMENT OF B. TILMAN JOLLY, MD

Mr. Chairman, Ranking Member McCaul and Members of the Subcommittee:

Thank you for the opportunity to testify before the Subcommittee to discuss the progress of the National Strategy for Pandemic Influenza and its Implementation Plan. I am Dr. Til Jolly, Associate Chief Medical Officer for Medical Readiness, within the Office of Health Affairs at the Department of Homeland Security (DHS). Before I begin, I would like to take this opportunity to thank you and Members of the full Committee on behalf of Secretary Chertoff for your continued willingness to work alongside the Department to provide leadership in protecting and ensuring the security of our homeland. I would also like to thank our partners at the Department of Health and Human Services (HHS) and others with whom we work every day.

To begin, I would like to take a few moments to review some basic facts about pandemics and their potential impacts on our nation. Pandemic influenza occurs when a novel strain of influenza virus emerges that has the ability to infect humans and to cause severe disease, and when efficient and sustained transmission between humans occurs. This scenario creates unique challenges. Unlike other incidents, a pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, passing through communities of all sizes across the nation and the world simultaneously. The complete pandemic cycle may last as long as 18 months. Based on projections modeled by the Department of Health and Human Services from prior pandemics, an influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity. Further, an influenza pandemic could have major impacts on society and the economy, including our nation's critical infrastructure and key resources, as many of our nation's workforce could be absent for extended periods of time, either sick themselves or caring for loved ones at home.

The Implementation Plan for the National Strategy for Pandemic Influenza was released over a year ago by the President's Homeland Security Council to guide our nation's preparedness and response to an influenza pandemic. DHS has been actively engaged with its federal, state, local, territorial, tribal, and private sector partners to prepare our nation and the international community for an influenza pandemic. As outlined in the Implementation Plan DHS is responsible for the co-

ordination of the overall domestic Federal response during an influenza pandemic, including implementation of policies that facilitate compliance with recommended social distancing measures, development of a common operating picture for all Federal departments and agencies, and ensuring the integrity of the Nation's infrastructure, domestic security and entry and exit screening for influenza at the borders.

To date DHS has accomplished over 80% of the requirements outlined in the Implementation Plan. DHS recognizes the key role of HHS in its responsibilities to lead clinical disease surveillance and rapid detection during a pandemic, and, under Emergency Support Function (ESF)-8, to plan, prepare, mitigate and support the coordination of the public health and medical emergency response activities during a pandemic under ESF-8, including the deployment and distribution of vaccines and of antivirals and other life-saving medical countermeasures from the Strategic National Stockpile. DHS also recognizes the Department of State's role to lead the coordination of international efforts including U.S. engagement in a broad range of bilateral and multilateral initiatives that build cooperation and capacity to fight the spread of avian influenza, to prepare for a possible pandemic, and to coordinate with our neighbors Canada and Mexico. The Department of Agriculture (USDA) conducts surveillance for influenza in domestic animals and animal products, monitoring wildlife in partnership with the Department of the Interior, and working to ensure an effective veterinary response to a domestic animal outbreak of highly pathogenic avian influenza.

In working with our partners DHS has developed and implemented a number of initiatives and outreach to support continuity of operations planning for all levels of government and private sector entities. I will highlight a few noteworthy accomplishments and responsibilities under the Implementation Plan particular to DHS.

DHS produced and released the *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources (Guide)*. Tailored to national goals and capabilities, and to the specific needs identified by the private sector, this business continuity guidance represents an important first step in working with the owners and operators of critical infrastructure to prepare for a potentially severe pandemic outbreak. The *Guide* has served to support business and other private sector pandemic planning by complementing and enhancing, not replacing, their existing continuity planning efforts. With that in mind, the Federal government developed the *Guide* to assist businesses whose existing continuity plans generally do not include strategies to protect human health during emergencies such as those caused by pandemic influenza or other diverse natural and manmade disasters.

DHS is currently leading the development of specific guides for each of the 17 critical infrastructure and key resource sectors. These include agriculture, food, and water, public health, emergency services, telecommunications, banking, defense systems, transportation, energy resources, and others. These guides are being developed utilizing the security partnership model and in collaboration with our Federal partners.

In coordination with other Federal departments and agencies, DHS is developing a coordinated government-wide planning forum. An initial analysis of the response requirements for Federal support has been completed. From this analysis, a national plan defining the federal concept for coordinating response and recovery operations during a pandemic has been developed and will be undergoing interagency review. Utilizing this planning process, a coordinated federal border management plan has been developed and is currently in review. This process included state, local, tribal, territorial, and private sector stakeholder input, along with our Federal interagency partners.

DHS has conducted or participated in federal and state interagency pandemic influenza exercises which have focused on varied issues related to preparedness. These exercises have included:

- FEMA's Determined Accord series for continuity of operations with federal, state, local, tribal, territorial entities.
- Several Customs and Border Protection exercises—addressing transportation and border challenges.
- A U.S. Fire Administration tabletop exercise for development of best practices models and protocols for EMS, 911 Call Centers, Fire Services, Emergency Managers, Law Enforcement and Public Works. This will allow for further integration of a unified Federal, state, local and private sector emergency response capabilities.
- HHS sponsored regional National Governors Association Pandemic Influenza exercises, CDC funded and provided guidance for state and local exercises, and DOD pandemic influenza exercises.

- Multiple workshops and forums with the owners and operators of critical infrastructure and key resources.

Consistent with his role under Homeland Security Presidential Directive (HSPD) 5, Secretary Chertoff pre-designated Vice Admiral Crea, the Vice Commandant of the US Coast Guard, as the National Principal Federal Official (PFO) for pandemic influenza and has pre-designated five regional PFOs and 10 deputy PFOs. Likewise, our partners have pre-designated Infrastructure Liaisons, Federal Coordinating Officers, Senior Officials for health as well as Defense Coordinating Officers. VADM Crea and the Regional PFOs have participated in several training sessions regarding preparedness duties, and have held two orientation sessions to date. These sessions included updates from the Department of State, the Department of Agriculture, the Department of Health and Human Services, the Department of Defense, as well as updates from various DHS components and staff regarding their work to date. Additionally, the PFO teams have begun outreach both nationally and in their regions in advance of a more formalized exercise program which is being developed by DHS.

On an ongoing basis, DHS participates in interagency working groups to develop guidance including community mitigation strategies, medical countermeasures, vaccine prioritization, and risk communication strategies. These groups bring together a wide range of federal partners to discuss preparedness issues.

In closing, significant progress that has been made in national preparedness for pandemic influenza. In fact, September is National Preparedness Month, which encourages all Americans to prepare for emergencies and take the necessary actions for all-hazards. Many of these accomplishments can be incorporated into an all-hazards framework to promote the national culture of preparedness. DHS looks forward to continuing its partnership with the federal interagency, state, local, tribal, territorial, and private sector stakeholders to complete the work of pandemic preparedness and to further the nation's ability to prepare for, respond to, and recover from all-hazards.

Thank you again for the opportunity to testify on behalf of the Department of Homeland Security on these issues of critical importance to our nation's security and well-being. I would be happy to answer any questions you might have.

Mr. LANGEVIN. Thank you, Dr. Jolly, for your testimony.

I now recognize Dr. Vanderwagen to summarize his statement for 5 minutes.

Welcome.

**STATEMENT OF RADM W. CRAIG VANDERWAGEN, MD,
ASSISTANT SECRETARY FOR PREPAREDNESS AND
RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. VANDERWAGEN. Thank you, Mr. Chairman.

And it is a great opportunity to come and visit with you about the partnership between the legislative and the executive branch that I think we have moved forward aggressively on over the last couple of years.

As you may know, the Assistant Secretary for Preparedness and Response was established approximately 10 months ago under the Pandemic and All-Hazards Preparedness Act.

We had significant responsibilities transferred to us and significant new authorities. We have tried to execute those in a very timely manner. We have transferred NDMS. We have transferred the Hospital Preparedness Program. We have transferred the ESAR-VHP program.

We have taken on new authorities under BARDA. We are standing up the National Biodefense Science Board. And the list of accomplishments requested under the law we would be happy to share with you in detail if you are interested.

However, I would note that in August there was a transfer of responsibility to the ASPR from the Assistant Secretary for Health for pandemic planning and coordination within HHS.

So I am here today to speak specifically about pandemic flu. And you have articulated, I think, most succinctly the threat, the risk and what the challenges are.

I believe that over the last year there has been significant progress. I agree with Mr. McCaul. There has been significant progress jointly among the states and the federal government.

There is a strong federal lift strategically planned to purchase the ability to develop and deliver vaccines as part of our overall strategic goal.

And as was noted by both of you, our strategic goal here, our theory of victory, is a delay of this disease spread and a reduction in the absolute number of individuals who will be affected by the disease.

And the first line investments to assure that included the development of domestic capability in the production and delivery of vaccines and antivirals and diagnostics that would allow us to be very astute in the way we employed those techniques in reducing the rate of infection.

But as has been noted, it is also now time for us to review and update what are the gaps that still persist and what are the challenges that are ahead.

Our belief is it should be built upon some of the success that has occurred.

Accordingly, with our vaccine investments and our investments in newer antivirals and in diagnostic capability, we are monitoring those production capabilities and we have set up milestones for that performance of activity and our funds that we have remaining, and we have spent about \$3 billion or so.

The balance of funds are established as a reserve to continue that progress and development as they achieve certain milestones.

But there are persistent gaps, as I said. Those gaps exist in respiratory protection. They exist in how we can make community mitigation even more effective potentially using the expanded production capability in antivirals to perhaps use antivirals in a prophylactic mode as opposed to a pure treatment mode, which is where our previous investments have been.

These next steps, however, have to be built upon the concept of shared responsibility. Again, as you both stated, the role of state and local governments, of business and, indeed of individuals and families needs to be explored further.

And their engagement in the gap filling process needs to be active and needs to be present. We have started that process here in the last couple of months and have met with business interests, public health interests, medical interests in Seattle, in Raleigh.

We have other opportunities planned ahead for engagement of those stakeholders in this process. And we think that that will help us to determine how to divide the shared responsibility for development of approaches to meeting those gaps.

There is a sustainment challenge that also lies out there in front of us as well, because what we build today has to be sustained over time, and those issues will need to be addressed. If not right this minute, they will need to be addressed in the way ahead.

So in summary, ASPR has stood up. We accept the responsibility. We work closely with our partners and view ourselves as being an

integral part of the team led by DHS, but our shared responsibility demands that we reach out to our stakeholders at the state, local, family and individual level if we are going to move ahead with the new steps that remain to be addressed.

And with that, I will stop and be happy to address questions.
[The statement of Dr. Vanderwagen follows:]

PREPARED STATEMENT OF RADM WILLIAM C. VANDERWAGEN, MD

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 Million (\$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 fiscal year 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.

T3Countermeasure 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 million doses)
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

- **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.

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

- *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 fiscal year 08 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 million doses 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:

—*Maine*

- 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.

Mr. LANGEVIN. Thank you, Dr. Vanderwagen.

I thank all the witnesses for their testimony. Each of the members will have 5 minutes to question the panel. And I now recognize myself for questions.

Again, I want to thank you all for your testimony. Let me address a question to the panel.

To me, it would seem that an effective system of planning and response to pandemic influenza is one in which it would have broad-ranging benefits in other areas of public health threat, whether naturally occurring or manmade.

So my question would be how does pandemic flu planning help in other ways? And what are we doing to ensure that it is helping in other ways?

Again, it would seem to me that we should be thinking about this as we develop plans so that we might spend dollars more efficiently.

Dr. JOLLY. I will begin, sir. I think that you are correct. There are a number of ways in which a pandemic planning process can assist other planning processes.

In the health focus, which I think Admiral Vanderwagen will focus on, there are certainly some areas of synergy. And outside of the purely health realm, when we think of operations of critical infrastructures, continuity planning and complex organizational structures that may be required for complex crises, the pandemic planning we have done related to those issues certainly can help those.

There are some unique aspects, as we have discussed, with pandemic—the length of time that it lasts, the wave nature and some of the specific issues. But some of those continuity planning processes and the operational planning at the federal level certainly apply to those.

And we have really taken the tack now of trying to apply those to a broader set of hazards.

Dr. VANDERWAGEN. Yes, I agree with Til wholeheartedly, and I will just give you one example. And, sir, I have been to your state, Rhode Island, and visited the Rhode Island Medical Center, visited with the staff up there.

There are great examples of how all-hazards preparedness as applied to pandemic or any other disaster are demonstrated, and I expect that we will hear some of that today.

This first part of the week I was down in North Carolina for a couple of days visiting with them around their planning. And last year alone in North Carolina, they conducted 87 exercises for pandemic flu.

But what was clear was that they were using assets that they would deploy and involve in just about any sort of hazard. Hurricane is one that they live with frequently there in North Carolina.

But the exercises, while focused on pandemic flu and some of the unique qualities, as Til suggested, they were exercising the whole system—the communication between public safety and health, the delivery of assets to communities, and that could be for any infectious disease or other demand.

So I think there are some great examples where the states and localities really are using pandemic to build an all-hazards response base while having the unique capabilities for pandemic.

Ms. STEINHARDT. If I can just add to Dr. Vanderwagen's comments, the important thing in any emergency that requires the enormous amount of coordination across multiple sectors and multiple actors is building those relationships before emergencies occur.

You can't start getting to know people in the middle of an emergency. So having those relationships in place, understanding who one is supposed to turn to—all of that is very vital to being able to respond effectively in an emergency.

And so any kind of planning and exercising that forges those relationships is going to benefit us in any emergency.

Mr. LANGEVIN. Let me follow up with this. Some would argue that the grant strategy—the grants that are offered to states, for example, are not well coordinated and that, you know, you can spend money if it is for preparedness for pandemic flu, but you are not able to spend that money in other areas that could be part of the response system to a public health threat.

And someone argued that there is not good coordination in how you are writing and offering grants to states and other areas.

So can you comment on that, you know, the coordination between DHS and HHS grants, for example?

Dr. VANDERWAGEN. Yes. And there is a real risk there of a disconnect and bureaucratic silos at play.

But I think that the most recent amount of money that we provided to the states, \$75 million for pandemic flu, included guidance that would allow them to purchase assets that have utility in other than pandemic flu—ventilators, for instance, may be useful in a variety of settings not limited to pandemic flu.

In terms of engagement with our DHS colleagues—and again, I will give you a North Carolina example. They were looking to develop a paratransit capability for evacuation of patients with special needs.

And what they were able to do was merge USERA grants, CDC grants and the ASPR Hospital Preparedness grants using the authorities of each one of those to put together a package that would allow them to purchase and have constructed the appropriate paratransit equipment.

It takes extreme work and communication on our part at the federal level, but I think the states that have been most successful also take a collaborative internal approach to this where they look at all the grants and they look at how they can use it for the ends that they are really trying to achieve.

So I think it takes work at both the federal level and the state level to try and make those work effectively together.

Dr. JOLLY. And I would concur with Admiral Vanderwagen and Ms. Steinhardt that the opportunities in pandemic preparedness based on the grant funding for pandemic really play out in overall all-hazards preparedness, giving public health, emergency management, security, law enforcement—all the elements that come to play in complex crises—an opportunity to sit down together and go through scenarios, while mostly focused on pandemic in this case, allow them to get to know each other, get to know their various needs and the unique aspects of their roles, and help to coordinate those, and can only have benefits for other crises.

Ms. STEINHARDT. I hope to be able to answer your question better in a few months, because we are actually looking at these issues of state and local planning and exercising currently in an ongoing engagement for this committee.

But I want to say now that one of the things we have observed is that this is a longstanding, I think, challenge to better integrate not only the funding but the communities themselves of public health and emergency management.

They still speak different languages. They have different vocabularies. They are getting to know one another. And I think around pandemic planning is the immediate task at hand, but it will work in other areas as well.

Mr. LANGEVIN. Thank you.

Let me turn to the GAO, to Ms. Steinhardt, for a minute. I was troubled when I read in the GAO's report on the National Strategy that both the Secretary of Homeland Security and the Secretary of Health and Human Services would be co-leaders during an influ-

enza pandemic but that how they would actually lead at the same time has not yet been made clear.

You made reference to this in your opening statement. Could you expand on this finding?

Ms. STEINHARDT. This is a kind of new model for us in the federal government to have these shared responsibilities.

I think it is appropriate to recognize that for the major challenges like pandemic influenza that face the nation that it does take the efforts of multiple departments and competencies.

But how exactly that works still has to be figured out. That is why we argued so strongly for having tests and exercises. Only when you go through a simulation of an actual situation can those kinds of details be worked out.

We understand it conceptually, but how it would work in practice we need to see.

Mr. LANGEVIN. As a follow up, Dr. Jolly and Dr. Vanderwagen, during a pandemic when would the Secretary of Homeland Security lead and when would the Secretary of Health and Human Services lead?

Dr. JOLLY. Well, under the construct, the Secretary of Homeland Security is responsible for overall domestic preparedness and incident coordination at the federal level and would lead the overall federal activities, while the Secretary of Health and Human Services led the health and medical response, which is a very large job just by itself.

And our PFO group, our Principal Federal Official group, working with HHS, FEMA, our operations—and others are working through the exact specifics of how that works down at the lower levels.

Dr. VANDERWAGEN. Yes. I agree with that. We, I think, understand ourselves as having a finite and discrete responsibility under the overall leadership of DHS.

Where this becomes an incident that has national significance, there is no question, the leadership resides with the Secretary of Homeland Security.

With regards to public messaging, with regards to strategic thinking about application of assets to the medical and public health piece, we have that responsibility, but that still resides under the overall leadership of the secretary of homeland security.

And the constructs—that is, the actual operational planning—is as Til has described, and I think Ms. Steinhardt did as well. That operational construct is now being established.

And in fact, we have tested it some in that Vice Admiral Crea and some of her folks have participated in CDC exercises around pandemic flu to begin to see how the health nests under her leadership.

Mr. LANGEVIN. Well, this is obviously an area we want to continue to watch and to be involved in. Obviously, we can't wait until an actual event occurs and hope that, you know, the left hand knows what the right hand is doing.

And as Ms. Steinhardt pointed out, you know, conducting exercises and actually simulating this is really the best way to make sure it is going to function properly in the event that a national emergency like this would occur.

With that, I now recognize—well, actually, before I do that, let me just welcome the gentleman from New Jersey, Mr. Pascrell, who has joined us, and was an original member of the Homeland Security Committee when it was a select committee and left for a brief time when he went on the Ways and Means Committee. And now he is back joining us, as well as being on Ways and Means, also on the Homeland Security Committee.

Welcome back, Bill.

The chair now recognizes the gentleman from Texas for 5 minutes for the purpose of questions.

Mr. McCAUL. I thank the chairman.

I do want to welcome back Mr. Pascrell to the committee. It is good to have you here.

As we approach the flu season, it is a joyful time of the year. I get to drag my five little children, kicking and screaming, to the doctor's office, holding them down as they get their flu vaccines.

We try to anticipate the next sort of mutation, if you will, in preparation for this vaccine, and overall I think we have been very fortunate in terms of our ability to predict and foresee.

The issue with a pandemic would be a mutation that would be unforeseen, some sort of variation like the avian flu that suddenly becomes, you know, transmittable human to human.

And that is a scenario that we obviously are most concerned with. And how do we stop it? As we all know, it has been about 40 years since we have had one in this country, and we are long overdue for that.

My first question is more science related. So for the two doctors that we have, in terms of vaccines, you know, it seems to me that in the event we have a pandemic that is an unforeseen mutation of a virus, the ability to quickly develop a vaccine would be key in terms of minimizing the loss of life.

I know that there has been some research now going from egg-based to cell-based vaccines, and I would like to hear from you in terms of the progress that we have made in that regard in terms of developing, you know, vaccines that we can get to, you know, the market more quickly.

Dr. VANDERWAGEN. Yes. Well, it is an extremely good question, and one that we have really tried to focus on pretty steadily.

Our investments have been with multiple manufacturers to develop cell-based technologies for production in this country.

That doesn't provide a tremendous amount of shortening of the time period from the time the virus is identified until you have a manufacturing capability to put it out there, but it is a cleaner, more modern and sophisticated technology that doesn't depend on chickens for eggs.

And in an avian flu, that is—you know, we have biosecurity and so on, but still, it is shifting to that new technology.

Where we think there will be the breakthrough in terms of reducing the production time from the identification of virus to the actual production capability of vaccine at production levels is with the development of a recombinant vaccine.

And we are about ready to award a contract for a producer of that, and we hope to have a couple producers in that game, not limited to one, that would allow us to see if, in fact, the promise

of an 8-week turnaround instead of a 20-week turnaround is as we think it might be.

That combined with the developments now in adjuvant therapies added to the antigen—remember, the vaccine has an antigen that stimulates your immune system—now the technologies of developing adjuvants that augment that immune response at a much lower dose of antigen.

And the research in this area is also very promising. If it plays out, and there are clinical studies under way now to assure that they are safe and effective, as advertised—if that works out, it may give us a twentyfold increase in our existing pre-pandemic vaccine stockpiles.

And in the future, if we have to produce a new vaccine, it will change the character of how much we need to develop an antigen in order to get a good vaccine with a good immune response.

So progress is moving along very smartly in the technology and science arena here with vaccine development for influenza, particularly pandemic flu.

Mr. MCCAUL. Can you forecast maybe the time frame that that technology would be available?

Dr. VANDERWAGEN. I think the RPA that is the recombinant technology for this—proof of concept is out there. We are talking a year or so. 2010 we think we will have that available—is the way we are thinking about it.

The adjuvants that I mentioned to you may occur sooner than that. In 2009, perhaps we will have final clinical efficacies, and everybody will be convinced that we have got the safe product for pre-use.

Mr. MCCAUL. Dr. Jolly?

Dr. JOLLY. We certainly support that. I think the planning and the community mitigation guidance and other strategies take into account the current situation, but we certainly support further research.

And I think this argues for a couple of things. One, the vaccine research for pandemic can only benefit vaccine research for other diseases.

And I think there is a wide range of things both in the emergency management realm and just in public health that this can really help. If this technology works for one, it can certainly work for others.

I also applaud and sympathize with your efforts to get your family vaccinated.

And that really argues for our increased vigilance and message to the public about seasonal flu and to really utilize the seasonal flu vaccine because seasonal flu is not a trivial matter just by itself.

Mr. MCCAUL. Well, I find it to be a very exciting and promising area, and the other—this is also sort of more science-based, but antivirals—where are we with those?

And also, where are we with the stockpiles in the event of an outbreak?

Obviously, as you mentioned, Dr. Vanderwagen, about the idea of them being used as both prophylactic and after exposure—do we have enough, say Tamiflu and other antivirals? Do we have enough stockpiled right now in the event there is a pandemic outbreak?

Dr. VANDERWAGEN. Well, let me answer the first part of that first, and that is where are we. We are on plan. You may recall that we strategically made the decision to purchase enough to treat everyone that we thought would be at risk and got ill.

And so the planned investment was to purchase adequate amounts with our state partners to treat 25 percent of the population who we projected would be ill. We are on plan for that.

The last purchases to fill out the 81 million treatment courses for that will occur in fiscal year 2008.

With regards to the use of antivirals in prophylaxis, we made that strategic decision about purchasing for treatment because at the time, production capability was fairly limited, 15 million or so a year treatment courses.

Now that production capability is much more robust than that, which gives us the opportunity to visit with our stakeholder partners—the states, businesses, even down to individuals and families—the question of where is the responsibility for shared acquisition if, in fact, the science supports the use.

And that is sort of a question that we are analyzing right now. What is the science base for using antivirals in a prophylaxis environment and what are the risks of doing that in terms of developing resistance, for instance, and therefore losing the utility of the tool?

We are also developing additional antivirals, at least one that attacks at the same spot that Relenza and Tamiflu—I am drawing a blank there—aging, what can I tell you—that is similar in action but can be delivered through the bloodstream parenterally, as we say in medicine, which for extremely sick people would be another alternative that would be very useful.

So there are developments on the horizon. There are some gap questions to be answered both from a science perspective and from a shared responsibility perspective.

But if, in fact, the science supported it and we worked out the shared responsibility, there is a potential use there in post-exposure prophylaxis and for those who are at high risk like medical workers of acquiring the disease.

We know, for instance, in seasonal influenza 15 percent to 30 percent of health workers in hospitals taking care of very ill people with flu get sick. So there is another target population at risk that we need to consider.

Mr. MCCAUL. Ms. Steinhardt and Dr. Jolly, if you could comment on that as well, is our stockpile, national stockpile, of antivirals adequate to meet the need if a pandemic occurs this year?

Ms. STEINHARDT. Well, I can't say that we have assessed that specifically, but I think a lot of it has to do with whether we change the use of antivirals.

If we are using them just as treatment—and obviously, we don't have enough to treat the entire population—or if we are going to use them prophylactically.

But I must say that this is now the opportunity to think about if we do have limited supplies, whether of antivirals or vaccines, if we were to have pandemic influenza in the nearer term, what sort of priorities are we going to set for distributing those supplies. That is, I think, a key question for us.

Mr. MCCAUL. Dr. Jolly?

Dr. JOLLY. I would agree with Craig. We are building up the stockpile, and we are shifting from an analysis that involves purely treatment to potentially a larger amount of that for prophylaxis and trying to develop the science base, because there is no medicine that doesn't have a risk associated with it, and there certainly are risks associated with wide use.

And the other point I would make is that antivirals are not the entire answer. We really want to be careful to make everyone understand that having an antiviral isn't necessarily 100 percent curative or preventative.

But in fact, it is incorporated into a wide range of strategies that don't include pharmaceuticals such as the community mitigation strategies that were led by the CDC with multiple agencies involved that are really part of the overall strategy.

Mr. MCCAUL. I see my time has expired, but I want to close with the same point that the chairman made, and that is the exercises. I think there has been one exercise to date. Was that a tabletop or was that a field exercise?

Ms. STEINHARDT. It was a tabletop exercise, and it was before actually the issuance of the Plan.

Mr. MCCAUL. The Plan. Yes.

I would strongly encourage, Dr. Jolly, that you consider conducting a field exercise in the event a pandemic broke out.

I think having worked with the Joint Terrorism Task Forces in my prior lifetime, I think when you do these things in the field, you kind of get a better sense for who is supposed to be doing what in a real sense.

So with that, I will yield whatever time I have left, which I see is zero.

[Laughter.]

Mr. LANGEVIN. And then some.

[Laughter.]

Mr. LANGEVIN. I thank the gentleman.

And the chair now recognizes the gentleman from New Jersey for 5 minutes.

Mr. PASCRELL. Thank you, Mr. Chairman. It is good to be back.

I follow this issue very carefully, and I have some questions for the Rear Admiral Vanderwagen.

I want to thank you for convening the hearing. I appreciate the administration appearing today. This is very important, because I believe that the sense of urgency shown by Congress and the administration has diminished, and not increased, in recent months.

Despite the fact that the World Health Organization has now confirmed a total of 327 cases of avian flu and 199 deaths, including recent disturbing reports out of Vietnam, Egypt, and Indonesia.

To date, I understand the administration has requested and Congress has appropriated \$6.1 billion for implementation of the \$7.1 billion National Strategy on Pandemic Influenza, including \$2.3 billion most recently on the fiscal year 2006 emergency supplemental appropriations bill.

This administration has been evasive in answering questions about why the funds allocated for the purchase of the antiviral drugs have not been spent to complete the stockpile.

I have here in my hand three letters. These three letters went to Secretary Leavitt from the House Republican leadership in June, one letter came from the House Democratic leadership in August, and the last letter is from Senator Thad Cochran, who wrote that letter to the Secretary in September.

All of them ask the question why we have only purchased enough drugs for 15 percent of the population when the NSPI calls for 25 percent of the population to be covered by the stockpile.

And my first question to you, Rear Admiral, is why have these letters gone unanswered?

Dr. VANDERWAGEN. I can't speak to that, sir. I will have to ask that question of the executive secretary and the folks who manage the correspondence.

Mr. PASCRELL. You don't know why the letters have been unanswered. I mean, they came from all sectors of the campus here, and we still don't have an answer for them.

This committee doesn't have an answer for them. The Congress doesn't have an answer for them. Who in God's name do you think you are kidding? Who do you believe we'll believe on this side of the aisle—excuse me, if I may continue—the urgency of this situation?

Who do you think is going to believe you?

Dr. VANDERWAGEN. Let me go back to your first question.

Mr. PASCRELL. Sure.

Dr. VANDERWAGEN. I have just been informed that two of those answers have been provided to the Hill for the first two of those, and we will provide documentation of that for you, sir.

Mr. PASCRELL. We don't have those answers yet, and we would like to have those answers.

Dr. VANDERWAGEN. Right.

Mr. PASCRELL. Do you know what is contained in them?

Dr. VANDERWAGEN. I haven't seen them myself, no, but I—

Mr. PASCRELL. In addition, Rear Admiral, how much of the funding allocated to you has been set aside for antiviral purchases, and how much has been set aside for vaccine purchase and development?

Dr. VANDERWAGEN. Right.

Mr. PASCRELL. Have all of these funds been spent?

Dr. VANDERWAGEN. We currently have obligated \$3.2 billion, \$2.4 billion of that for vaccines including cell-based vaccines, antigen sparing activities, facilities retrofitting, international vaccine development, the H5N1 pre-pandemic stockpile.

We have a total commitment of \$796 million for antivirals. That includes \$103 million for advanced development, \$523 million for federal stockpiles and \$170 million for state stockpiles. We have an additional \$27 million invested in advanced diagnostics.

Mr. PASCRELL. So how much haven't you spent?

Dr. VANDERWAGEN. We have a balance remaining that is set aside in reserve for those advances that we have agreed to work with the vaccine companies to do. We are monitoring their progress. We have agreed to milestones. And when they achieve those milestones, we would continue to make investments.

That was our business arrangement with those producers, that if they hit certain milestones in production, we would then advance further investment.

Mr. PASCRELL. Why is it that we apparently had—and there is no seamless solution. We understand that. But why haven't we used our capacity to purchase and stockpile the very drugs we know that work?

And we have sent mixed signals to the pharmaceuticals. They are not going to continue to make these unless, you know, we purchase them.

And if they have been tried, if they have been tested, it seems to me that we are circumventing the solution, not exercising urgency and talking about developing another set of solutions, which you know is going to be 3 years to 5 years. Let's go back to the history of these things.

I don't understand that. Maybe you can help me understand.

Dr. VANDERWAGEN. The investments that we were to make for antivirals for treatment are on plan. We have stated forthrightly that we would purchase X amount in 2007 and we would purchase the balance of that in 2008. There has been no real change in that plan. That is out there in the marketplace. That has been a consistent message from us.

The advanced development investments we think by 2010 will have payoffs that have huge benefits for the population, as you may have heard me respond to Mr. McCaul.

Mr. PASCRELL. I think that, Mr. Chairman, if I may conclude—my time is up—I really still don't sense the urgency that is necessary that on both sides of the aisle has been expressed and is not being implemented.

And I would hope that through the chair and through the ranking member that this could be brought to bear, in that we can get the answers that they talk about in these letters, which started 4 months ago, 5 months ago.

And now we are hearing at this committee hearing that there are answers but they just haven't gotten to us yet. Would you please follow up on that, sir?

Mr. LANGEVIN. Absolutely.

Mr. PASCRELL. Thank you.

Mr. LANGEVIN. I can guarantee that to the gentleman. And I thank the gentleman from New Jersey for his questions. You clearly have not lost your passion for homeland security issues. I thank the gentleman.

In consultation with the ranking member, what we would like to do—there are two votes on right now. Hopefully that will go quickly.

We would like to go for a second round of questions with this panel, since many members are at markups and other meetings right now. We will go for a very brief second round with this panel and then go to the second panel when we return.

I would say that we should be back here in about 20 minutes.

With that, the committee stands in recess.

[Recess.]

Mr. LANGEVIN. The committee will come to order. I thank the witnesses for waiting.

And I understand that at least two of our guests have a meeting at the White House actually for an exercise that is going on right now, so we are going to be very brief and adhere to the 5-minute rule, and hopefully we will get you out of here in just a couple of minutes.

If I can talk to Dr. Jolly and Dr. Vanderwagen—let me address my questions there. We were talking about earlier how we can better coordinate homeland security and HHS grants with respect to pandemic flu that could be also beneficial in other areas.

Let me ask this. How can we better coordinate all public health grant monies, especially those that come from HHS? Again, my understanding is that not all grants have common goals and performance measures.

My question is: is there a system in place at HHS to coordinate things like goals and performance measures, especially when there are multiple grants, perhaps some from CDC, some from the ASPR, dealing with the same topics, such as pandemic flu?

Dr. VANDERWAGEN. Yes, sir, Mr. Chairman, and indeed, there is a fairly well defined process of planning that goes into the grant guidance that we provide, remembering that the Centers for Disease Control's investments are more targeted at public health types of interventions and public health programs at the community level, where the hospital preparedness dollars are really targeting the medical side of that.

Our interest here is to see the public health and the medical community act in concert on these activities. And unfortunately, in this country, we had seen a large gap develop between the public health and medical communities.

And one of our goals is to bring them into greater proximity. Accordingly, we are not only trying to align the expectations from the grants, recognizing that public health is slightly different than clinical medicine, we are also now trying to bring our grants into the same time sequence as the DHS grants so that the states and communities are looking at the whole grant package in the same time frame rather than looking at one in March and then one in August and then maybe one in October.

And so those are the active steps that we are taking. First meeting before we issue guidance to assure that they synchronize. And secondly, to try and fix the timing on our public health and hospital grants to align more closely with DHS and their timing.

Dr. JOLLY. And to add on Admiral Vanderwagen's statement, Mr. Chairman, the timing and sequence are quite important, and also the content of the grants.

We have an active effort now growing within DHS and HHS to communicate among those that are responsible for the grant guidance at one agency so that the other agency knows what that grant guidance is and can help to harmonize that.

And one of the roles—as you know, our office is a relatively new office in Health Affairs. One of the roles of our division of medical readiness is to take a look at the DHS grants and also coordinate across the HHS grants and try to harmonize those.

And it is going to be a stepwise process over time, but I think we can make some real improvements in that.

Mr. LANGEVIN. Well, I plan to pay particularly close attention to that, and that will be part of our oversight as we go forward. I think it is beneficial for both departments and the country, and ultimately the states and our citizens are going to benefit.

Very quickly, for DHS and HHS once again, when we conduct exercises—we spoke about exercises earlier here, and practice, and making sure that we are ironing out the issues before they actually occur.

When we conduct exercises, it is important to conduct them in the most realistic way possible and, to the extent we can, use current requirements to show us how well we might do in future situations.

During a pandemic, DHS and HHS will be the lead federal agencies in terms of managing the response, as we discussed earlier. I believe that we should test our systems now using, for example, seasonal influenza as a proxy for pandemic influenza.

So my question for you, Dr. Vanderwagen, is why don't you take this year's influenza season and make a concerted effort to see how many people we can vaccinate in the shortest period of time, basically pretending that seasonal influenza is actually pandemic influenza?

Can you get HHS programs such as the National Immunization Program to step up and work with other HHS entities and systems to exercise in this way?

Dr. VANDERWAGEN. Yes, sir. And in fact, in 2006 I—you know, I live in Howard County up the road here, and the state of Maryland was test driving its ability to deliver vaccines in an event of a pandemic by using the seasonal flu as the test bed.

And essentially, they had a drive-through approach so that we could maintain social distancing and yet provide access to vaccines for the population.

It took me 3 hours to get my vaccine, but it worked. And we are promoting more of that kind of use of vaccination opportunities as a test drive of how they would do mass prophylaxis in the environment of a pandemic flu.

I think that is a capital idea. Some states have done it. We are trying to promote it more holistically to all states.

I think Dr. Gerberding on Wednesday this past week, a week ago, when she made the announcements regarding this year's seasonal flu—that was one of the points that she tried to make.

So I think we are on the same page with you, sir. It remains for us to demonstrate to you how that went off.

Dr. JOLLY. And I would agree that some of the operational elements of vaccinating individuals and some of the other things—countermeasure issues can benefit from those types of exercises.

That is a very good idea, and something that other states have tried and will continue to refine.

And on some of the larger exercise issues, we have plans within our Principal Federal Official group to exercise within that group and then lead that into a series of leadership level interagency exercises and to culminate in another cabinet-level exercise over a period of time as the schedule develops.

Mr. LANGEVIN. Very good. Well, I see benefits across a range of areas in conducting such an exercise, so—well, I thank you for the answers.

And I now recognize the gentleman from Texas for 5 minutes for questions.

Mr. MCCAUL. Thank you, Mr. Chairman.

I will be brief. We have a vote in, I think, 15 minutes.

Ms. Steinhardt, you mentioned in your testimony certain gaps that are currently, in terms of our readiness, our preparedness.

I would like, if you could, to focus on sort of the highlights of those gaps and how we can do a better job.

Ms. STEINHARDT. Yes, I would be happy to. Ones I think that I wanted to highlight in particular—first, the fact that there are—in the National Strategy and Plan there is no mention of the resources that are going to be required to carry out the Plan. There are well over 300 action items in the plan.

Dr. VANDERWAGEN AND DR. Jolly mentioned earlier the vaccine program and supplemental appropriations. But there are many others that are called for in the Plan beyond those that are covered in the supplemental appropriations, and there is not even an estimate of what would be entailed.

So that is one important gap. And certainly, from an oversight perspective, it is really critical.

Another gap that we were particularly mindful of was the fact that state and local and tribal entities weren't involved in actually producing the plan and preparing the plan.

They are responsible for close to 100 of the action items, either as the lead or in some sort of support capacity, and yet they weren't consulted when the plan was being developed, and that I think is something that needs to be addressed.

And then the plan itself—within the plan there is no institutional process for updating it as new events unfold, as we learn from exercises and so on. There is no process to update the plan or to monitor progress on a regular basis.

There are several others that we point out in our report and statement, but those are the ones I would highlight.

Mr. MCCAUL. Thank you.

And I do want to thank the witnesses again. I think we have made some progress. And as Dr. Vanderwagen mentioned, I think we are partners in this, and so I look forward to working with you to make sure we are prepared. Thank you.

Mr. LANGEVIN. I thank the gentleman.

And with that, no further questions. I thank the panel for their testimony, your presence here today and for the work that you are doing on behalf of the country.

And we look forward to continuing oversight in this area and partnership with you in this effort. Thank you very much.

With that, the first panel is dismissed. And if we can have the second panel come to the front. Very good.

Well, gentlemen, thank you for being here. I want to welcome the second panel of witnesses.

Our first witness is Dr. Anthony Cirillo, the chief of the Center for Emergency Preparedness and Response in the state of Rhode Is-

land Department of Health. He is also a practicing emergency room physician.

In addition to that, prior to his present post, he was chief of emergency medicine at Pawtucket Memorial Hospital in Rhode Island.

Welcome, Dr. Cirillo.

Our second witness is Dr. Peter Shult. Dr. Shult is the director of the Communicable Disease Division and Emergency Laboratory Response and Chief Virologist of the Wisconsin State Laboratory of Hygiene.

He is also clinical associate professor of the Department of Medical Microbiology and Immunology at the University of Wisconsin-Madison.

Welcome.

And our third witness is Dr. Michael Caldwell, commissioner of the Dutchess County Health Department of Poughkeepsie, New York. Dr. Caldwell is the immediate past president of the National Association of City and County Health Officials.

He is also an internal medicine physician and a public health officer with 12 years of experience in local public health practice.

Our fourth witness is Dr. David Lakey, commissioner of the Texas Department of State Health Services.

We want to welcome all of our panel here today. I thank all four of our witnesses for their service to their states and to the nation and again for being here today.

Without objection, the witnesses' full statements will be inserted into the record. I now ask each witness to summarize his statement for 5 minutes, beginning with Dr. Cirillo.

STATEMENT OF DR. L. ANTHONY CIRILLO, CHIEF, CENTER FOR EMERGENCY PREPAREDNESS AND RESPONSE, RHODE ISLAND DEPARTMENT OF HEALTH

Dr. CIRILLO. Mr. Chairman and members of the committee, I would like to thank you for allowing me to testify today to discuss the current successes and ongoing challenges in planning and preparing for a pandemic influenza event.

I would like to share with you my dual perspective as both the coordinator of public health emergency preparedness for our nation's smallest state and as a practicing emergency physician in an urban community hospital.

Today I can share with you that although significant progress has been made in preparing the public health and health care sectors for response to a pandemic, there is still considerable work that needs to be done, and there are challenges both in scope and depth of preparation that will need to be addressed in order for our country to meet the challenge of a pandemic event.

In Rhode Island, the Department of Health serves as the sole public health agency within the state, as there is no other city- or county-based public health infrastructure.

As such, the department is responsible for the administration of all traditional public health programs both promotional and protectional.

The Center for Emergency Preparedness and Response oversees all public health emergency preparedness grants, including the

CDC Public Health Emergency Preparedness Grant and the Hospital Preparedness Program Grant administered through the office of the ASPR.

Under the leadership of U.S. Secretary of Health and Human Services Michael Leavitt, who issued a challenge to prepare for a pandemic during his state visits in 2006, Rhode Island undertook a spectrum of activities.

The successes that have been achieved in pandemic preparedness in Rhode Island have come, to a great extent, due to the strength of our partnerships and working relationships within the state and the New England region.

In Rhode Island, we have strived to develop an integrated and coordinated system for the public health and health care sectors to respond to any public health emergency, including a pandemic.

Ongoing coordination with our hospitals through the Hospital Preparedness Program facilitated the establishment of 10 health care coordinating service regions in the state in order to respond to the needs for health care during a pandemic.

Stockpiling of critical supplies at the state level, including patient care equipment, personal protective equipment, ventilators and other support materials has begun in order to provide an initial cache of medical equipment needed to supply alternate care sites during a pandemic.

Outreach and risk communication messaging in the senior community, other special populations and the general public through brochures, newspaper inserts, classroom materials and public service announcements has already occurred.

Regional interstate coordination in pandemic preparedness has also occurred among the six New England states and the state of New York. Each of these states has participated together in work groups focused on a number of pandemic topics.

This collaborative effort resulted in a 2-day summit and a multistate tabletop exercise held to coordinate the interstate response to a pandemic.

Despite the progress that I have described, there is still considerable work to be done. Ongoing challenges include, number one, inadequate funding and resources to purchase enough material to ensure care of anticipated numbers of patients during a pandemic.

Two, shifting and evolving federal grant priorities related to pandemic flu and overall public health preparedness which create inefficiencies in program management.

Three, the disincentives to the purchase of antiviral medications Tamiflu and Relenza due to exclusion from the shelf-life extension program of state health supplies of these medications.

Now, as an emergency physician, I have personally witnessed the increasing demand for medical care being placed on hospital emergency departments. With the number of uninsured Americans now in excess of 47 million, more and more individuals do not have appropriate access to medical care.

In the absence of a medical home, people who experience injury or illness will seek care in the one environment where they know they will never be turned away, and that is the emergency department.

However, emergency departments today are overcrowded. Surge capacity is diminished or being eliminated altogether. Ambulances are diverted to other hospitals. And the shortage of medical specialists is worsening.

According to data recently released by the CDC, emergency department visits are at an all-time high of 115 million in 2005. That was an increase of five million visits in just 1 year alone.

And from 1995 through 2005, emergency department visits increased by 20 percent, while the number of functioning and operating emergency departments decreased by 9 percent.

Because of the extraordinary demands that a pandemic will place on the health care delivery system, it is imperative that we are able to engage the general public and encourage them to assume responsibility for their own preparedness.

Just as the saying goes that all disasters are local, so is the response to a disaster. In the truest sense for a pandemic, this means that preparedness must begin with individuals, families, neighborhoods and communities.

It is critical to the successful response that we develop a culture of preparedness in this country in order to ensure that those who have the means to prepare for themselves do so.

If we can accomplish this, then the burden of response on government will be reduced so that scarce resources available can be shifted and allocated to those who are most at risk.

In conclusion, I would like to share with you the following closing thoughts. States and local health entities are willing partners in the development of systems to respond to a pandemic event or other public health emergency.

However, the resources and support of the federal government are essential to creating and sustaining the capability and capacity required to prepare for and respond to all public health emergencies.

Incorporating new grant requirements and updates to national planning documents related to a pandemic or other public health emergency requires considerable time at the state and local level and utilization of resources in order to effectively reach the entire health care responder community and the general public.

Therefore, it is critical that all federal preparedness programs related to pandemic or other public health emergencies be more closely aligned and coordinated so that we at the state level can more effectively develop an appropriate response to all public health emergencies.

Mr. Chairman and members of the committee, I thank you for the opportunity to discuss these important issues with you today and would be happy to answer any questions you may have.

[The statement of Dr. Cirillo follows:]

PREPARED STATEMENT OF L. ANTHONY CIRILLO, MD, F.A.C.E.P

Mr. Chairman and members of the committee, my name is L. Anthony Cirillo, M.D., F.A.C.E.P. I serve as the Chief of the Center for Emergency Preparedness and Response (CEPR) for the State of Rhode Island Department of Health and as a practicing emergency department physician employed by Emergency Medicine Physicians (EMP), a single specialty medical group practice.

I would like to thank you for allowing me to testify today to discuss the current successes and ongoing challenges in planning and preparing for a pandemic influenza event. I would like to share with you my dual perspective as both the coordi-

nator of public health emergency preparedness for our nation's smallest state and as a practicing emergency physician in an urban community hospital. As of today, I can share with you that although progress has been made in preparing the public health and healthcare sectors for response to a pandemic influenza event, there is still considerable work that needs to be done, and there are challenges both of scope and depth of preparation that will need to be addressed in order for our country to meet the challenge of a pandemic influenza event.

The Rhode Island Experience

The Rhode Island Department of Health serves as the sole public health agency within the state as there is no other city / county based public health infrastructure. As such, the department is responsible for the administration of all traditional public health promotional and protection programs, including Healthy People 2010, food and water protection, laboratory, epidemiology and disease control. Beginning in early 2006, the Center for Emergency Preparedness and Response (CEPR) was established by Dr. David Gifford, the Director of Health. CEPR was established to coordinate all public health emergency preparedness activities on behalf of the department. CEPR serves as the liaison entity, on behalf of HEALTH, for all other emergency preparedness efforts within the state and is the designated lead agency for Emergency Support Function 8 (ESF-8), Health & Medical, within the state's Emergency Operations Plan.

In my role as the Chief of CEPR, I serve as the Principal Investigator, on behalf of the department, for both the CDC Public Health Emergency Preparedness (PHEP) and the Hospital Preparedness Program grant administered through the office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health & Human Services. In addition, CEPR serves as the representative entity in participation in the development of investment justifications under the Department of Homeland Security grant funded programs.

The successes in pandemic preparedness in Rhode Island have come, to a great extent, due to the strength of our partnerships and working relationships within the state and the New England region. I would like to acknowledge here today, two other Rhode Islanders who represent key partners within the state with whom the Department of Health has worked closely with in these efforts. Mr. Thomas Kilday, who currently serves as the Homeland Security Grant Manager at the Rhode Island Emergency Management Agency, is a paramedic and previously served as the Program Manager for the Hospital Preparedness Program at the Department of Health. Mr. Peter Ginaitt, who currently serves as the Director of Emergency Preparedness for Lifespan, the state's largest healthcare system, is a former state representative and retired Captain of Emergency Medical Services for the City of Warwick.

In Rhode Island, we have strived to develop an integrated and coordinated system for the public health and healthcare systems to respond to a pandemic influenza event or other public health emergency. Ongoing coordination with our hospitals through the Hospital Preparedness Program facilitated the establishment of ten healthcare coordinating service regions in the state for pandemic influenza. In this model, each of the ten acute care hospitals within the state would serve as the coordinating entity for a geographic area. Utilizing the Hospital Incident Command System for management of healthcare in that area, each hospital will report to the Department of Health as the coordinating entity for all ESF-8 activities within the state.

Volunteers during a pandemic event will be coordinated through Volunteer Reception Centers (VCRs) which will be managed by the Volunteer Center of Rhode Island (VCRI), a non-profit organization with expertise in volunteer coordination. VCRI has been provided funding through the Pandemic Flu grants and has established a single, unified statewide volunteer management system. VCRI will be able to open ten volunteer reception centers simultaneously to manage volunteers throughout the state. Volunteers will be pre-credentialed utilizing the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP), another program funded under the Hospital Preparedness Program grant.

Stockpiling of critical supplies including patient care equipment, personal protective equipment, ventilators, and other support materials at the state level has begun in order to provide an initial cache of materials to equip Alternate Care Sites (ACS) in each of the hospital coordinated healthcare regions.

Outreach and risk communication messaging to the senior community, other special populations, and the general public through brochures, newspaper inserts, classroom materials, and public service announcements has already occurred.

Regional interstate cooperation in pandemic preparedness planning has also occurred among the six New England states and the State of New York. Early in 2006, after US Secretary of Health and Human Services Michael Leavitt's visits to

the states to discuss pandemic preparedness, coordinated planning and response to a pandemic event, representatives from each of the Departments of Health in seven states participated in workgroups on the following topics:

1. Community Containment
2. Personal Protective Equipment
3. Antiviral Medication / Vaccine Utilization
4. Laboratory Testing / Disease Surveillance
5. Fatality Management
6. Surge Capacity

These workgroups met in person or by teleconference for~ 3 months culminating in a two-day summit held in Boston in late June 2006. These workgroups identified common best practices among all the states, as well as the areas of differing response strategies. A key lesson from the summit meeting was that in order for there to be effective public health response to a pandemic, this response needed to be coordinated with state governmental leadership and emergency management agencies as well. Therefore a tabletop exercise was held at the Naval War College in Newport, RI in August 2006. Participating in this exercise was the seven states noted above as well as representatives from the FEMA Region I and HHS Region I offices.

Despite the progress referenced above, there is still considerable work to be done. Ongoing challenges include:

1. Inadequate funding to purchase enough materiel to ensure care of anticipated numbers of patients during a pandemic influenza event, as federal funding for preparedness continues to decrease.
2. Shifting and inconsistent federal grant priorities related to pandemic flu and overall public health emergency preparedness efforts which create inefficiencies in program management.
3. Disincentives to the purchase of antivirals due to exclusion of state held cache from Shelf Life Extension Program (SLEP).
4. Continued need to coordinate planning across state borders, especially in those states with multiple and close state borders.

The Emergency Department Experience

As a practicing emergency physician, I have personally witnessed and shared with my colleagues across the country, the increasing demand for clinical services being placed on emergency departments. With an increase in the number of uninsured Americans now in excess of 47 million, more and more individuals do not have appropriate access to medical care. In the absence of a medical home, people who experience injury or illness of themselves or loved ones will seek care in the one environment where they know they will never be turned away, the Emergency Department. Emergency departments are the health care safety net for everyone in this country—the uninsured and the insured.

Emergency departments are overcrowded, surge capacity is diminished or being eliminated altogether, ambulances are diverted to other hospitals, patients admitted to the hospital are waiting longer for transfer to inpatient beds, and the shortage of medical specialists is worsening. These are the findings of the Institute of Medicine (IOM) report "Hospital-Based Emergency Care: At the Breaking Point," released in June 2006.

On June 29, the Centers for Disease Control and Prevention (CDC) released its results from its 2005 National Hospital Ambulatory Medical Care Survey (NHAMCS), the longest continuously running, nationally representative survey of hospital emergency department and hospital outpatient department use.

According to the CDC data:

- Emergency visits are at an all-time high of 115 million in 2005—an increase of 5 million visits in one year.
- From 1995 through 2005, the number of emergency department visits increased by 20%, from 96.5 million to 115.3 million visits annually. This represents an average increase of more than 1.7 million visits per year.
- During this same period, the number of hospital emergency departments decreased by 9%, from 4,176 to 3,795.

Hospitals and Emergency Departments in this country are being challenged to meet the everyday demand for healthcare services. As the population grows and ages there will be more people requiring healthcare services. As the number of uninsured Americans increases, more and more of this care is provided without reimbursement. The overall effect of this increase in demand for healthcare services at the emergency department and hospital level is to significantly reduce, and in many facilities eliminate, any surge capacity for response to a public health emergency, whether it is a pandemic event or a mass casualty incident.

Every day emergency physicians save lives across America. Emergency departments provide an essential community service and are the safety net of medical care

in this country. However, emergency departments are at the breaking point and additional resources and long-term solutions must be provided before systemic failure eliminates the ability of emergency physicians to provide care when and where it is needed.

There is a secondary concerning effect of the increase in the demand being placed on hospitals and emergency departments that is a reluctance to invest in preparedness activities. As the healthcare delivery system has become more stressed, both in terms of volume of services and uncertainty in levels of reimbursement, there is an increased reluctance to expend financial resources on preparedness activities, both in support of training and exercises. Although regulatory demands on hospitals and other healthcare facilities to prepare for public health emergencies continue to increase, there is no reimbursement for such activities from private insurers. This puts a greater demand on funding for preparedness activities to come from federal or state sources.

Hospitals today operate utilizing just-in-time inventory management systems, making the delivery of healthcare more cost-effective, but significantly reducing the on-hand availability of additional materiel needed to respond to large scale public health emergencies. Again, this places a greater demand on funding from federal or state sources to meet this critical need.

Engaging and educating the largest part of the response pyramid.

Given that it is unlikely that there will be adequate stockpiles of supplies and equipment for an entire pandemic event, it is imperative that we are able to engage the general public and encourage them to assume responsibility for their own preparedness. Just as the saying goes that “all disasters are local”, so is the response to a disaster. In the truest sense for a pandemic, this means that preparedness must begin with individuals, families, neighborhoods, and communities.

It is this last challenge that is the most difficult, and likely the most important in ensuring that society at large will remain intact during a prolonged pandemic event. As the perception of risk of a pandemic event wanes in the media and general public, the receptiveness of the public to risk communication related to preparedness also wanes.

It is critical to the successful response to a pandemic event that we develop a “culture of preparedness” in this country, in order to ensure that those who have the means to prepare for themselves do so. If we can accomplish this through risk communication and broad-reaching educational programs, then the burden of response on government will be reduced so that scarce resources can be shifted to those who are most at risk.

However, reaching and educating the base of the pyramid takes time. While those of us directly involved in preparedness activities can devote the necessary time to incorporate new information and plans regarding a pandemic or other public health emergency into our working knowledge, it is not the primary focus of the general public or other healthcare professionals.

Conclusion

States and our local healthcare partners are willing participants in the development of systems to respond to a pandemic event or other public health emergency. While the resources and support of the federal government is essential to the creating and sustaining the capability and capacity required to sustain a response to a large scale ongoing incident like a pandemic event, the coordination of all large scale public health emergencies will be at the state and local level.

It is important to understand that increased requirements to deliver training and undertake exercises and drills related to pandemic event or other public health emergencies require considerable planning time and utilization of resources in order to be effective. In many cases, these resources are being stretched very thinly, both at the state and healthcare facility level. As the requirements for delivery of more training, drills and exercises increase under federal grant programs it is critical that all federal preparedness grant programs related to pandemic influenza or other public health emergency be more closely aligned and coordinated so that we at the state level can more effectively develop an appropriate response to whatever public health emergency may occur.

Mr. Chairman and members of the committee, I thank you for the opportunity to discuss these important issues with you this morning and would be happy to answer any questions at this time.

Mr. LANGEVIN. Thank you, Dr. Cirillo.

With that, I want to recognize Dr. Shult to summarize his statement for 5 minutes.

Welcome.

STATEMENT OF PETER A. SHULT, DIRECTOR, COMMUNICABLE DISEASES DIVISION, WISCONSIN STATE LABORATORY OF HYGIENE

Mr. SHULT. Thank you, Mr. Chairman and members of the subcommittee. I am here today representing the Association of Public Health Laboratories, of which the Wisconsin State Laboratory of Hygiene is a member.

As the name implies, the APHL is the association for state and local governmental laboratories that perform testing of public health significance.

In the event of an influenza pandemic, it is currently highly unlikely that a well-matched vaccine, the best countermeasure, will be available when a pandemic begins.

Instead, current national plans call for the initiation of drastic community mitigation measures augmented with distribution of limited antiviral supplies to impede the pandemic's progress.

This will require documentation of the emergence of a novel influenza virus and confirmation of sustained community transmission of the virus using highly specialized laboratory testing performed solely by a public health laboratory.

Maintaining this capability and response readiness will be a challenge for the public health laboratory, given limited and now declining federal support and a greatly expanded role, well beyond diagnostic testing, in emergency preparedness and response.

Public health laboratories are the leaders in laboratory preparedness and response efforts, key national security assets that serve as reference laboratories in the National Laboratory Response Network.

These laboratories are capable of performing highly advanced, accurate tests that allow rapid detection and identification of biological agents of public health significance, including seasonal influenza strains and newly emergent subtypes of influenza with pandemic potential such as the H5N1.

This testing capability is critical to state and national influenza surveillance.

Furthermore, because of the potential introduction of a novel virus into the United States from international travelers, CDC now requires that states conduct this surveillance year-round.

The public health laboratory must also work closely with private-sector laboratories that provide diagnostic testing to support patient care, with agriculture and veterinary laboratories responsible for monitoring influenza within animal populations, and with a host of other public health and emergency first responder partners.

Maintaining these networks is resource-intensive and difficult to accomplish without adequate funding.

The public health laboratories are heavily reliant on the expertise at CDC—in this case, the CDC's influenza division—to assist in outbreak response and to develop new methods for detection of influenza.

The CDC is also critical in helping facilitate collaboration among laboratory partners to ensure adequate testing surge capacity is available for pandemic response.

DHS has created the Integrated Consortium of Laboratory Networks to address coordination and integration of the different federal level agency networks.

However, the work of the ICLN has not yet been apparent to the front line public health laboratory serving an all-hazards mission with diminishing resources.

Traditionally, public health laboratories have relied on state resources and minimal allotments from the CDC's epidemiology and laboratory capacity funding to support laboratory influenza surveillance.

Although further supplemental funding has been appropriated for pandemic influenza preparedness, to date few public health laboratories have benefitted from these funds, despite increased expectations for rapid testing and year-round surveillance.

Only because of funding from the CDC's public health emergency preparedness program has substantial laboratory emergency response infrastructure to respond to bioterrorism, pandemic influenza and other public health emergencies been developed. However, this funding has also begun to decline.

In conclusion, given the critical role of the public health laboratory in detecting and monitoring both seasonal and novel potentially pandemic strains of influenza, as well as other potential public health threats, the substantial testing capabilities and capacities that have been developed and that I have described in my written testimony need to be sustained.

And future improvements in diagnostic technology and networking activities, such as communications and information-and data-sharing among laboratories and with response partners need to be made.

Without sustained federal funding from CDC and other agencies, our ability to fulfill this pandemic and all-hazards public health and national security mission will be compromised.

I ask your help in not letting this happen. Thank you very much, and I would be glad to answer any questions.

[The statement of Mr. Shult follows:]

PREPARED STATEMENT OF DR. PETER SHULT

My name is Dr. Peter Shult and I am here today representing the Association of Public Health Laboratories, APHL. I am currently the Director of the Communicable Diseases Division of the Wisconsin State Laboratory of Hygiene. As its name implies, APHL is the association for state and local governmental laboratories that perform testing of public health significance.

Public health agencies worldwide have been tasked with leading preparedness and response planning efforts necessary to minimize the impacts of seasonal influenza epidemics as well as the next pandemic. In the case of pandemic influenza, it is currently highly unlikely that a well-matched vaccine, the best countermeasure, will be available when a pandemic begins. In addition, sufficient supplies of influenza antiviral medications might not be available. Consequently, current national plans for pandemic response call for attempting to mitigate the effects of a pandemic early on by relying on strategies for case containment (isolation and quarantine), social distancing (school closures and social distancing of adults in the community and at work) and infection control (hand hygiene, cough etiquette). Initiation of these rather drastic measures will require documentation of emergence in the U.S. of a novel influenza A subtype and confirmation of sustained community transmission of the virus. This will require laboratory testing; the responsibility for this testing role will rest with the public health laboratory—state and local governmental laboratories tasked with supporting their public health jurisdictions in preparedness and response activities.

Role of the public health laboratory

The public health laboratory is the leader in laboratory preparedness and response efforts. Public health laboratories, serve as reference labs in the Laboratory Response Network (LRN). They are a key national security asset, providing some of the most advanced and rapid testing available in the LRN. These laboratories are capable of performing tests to rapidly detect and identify highly dangerous biological agents. Public health laboratories also have established linkages with law enforcement, including the FBI, and utilize chain-of-custody and testing protocols consistent with legal evidentiary requirements. The state public health laboratory has developed a culture of emergency response. There is an expectation that we follow incident command structure, and that we have continuity-of-operations plans. We coordinate with other first responders, hazardous-materials teams and law enforcement on a regular basis responding to unknown threats and suspicious packages. We're emergency responders from the lab perspective.

The LRN was established to address only those agents that could be used for biological terrorism (BT). However, since that time, the LRN has been utilized to address non-terrorism agents as well, an "all hazards" philosophy. At the state level, infrastructure developed as a result of funding from the Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreements, like upgrading laboratory facility biosafety levels, purchasing state-of-the-art molecular detection equipment, and hiring staff with advanced diagnostics expertise, has significantly improved the public health laboratory's ability to respond to emerging diseases. In Wisconsin, we could not have weathered the SARS, monkeypox and mumps outbreaks of recent years without the resources provided through the PHEP and LRN. These resources are also helping us improve annual influenza surveillance using state-of-the-art methods, and prepare for a potential pandemic. The public health laboratory will be an integral part of any public health response to pandemic influenza and must be included in comprehensive local, state or federal plans for preparedness and response.

Laboratory results are critical for influenza surveillance and for public health decisions during both routine "seasonal" influenza and during pandemic alerts and pandemic periods. Public health laboratories contribute significantly to surveillance efforts within each state and to national surveillance efforts as members of a network of World Health Organization collaborating laboratories, coordinated in the U.S. by the CDC. Specifically, public health laboratories provide highly accurate and rapid testing for confirmation and identification of "seasonal" influenza strains as well as newly emergent subtypes of influenza such as H5N1. This testing incorporates the use of newer state-of-the-art methods as well as traditional methods that require growing the virus. Laboratory testing is the only way to attribute "flu-like" illness to a specific pathogen, either influenza or one of the hundreds of other viral respiratory pathogens that circulate each year.

In addition, during "seasonal" influenza, laboratory testing is critical to:

- determine when, where and which strains and subtypes of influenza viruses are circulating;
- monitor the extent and duration of the epidemic;
- detect novel influenza subtypes such as H5N1;
- optimize the use of vaccines and antivirals including monitoring for antiviral resistance

Public health laboratories also provide virus samples to CDC for further characterization throughout "seasonal" and pandemic periods, and this information contributes to the selection of future vaccine strains. In fact, one of the viruses used to make last year's vaccine came from the Wisconsin State Laboratory of Hygiene.

Because of the potential introduction of a novel virus into the U.S. from international travelers, CDC now requires that states conduct year-round surveillance. Although it has become commonplace these days to think of planning for a pandemic only in terms of avian flu or more specifically H5N1, the reality is other avian influenza viruses have been implicated in human disease (including avian influenza H7N7, H9N2, H7N2, H7N3). It is essential that current influenza surveillance programs provide for rapid detection of *any* novel strain.

While the public health laboratory focus is on surveillance to support response and control measures, they must also work closely with private sector laboratories that provide diagnostic testing to support clinician diagnosis and treatment of their patients. Public health laboratories provide confirmatory testing for clinical laboratories, education to clinicians and clinical labs regarding the use and interpretation of rapid influenza tests, and guidance for handling and submission of suspect pandemic strains from clinical and physician office laboratories. These are resource intense activities that are difficult to maintain without funding.

During the early stages and throughout a pandemic, additional goals for diagnostic testing at public health laboratories will include:

- detecting and confirming initial cases of pandemic influenza in communities and confirming that sustained person-to-person transmission has occurred to initiate targeted community-level interventions including containment (isolation and quarantine), social distancing strategies and infection control;
- differentiate patients with pandemic influenza from those infected with the “seasonal” strain or other respiratory viruses;
- monitor the pandemic’s geographic and regional spread through laboratory testing;
- measure the impact of interventions such as vaccination, antiviral therapy, and non-pharmacologic interventions; and
- monitor the pandemic strain to determine the effectiveness of any vaccine (when available and the emergence of antiviral resistance)

In addition to these direct response roles, we provide the diagnostic expertise in the development of pandemic preparedness and response plans and their exercise within states, and provide faculty and expertise to support CDC laboratory training efforts domestically and internationally. Public health laboratories also maintain a close working relationship with agricultural and veterinary diagnostic laboratories to monitor influenza activity within animal populations that may impact human populations.

While state public health laboratories have significant expertise in infectious disease testing, we heavily rely on the expertise at CDC to assist in outbreaks, and develop new methods for detection of emerging pathogens that can rapidly be deployed to our laboratories. CDC’s influenza division has developed the advanced detection tools currently available in public health laboratories to detect and subtype the influenza A virus, to monitor seasonal circulating strains and detect novel viruses strains. Beginning in 2003, CDC has provided protocols and training for state public health laboratories to perform real-time RT-PCR for molecular detection of Influenza A & B viruses, and for subtyping Influenza A H1, H3, H5 and H7 subtypes. The currently circulating H5N1 strains have been undergoing rapid evolution, so it is essential that CDC continue to carefully monitor the performance of the real-time RT-PCR assays currently in use in public health laboratories by testing H5 samples received from other countries.

The CDC is also working with APHL and other partners on other critical issues related to pandemic influenza response. I have no doubt with the first emergence of a pandemic influenza strain—particularly if it happens to be H5N1—there will be a panic with consequent pressure on public health, including the laboratory, to respond immediately. How much laboratory capacity will be needed for surveillance and diagnostic support during the early stages of a perceived or real influenza pandemic affecting the U.S.? What is the best way for public health and private sector laboratories to collaborate and support any surge in testing needs? There will, no doubt, be a need for other surge capacities to ensure adequate materials and supplies for diagnostic testing and enhanced transportation mechanisms to move these goods and supplies as well as patient specimens to the laboratories.

It is important to point out that currently there exist no stockpiles of critical laboratory supplies and materials analogous to those developed for pharmaceuticals and other critical emergency response supplies. This could prove to be a critical shortfall! These questions and issues are currently being addressed through an APHL/CDC clinical laboratory partner’s workgroup. From a public health perspective, it is assumed that as the pandemic peaks, every ill patient will not need laboratory testing. However, the demand for testing from patients and doctors will rapidly outstrip testing capacities. These are critical issues that must be addressed pre-pandemic. APHL is also working with CDC to develop guidance on the use of various diagnostic tests from the introduction of the novel strain, through the peak of the pandemic, and into the recovery period.

Resources to support the public health laboratory

Traditionally public health laboratories have relied on state resources and the CDC’s **Epidemiology and Laboratory Capacity (ELC)** funding to support laboratory influenza surveillance. In 2006, ELC provided \$2.2 million to support epidemiology and laboratory activities for seasonal influenza surveillance across 50 states. Although supplemental funding has been appropriated for pandemic influenza preparedness, to date many public health laboratories have not benefited from these funds, despite increased expectations for rapid testing and year-round surveillance.

Substantial state public health laboratory capability and capacity to respond to bioterrorism, pandemic influenza and other public health emergencies has been de-

veloped in States over the last several years with the help of other federal funding sources. The degree to which this has been accomplished is related to the distribution of this funding to public health laboratories which has been highly variable on a state-by-state basis both in terms of the type and amount of funding received and the period of time over which it was received.

In general, **Public Health Emergency Preparedness (PHEP) funding from the CDC** has supported laboratories' efforts to:

- build state-of-the-art diagnostic capability and capacity for rapid and accurate laboratory diagnosis of primary agents of bioterrorism (BT) and other major public health threats such as SARS and pandemic influenza as a Laboratory Response Network Reference laboratory.
- develop state-based networks of clinical laboratories, and provide them with emergency response and specimen shipping guidelines and protocols, 24/7/365 state courier systems to ensure rapid transport of specimens, emergency messaging and electronic data sharing capabilities, training in diagnostic testing to recognize and rule-out the presence of priority bioterrorism agents or other agents of public health importance.
- develop and support training programs for Hazardous Material teams to improve coordinated response to hazardous materials incidents involving "white powders" and other unknown substances,
- to support preparedness and response planning and develop emergency response protocols with other response partners including state food testing and veterinary diagnostic laboratories,) and Federal (CDC, FBI, USPS) response agencies.

The outcome of these efforts in Wisconsin and other states can be measured in part by the significant role the public health laboratory, with these enhanced capabilities and capacities, and the clinical laboratory networks, with whom they collaborate closely, played in a number of recent, high profile outbreaks including SARS (2003), Monkeypox (2003), pertussis (2003–06), mumps (2006), norovirus (2006–07) and the E.coli O157:H7 spinach outbreak (2006) to name but a few.

In addition to responding to bioterrorism, pandemic influenza and other public health threats, public health laboratories are serving an all-hazards mission, providing environmental testing for bioterrorism and chemical terrorism agents, participating in the Food Emergency Response Network sponsored by FDA and USDA, and responding, sometimes daily, to a host of unknown threat emergencies. DHS has created the Integrated Consortium of Laboratory Networks to address coordination and integration of the networks at the Federal level. The ICLN is charged with assuring coordination across the networks. The work of the ICLN has not yet been apparent to the front-line public health laboratory serving an all-hazards mission with diminishing resources.

In Wisconsin and in many other states, substantial laboratory emergency response capability, capacity and infrastructure has been developed. But this is only the beginning of addressing laboratory needs; what has been built needs to be sustained and this is where the greatest problem may lie.

Maintenance of what has been built in terms of emergency laboratory response capability much less continuous future improvements in diagnostic technology, information and data sharing, etc. now may be in jeopardy.

- Despite the ongoing threat of pandemic influenza and in the face of numerous infectious disease outbreaks many state and local public health laboratories have suffered recent substantial cuts in funding. In Wisconsin, fiscal year 2007 PHEP funding to the public health laboratory was cut by nearly 60% and this cut will be carried over to fiscal year 2008. ELC funding to the Wisconsin public health laboratory also has dropped substantially over the past 5 years.
- A number of state public health laboratories did not receive any ELC or Pandemic Influenza Supplemental funding and received substantially less PHEP funding than Wisconsin because these funds were not allocated to them by their states. Further cuts to these public health laboratories would be devastating.
- Costs (salaries, diagnostic equipment maintenance, materials, etc.) to maintain this laboratory response infrastructure are significant and, in fact, are increasing and will continue to do so.
- *Direct* state support of these emergency laboratory response efforts is variable and in many cases non-existent (this is the case in Wisconsin). This forces the laboratory to have to re-allocate their state funding allotment or perhaps collected fees to emergency preparedness and response at the expense of other laboratory activities that may still have public health importance.
- The clinical laboratories, who will be on the front line in response to public health emergencies such as pandemic influenza and bioterrorism and with whom the state public health laboratories have formed critical partnerships are

now highly dependent on the public health laboratory for reference and confirmatory testing, training, communications and data sharing, emergency response guidance, etc. And the fact is, in many circumstances, the public health laboratory may not be able to mount an effective laboratory response to a public health emergency without their clinical lab partners.

Federal funding must continue to sustain the laboratory capability and capacity necessary to effectively support the public health response to pandemic influenza, bioterrorism and other public health threats, and the expanding all-hazards mission. What will be the outcome if funding of these laboratory efforts continues to diminish or is eliminated altogether?

- Diagnostic capability and laboratory technical expertise needed to respond to current and future threats within the state public health laboratory, the nation's LRN reference laboratories, will not be maintained.
- Adequate staffing levels of diagnostic and support personnel will not be maintained. This is a particularly bad outcome in terms of surge capacity needed during an influenza pandemic when perhaps 30% or more of the workforce may be incapacitated at various points of time during the pandemic.
- The ability to bring online the newest diagnostic technologies needed for response to current and future infectious disease threats will be severely diminished.
- The ability to sustain the highly effective network of LRN Sentinel clinical, LRN reference public health and other laboratories (food testing, veterinary), the very backbone of the LRN, will be lost.
- Training of clinical laboratorians in diagnostic procedure to support public health emergency response will cease to be available through the public health laboratory, the current major provider of such training.

Conclusion

In conclusion, the public health laboratory likely will be a critical component of the trigger that initiates the pandemic response plan and community mitigation strategies. The ability to confirm that a patient is infected with a novel strain of influenza resides solely in public health laboratories. Public health laboratories must be prepared to provide crucial influenza diagnostic and surveillance services to quickly detect and monitor the progression of a novel virus and provide testing to support ongoing response decisions. Pandemic influenza preparedness plans depend upon the public health laboratory delivering effective and coordinated diagnostic services, results, and communication. Epidemiologic surveillance programs that monitor for pandemic influenza rely heavily on accurate laboratory testing and, therefore, must have timely information. Furthermore, in the event of pandemic influenza, the appropriate use of antivirals and vaccination can only be accomplished with public health laboratory support. Public health laboratories are now called upon to fulfill a pandemic and all-hazards public health and national security mission. Without sustained federal funding from CDC and other agencies, our ability to respond to the increasing number of potential threats will be compromised.

Appendix-Influenza Primer

Influenza is a major public health concern in the U.S. as well as globally. Two types of influenza, A and B, are responsible each year for **seasonal** epidemics that affect 5–20% of the population causing significant illness with resultant lost time from work and school across all ages. The highest rates of illness occur in the very young often resulting in severe illness and hospitalization. Young pre-school and school-aged children are also responsible for initial transmission of influenza in the community. The elderly, particularly those over the age of 65 also suffer high rates of hospitalization and a disproportionate percent (90%) of the mortality which totals over 35, 000 each year in the U.S. This morbidity and mortality occurs despite the availability of effective prophylaxis (vaccine) and treatment (antivirals) measures

In recent years, *avian influenza*, so-called "bird flu" also has become a major concern. Aquatic bird species world-wide serve as the natural host for all of the subtypes of type A influenza known. Usually these viruses cause little or no illness in their natural host. Occasionally, however, certain subtypes mutate and become capable of causing severe illness with very high mortality, particularly within domestic poultry populations. These novel subtypes can also become capable of infecting humans resulting in very severe disease with high mortality. This is the situation that has been unfolding in the Far and Middle East, countries of Africa and Europe with the emergence of the H5N1 subtype of influenza since 2003. Since then, this virus has been responsible for the direct death or slaughter of hundreds of millions of poultry in affected countries. In addition, 328 human cases with 200 deaths have been documented in 12 countries. Almost all of these human cases, mostly children and young adults, have resulted from direct contact with infected

poultry; there is no evidence thus far of *sustained* human-to-human transmission. Should sustained human-to-human transmission of this or another *novel subtype* of influenza A occur, the result would likely be a worldwide epidemic, or **pandemic of influenza**.

During the past century, 3 influenza pandemics occurred with the biggest occurring in 1918–1919. This *Great Influenza Pandemic* or *Spanish Influenza Pandemic* as it was called was responsible for over 20million deaths worldwide and over 500,000 deaths in the U.S. while infecting an estimated 45% of the entire global population. The two subsequent pandemics in 1957 (“Asian influenza”) and 1968 (“Hong Kong influenza”), although milder in terms of morbidity and mortality, nevertheless had profound impacts on the global population.

Most experts feel that another pandemic is inevitable and many feel that we are now overdue. With today’s much greater population and global interconnectivity even a mild to moderate pandemic, similar to the last two, occurring as multiple waves over a period of two years or longer, would rapidly affect the world with rates of infection of up to 50%, mortality measured in the millions (100,000s in the U.S.) and severe social, infrastructure and economic disruptions.

Mr. LANGEVIN. Thank you, Dr. Shult. I appreciate your testimony.

And the chair now recognizes Dr. Caldwell to summarize his statement for 5 minutes.

Welcome.

**STATEMENT OF MICHAEL CALDWELL, MD, MPH,
COMMISSIONER, DUTCHESS COUNTY HEALTH DEPARTMENT,
POUGHKEEPSIE, NEW YORK**

Dr. CALDWELL. Good afternoon, Chairman Langevin, Representative McCaul. It is a pleasure to be here to speak to you on behalf of all the local departments of health in our country.

I come from Dutchess County, New York, the place and the home of Franklin and Eleanor Roosevelt, so greetings from there, and please, if you do come to visit, please let me know.

You know, Franklin Roosevelt won the presidency four times. Did you know that his home town of Hyde Park in the county of Dutchess never voted for him? Never. It was sad for Franklin.

And I tell you, it is kind of a microcosm of what it is like doing public health in Dutchess County. It is a challenge. We have a challenge in our county and we have a challenge in our country.

The combined efforts of my colleagues in local public health departments in first response will determine the initial as well as the ultimate impact of an influenza pandemic on the people of the United States.

Health departments are planning, but the success of those plans relies on the crucial linkages that have been built between our local public health departments and a range of governmental and community partners at the local level, including also the state and the federal level.

The relationships among these responders in many disciplines across our commissions, regardless of who their federal counterparts may be—they are growing more robust. They are better coordinated.

And I really want to answer your question that you asked, very simply, are we more prepared, and the answer is, yes. Today I bring you a story of progress, a story of success at the local level, but clearly an opportunity to improve, and an opportunity that I think needs to be led and demonstrate the leadership at our federal level.

There is no question that local emergency preparedness has evolved into an all-hazards approach right now. It requires communities to assure that all capabilities are necessary to respond to a wide range of emergencies.

Our health departments do not and cannot stand alone. All of our planning must be integrated with all of our partners and first responders. And one of the great advances we have had is the strength and mandate of the National Incident Management System, the Incident Command System.

Just this past week, I spent 3 full days in Poughkeepsie, New York completing the ICS-300 training with colleagues from emergency response—police, fire, EMS, water plant operators, state emergency management officials, state troopers, public health nurses. We really have made progress in that area.

In Dutchess County, we have learned this new language and we have put it into effect.

But more really needs to be done. We need to strengthen these opportunities. We need to strengthen this planning. And we also need to exercise and evaluate.

It is very important to know that the greatest strength that we provide at the local level is the strength of our American workforce.

Our astute clinicians and the partnerships that we have with our colleagues, our trained health care professionals, our alert hospitals—these effective partners are forged between these entities and our capable colleagues in local public health.

Ultimately, the local public health departments are the boots on the ground element of our nation's disease system. My health department receives and responds to thousands of infectious disease reports each year.

After September 11th, our county's hospitals and emergency departments began reporting on our hospital emergency response data system.

We also have partnerships not only with our health care providers but veterinarians and pharmacists. Soon we will be also reaching out not only to schools and school nurses but colleges and businesses.

We are actively engaged in cross training our entire community to be aware and be prepared.

We are also providing and improving our community alert network, our reverse 911 system of communication. We think that is one of our major roles and something that we are working hard to improve.

Ultimately, we believe that we need a strategy of implementation, not just planning. And the implementation happens at our level. We need the resources. We need the people. We need to exercise and evaluate. And we need to improve. We need sustainable and a growing commitment from the federal government.

Unfortunately, we have seen mixed messages from our federal leadership. There does not appear to be adequate coordination or cooperation between the planners of Health and Human Services and the Department of Homeland Security.

We have seen clear examples of us being left out of the development of the national response plan.

It makes no sense to develop a plan among federal officials and then just tell the local officials how it is going to work without integrating them and involving them in the first place, and also including in the development of those plans the understanding of how it is going to be implemented and carried out.

We are hopeful that the federal colleagues of ours will hear this message, and as we improve the future planning and the future versions of these plans, we will be able to get feedback from our testing.

And we are going to learn nothing unless we exercise and test our plans and constantly revise them.

So we are hopeful today by you having this hearing. We want to thank you for the recognition that we have made progress, that we need to do better. We need to continue our conversation.

And we look to the federal government to be able to serve as an example to us at the local level. If we see that there is miscommunication and miscoordination at the federal level, that impacts us at the local level and makes our jobs more difficult.

If my emergency response department and my health department have different planning tools, it makes it more difficult for us to integrate those tools.

Overall, our community and families depend on us for leadership. They depend on us for competency, for guidance, but most importantly, for action. We should not and we cannot let them down.

Public health preparedness is a long-term challenge, whether it is for pandemic influenza or any other emergency. We obviously cannot do everything at once, but we are making great strides. I am pleased with it.

And I want you to know that local public health departments are integral in both the planning as well as the execution of any pandemic influenza efforts. Thank you very much.

[The statement of Dr. Caldwell follows:]

PREPARED STATEMENT OF MICHAEL D. CALDWELL, MD, MPH

Good Morning Chairman Langevin, Representative McCaul, and distinguished Members of the Committee. It is my pleasure to address you today on behalf of the nation's 2800 local public health departments, who work on the front lines to protect their communities from pandemic influenza, as well as a multitude of other public health threats. I am a Past President of the National Association of County and City Health Officials and I have had an opportunity to learn from my colleagues across the country. I have had the privilege of representing our local public health departments by participation in focus groups for the development of standards for Fusion Centers to capture, coordinate, and rapidly communicate intelligence among all levels of government. In my home County of Dutchess in New York, I have been deeply engaged in pandemic influenza preparations under the leadership of our County Executive William R. Steinhaus. Today, I am happy to report to you on the progress made by local health departments and their community partners. I will also point out areas of concern that we have identified as shortfalls in current national pandemic influenza preparedness.

The combined efforts of local health departments and our colleagues in first response will determine the initial, as well as the ultimate impact of an influenza pandemic on the people of the United States. I will describe how local health departments are planning our response to a worldwide influenza outbreak, with an emphasis on how the success of those plans relies on the crucial linkages that have been built between local public health departments and a range of governmental and community partners. Relationships among responders in many disciplines and sectors across our local communities, regardless of who their federal counterparts may be, are growing more robust and better coordinated. If we are to protect our commu-

nities adequately, we have no choice but to reach out, engage, communicate and cooperate with our local partners.

Pandemic Influenza Preparedness Must be Integrated into All-Hazards Preparedness

Local emergency preparedness is based on an 'all-hazards' approach. This approach requires communities to assure the essential capabilities necessary to respond to a wide range of emergencies: intentional or naturally occurring infectious disease outbreaks; chemical, explosive or radiologic accident or attack; weather-related disaster; or other emergency.

Since 2001, with the elevated awareness of the country's vulnerability to intentional attacks with biological agents, there has developed a better understanding of public health's unique role in protecting our homeland. Whether the communicable disease threat is a novel influenza virus, smallpox, anthrax, West Nile Virus, SARS, or other emerging pathogen capable of causing widespread illness and death, there is a core of universal public health response capabilities for which all local health departments across the country are planning, training, exercising and engaging in a process of continuous evaluation and improvement.

However, our local health departments do not and cannot stand alone. All planning and response is and must be integrated with other local entities, most notably public safety first responders, but also state, federal and non-governmental partners. Fundamental to such integration is a shared command and management framework. With its strong foundation in the Incident Command System (ICS), the broader National Incident Management System (NIMS) developed under Homeland Security Presidential Directive 5 provides this common underpinning for all public health and public safety preparedness. Adoption of NIMS is facilitating the integration of language, mental models and even certain cultural aspects of public safety by public health professionals.

Just this past week, I spent three full days in Poughkeepsie, NY completing the ICS-300 training with colleague emergency response partners which included local police, fire, EMS, water-plant operators, state emergency management officials, state troopers, public health nurses and many other disciplines mandated to be trained. These mandates, while burdensome, provide many important benefits, including opportunities to meet and work with the very individuals who we will likely meet in the Emergency Operations Center (EOC) during a real emergency. I have always said that the EOC should be the last place for exchanging business cards of introduction with your critical partners.

In Dutchess County, the staff of our health department have learned this new language and approach. They have grown accustomed to planning and exercising within an incident command system. We practice this in many ways. For instance, we use incident command for our seasonal influenza vaccination clinics, so that we will know exactly how to address a need for mass vaccination. We have worked closely with the local police to address traffic and safety issues in planning our system of PODS, or points of mass distribution sites, which we would need to distribute medication during a pandemic or other public health emergency.

Through these opportunities to strengthen relationships, our county emergency management agency now understands and uses the expertise that our health department offers in epidemiologic surveillance, environmental health, and medicine. We work side-by-side on planning, education and evaluation. The health department is now included in emergency drills undertaken by other county agencies and organizations. This enables us to uncover and address discrepancies between the emergency plans of individual organizations, so that the expectations of every responding agency are universally understood.

Key Elements of Front Line Pandemic Influenza Preparedness

1. DISEASE SURVEILLANCE

The purpose of a strong surveillance system is to create time in which to intervene and to eliminate or mitigate threats. In local public health, practical disease surveillance means a system by which clinicians in private practice or in hospital settings can detect and report a novel flu virus or a patient who is suspected to have a reportable disease or an unusual case presentation to a public health authority capable of receiving, interpreting and responding to such a report. Ultimately, the country may reach a point where electronic medical records and associated systems will enable automatic reporting of diseases or suspicious symptoms, but such capability will be immensely challenging in this intensely diverse and complex national environment. We cannot wait, nor can we depend solely on technology when so much is at stake.

Our greatest strength is in our American workforce—our astute clinicians, our trained healthcare professionals, our alert hospitals—and the effective partnerships that are forged between these entities and capable local public health departments. It is important not to underestimate the immediate and important utility of this model of disease surveillance. As we recently witnessed with the case of the mismanagement of the internationally traveling groom with multi-drug resistant tuberculosis, all electronic monitoring efforts can be thwarted by just one human error. All of our new multi-billion dollar monitoring systems must be complemented with continued vigilance, training, testing and evaluation of our front line agencies and their workers.

Local health departments are the 'boots on the ground' elements of our nation's disease surveillance system. My health department receives and responds to thousands of infectious disease reports each year. In preparation for pandemic influenza, we have determined that syndromic surveillance must accompany traditional methods of case reporting. Syndromic surveillance will allow prompt identification of potential communicable disease clusters and trigger response long before laboratory confirmation is received.

After 9/11, our county hospitals' emergency departments began reporting individual patient's symptomatology to the state and local health departments via the HERDS (Hospital Emergency Response Data System) data base. In addition to this statewide effort, our local health department makes direct phone contact daily with each emergency room to identify clusters of illness or unusual presentations. This ongoing networking effort with local emergency departments and infection control staff has proved to be crucial in the early identification and response to infectious disease. We have also partnered with select community health care providers and veterinarians to function as sentinel sites for syndrome and emergent infectious disease identification.

Our most recent effort for improving our surveillance capacity is to work with schools, particularly school nurses. We are training them in the basic principles of epidemiology and disease surveillance and asking them to report absences due to sickness to us more frequently. It is our intention to expand these syndromic surveillance efforts to local colleges and major businesses soon. We are actively engaged in cross-training the majority of environmental sanitarians and public health nurses in the basics of outbreak response so they can assist in case investigation, contact tracing and outbreak control efforts should a large scale event occur.

2. COMMUNITY AWARENESS & SELF-SUFFICIENCY

One thing that we understand about a pandemic is that there will never be enough hospital beds to take care of the sick. We can predict that we will be asking both the sick and the well to stay home to help stem the spread of pandemic influenza. But we also know that our community needs early education, rapid communication and preparation so they will understand this if a serious epidemic occurs. Therefore, in Dutchess County we are placing a great emphasis on community education and have reached out to the schools, the business community, law enforcement, emergency services and home care agencies. Reaching every Dutchess resident in a meaningful fashion is a huge task. We can't do it all at once, but we work at it consistently because we believe that community understanding and cooperation will be absolutely essential in reducing the toll of a pandemic.

Our county's home care agencies are developing a unified emergency preparedness home care plan. This will enable our residents to know that there will be people available to deliver some medical and nursing care in their homes if they get sick.

There is a tremendous desire for information regarding pandemic influenza across all sectors and there is a great deal of work ahead for local health departments in spreading the word. This effort will be worth the return if we can reduce panic and increase creative response options when the need arises, which it will.

3. COMMUNITY INFECTION CONTROL

Over the past several years, the legal foundation required for public health to adequately protect the public in a catastrophic health emergency has been significantly strengthened in many states. Both state and local health departments have closely examined our respective responsibilities to isolate and/or quarantine persons, to control private property, or otherwise to intervene in private activities. All these would be unprecedented actions, requiring enormous pre-planning.

Our health department has worked with the County Attorney's office to educate legal, law enforcement, and emergency medical professionals about isolation and quarantine. We also conducted a "tabletop" exercise to test our knowledge and we will be continuing to follow-up on these efforts.

4. MASS DISTRIBUTION OF VACCINES AND MEDICATIONS

Timely development of an effective vaccine, in sufficient quantity to immunize the population against a novel virus, is a huge challenge that the Federal government has taken important steps to confront. Local health departments are responsible on the ground for accepting delivery of the Strategic National Stockpile in which such a vaccine or anti-viral medications would be stored. Mindful that we do not now have the ability to manufacture sufficient quantities of such countermeasures, we must still have in place all of the planning, staffing and public information systems necessary to promptly distribute them to all priority populations in the county.

While we've not experienced a pandemic flu, local health departments have had parallel experiences and exercises that have tested our ability to provide mass vaccine and medication distribution. During the 2004 seasonal flu vaccine shortage, with delayed shipments causing the public to become extremely anxious to get their flu shots, our department gave 5800 doses in two days to our most vulnerable populations. (Dutchess County has a population of 300,000.)

Yet again, we could not have managed this mobilization without the full support of our public safety partners, who provided security, traffic control and emergency medical care. These are no minor feats in a mass setting, especially in a real life situation where emotions are running high and the chance of panic is never far away. The public already has benefited greatly from the collaboration between public health and public safety agencies. Only through a highly coordinated and very broad approach will we achieve maximum homeland security in the face of an influenza pandemic.

Another example of the ongoing efforts to enhance inclusiveness and communications between agencies is that I was invited and am now a member of our Dutchess County Chiefs of Police Association. When I entered public health school and when I began my position as Commissioner of Health back in 1994, I could not have imagined being a member of the Chiefs of Police Association. Times have changed and so have our thinking and response to new and emerging threats.

People are Key to Preparedness

Prior to 9/11, many local health departments were open only during conventional business hours. Unlike fire or police departments, there was no tradition, structure, or funding for operating 24/7. That has changed. Now we all have 24/7 coverage and an ability to call out our staff regardless of the hour. But we do it mostly by increasing expectations for existing staff. In Dutchess County, we have established two new positions for public health preparedness. We have no large cadre of new staff. However, our entire health department staff, from the clerical staff to the Commissioner, have received and will continue to receive training in the ICS system.

One characteristic of all the operational capacities needed for effective pandemic influenza planning I have described above is that they are labor-intensive. While we do need to make certain capital purchases in public health, such as communication equipment and personal protective gear, the bulk of our costs are for people. It is people who do the collaborative planning in the county and work closely with their state counterparts. It is people who learn new skills for their new roles in preparedness. It is people who educate the community. It is people who reach out to hospitals, businesses, schools, and all the non-governmental organizations whose help we need to prepare our communities for a pandemic.

The structure and funding of the nation's pandemic influenza preparedness efforts simply do not recognize this reality. A NACCHO survey showed that the average grant received by local health departments nationally for all-hazards preparedness declined by 20% from fiscal year 2005 to fiscal year 2006. Supplemental federal funds for state and local health department work specifically in pandemic influenza preparedness will terminate in August 2008. We are deeply worried that, as federal priorities change, our ability to sustain the workforce that must continue the complex job of preparedness will diminish. Our local funding for all-hazards public health preparedness has been eroding steadily.

Federal Leadership

It is a positive step that so many in this country are paying attention to pandemic influenza before we find that threat a reality. We often tend to focus on the last event, but in this case the focus has been on being proactive—a fact which is evidenced by the very existence of this hearing. Your leadership on this issue is appreciated.

However, there doesn't always appear to be cooperation and coordination between preparedness planners at the Federal level and those working at the local and state levels. In addition, the Department of Homeland Security (DHS) has made progress in understanding and integrating public health in fits and starts. Initial efforts toward fulfilling HSPD-8 showed limited understanding of what public health even was and how it would mount a response in an incident. As I described above, pan-

dem ic influenza response will require much more than medical care and hospital beds.

NACCHO has long been concerned that DHS planners, unlike their state and local counterparts, have little appreciation for the local public health role in pandemic influenza response and for the kinds of local operational realities I have described above. The vast assortment of DHS committees and task forces have only a smattering of public health representation and the opportunities for meaningful input have been scant. We respectfully suggest that, while including representation from the Department of Health and Human Services in DHS work is important, it is not an effective substitute for gaining the input of public health departments who are doing the operational planning every day.

For example, we share the frustration of many local and state officials about their lack of representation in the revision process for the National Response Plan (NRP), which will govern response to pandemic influenza, as well as all other national emergencies. DHS tasked 12 workgroups to focus on specific issue areas of the NRP. One of these workgroups focused on "State and Local Roles and Responsibilities," but had only six state government representatives and no local government representatives, compared to a group of approximately 40 federal representatives. None of the state representatives were public health officials. If DHS intends the new National Response Framework to address pandemic influenza effectively, local and state governmental public health experts should be engaged at the beginning, not during a comment period at the very end.

The input of local responders in public health and every other discipline of public safety must be brought to bear on DHS plans and guidance in a manner that enables serious listening and timely input. That is the only way to bridge the federal gulf between traditional emergency response and public health emergency response. At the local level, we believe that public health and its public safety partners understand the true meaning of "all-hazards" preparedness, as well as the special place that pandemic influenza planning has within that context. We strongly urge improvements in this regard at the federal level.

Federal agencies need to collaborate in sending coordinated and reinforcing messages to all grantees at state and local levels that multidisciplinary cooperation is a high priority. Through the structure of grant programs and the guidance provided, DHS and HHS can either facilitate local efforts in that regard or hinder them with inconsistent guidance. HHS guidance for public health emergency preparedness has been incorporating many dimensions of the NRP, such as required training in the National Incident Management System. In general, however, federal agencies are developing and disseminating uncoordinated, fragmented, and dissimilar plans for addressing pandemic influenza.

Finally, while much time is spent asking local and state emergency personnel to understand how the national response plan is structured, we need to remember that no matter how serious the emergency, the response always begins locally. And in the case of pandemic influenza, the effectiveness of that early response will determine how the emergency unfolds. Standardization is important to the extent that it can be realized, but national plans also must support a response in every corner of this diverse country. A top-down, one-size-fits-all approach simply will not be successful.

Whether pandemic influenza or some other disaster afflicts our nation, there is no shortage of dedicated Americans at every level of government working hard on homeland security. Continuing to promote, support, and build local partnerships among public health, health care, public safety, emergency management, and a host of private sector partners will only improve our ability to protect the health and safety of our communities.

Thank you, on behalf of all the nation's local health departments, for your concern and leadership.

Mr. LANGEVIN. Thank you, Dr. Caldwell.

Before I go to Dr. Lakey, there is a vote on right now. My intention is to go to Dr. Lakey for your statement and then we will recess for about 20 minutes, come back for a very brief round of questions and then conclude.

With that, I recognize Dr. Lakey for the purpose of summarizing his statement for 5 minutes.

**STATEMENT OF DAVID LAKEY, MD, COMMISSIONER, TEXAS
DEPARTMENT OF STATE HEALTH SERVICES, CENTER FOR
CONSUMER AND EXTERNAL AFFAIRS**

Dr. LAKEY. Good morning, Chairman and members. My name is David Lakey, and I am the commissioner of the Texas Department of State Health Services.

And I want to thank you for this opportunity to testify on the progress and the challenges we face in Texas preparing for pandemic influenza.

In order to understand these, you have to understand something about the Texas structure. The governor's department or division of emergency directs overall disaster response in the state of Texas.

Department of State Health Services, however, is the primary agency for coordinating health and medical preparedness and for coordination of pandemic flu prevention, detection, response and recovery.

We have significant experience in Texas in disaster response. However, pandemic influenza response is unique, as has been outlined here earlier today.

There are issues related to the geographical spread. There are issues related to the length and duration of the pandemic. And thus, pandemic influenza is not just a medical issue. It is a societal issue as we respond.

One of the strategies in public health to respond—one of the cornerstones is called social distancing, basically keeping individuals apart so they do not spread the disease one to another.

And this includes closing schools, canceling public events, working from home—and these are hard decisions. These decisions are made locally, and we have to work as a state with our local partners to make sure that there is continuity in how these decisions are made.

We also have to address worker safety issues to make sure that the first responders are safe when they respond to individuals with influenza, so they do not become the next victims.

We also are struggling with how do we continue our operations to make sure we have continuity of operation plans. In a situation where you have 30 percent or 40 percent of workers absent, how do we continue to keep government functional, businesses functional, utilities that are being provided?

We also have to look at hospital surge capacity, especially intensive care surge capacity. This will be a major stress on the hospital system and the medical system during a pandemic.

Thus, with that background, we have been working for several years now on how do we respond as a state to this threat. And we have done this in collaboration with many stakeholders, our local partners, our federal partners, so that we can develop comprehensive plans in the state of Texas for disaster response.

This is a part of the overall state disaster preparedness plan, and we have also developed a more comprehensive 122-page guideline for pandemic influenza that outlines what we specifically need to do in each stage of the pandemic.

We have worked to make sure that we can allocate and distribute the antivirals if they are available. We have worked to

make sure that we can vaccinate individuals very rapidly, as was discussed earlier today.

And we have made sure that we have set up a statewide laboratory diagnostic system, part of the Laboratory Response Network that was discussed just a minute ago, so that we can rapidly diagnose individuals with influenza in a matter of about 3 hours after the samples are sent to the system of 10 labs across the state of Texas.

We have also provided guidelines to the local health departments so that it is an integrated response in Texas and have developed information tool kits for health care providers and community leaders.

A couple other projects we have been working on this summer have been the development, working with the CDC, to look at our laws in the state of Texas to make sure we do have the right legal infrastructure during a pandemic.

And we have been working with state agencies across Texas to make sure that there are continuity of operation plans in all agencies in state government and that there is some consistency in H.R. policies throughout state government when a pandemic occurs.

We believe that there are really three critical components of a strong response to pandemic influenza. First, we need to build and maintain a strong public health system. This is locally, at the state and at the federal level.

We need to create partnerships between the federal, state and local level and international partners and private partners in this response.

And we need to recognize that there are differences between local areas and maintain the flexibility that allows states and localities to act effectively and efficiently during this threat.

It can't be overemphasized, the importance of a strong public health system. Texas' success has been due to building on the public health system and using an all-hazards approach for all types of threats, so we can identify them, monitor them, ensure that we can respond effectively, and that we communicate with our public and our private partners during this time period.

A couple of examples of the strengths that have occurred in Texas include the development of our Strategic National Stockpile Operations Plan. That has been reviewed by the CDC and it received a very high score this last month.

Our plans have had favorable recognition by the CDC. We learned during Katrina and Rita the need for a multiagency coordinating center during any type of disaster where we bring the individuals that need to take care of the logistic components of ICS, Incident Command System, together, all incident command systems, so we can have a coordinated response.

We have established a surveillance system for all viruses, respiratory viruses, so we can identify them early. And we have been coordinating with our CDC partners and other partners at the border ports of entry and at major airports.

And finally, we have developed a public health information network so we can disseminate information quickly to our partners throughout the state of Texas.

And again, it is important to have a very strong public health response. It is also important to have federal, state and local partnerships. This is not something that the state can do on its own. And this has to be coordinated through all these different partners.

This needs to be sustained. There has to be sustained commitment and consistent direction from the federal level in order to ensure that these programs that have been developed continue.

This is an ongoing threat, and in order for us to be successful, we have to have integration across all levels of government and coordination across jurisdictional lines.

We understand the need for partnerships in Texas. We have very large cities. Four of the 20 largest cities in the nation are in Texas, and we need to coordinate from the state level with these cities.

We have sea and airports that are among the busiest in the country. We need to partner with them as part of this disaster preparedness.

And over half the U.S.-Mexico border is in our state, and over a million individuals cross the border legally every day, and thus we need to work in partnership with our Mexican colleagues.

We also believe that there is an importance for flexibility in the overall response, that there is flexibility in preparing and responding to a pandemic and that different localities have different challenges that need to be addressed.

We need to have flexibility in the use of human, financial and medical resources.

Texas is a local-controlled state, and so many of the decisions for pandemic influenza will be made at the local level, and they need to have the flexibility to be able to respond appropriately.

Ninety-five percent of all the funds that come to Texas go to the local health departments to ensure their ability to respond.

In summary, as I said, there are three priorities that I think are critical. One is to have a strong public health system.

The second is to have consistent partnerships between the local, state, federal and international partners.

And third, we need to have flexibility, and it is essential, in order for the state to respond appropriately.

Federal funds allow Texas to build an emergency response infrastructure to enhance our overall preparedness, and it needs to be sustained in order for these programs to continue.

And we appreciate the investment from the federal level and look forward to a sustained partnership. And I appreciate your time today.

[The statement of Dr. Lakey follows:]

PREPARED STATEMENT OF DR. DAVID LAKEY

Opening

Good morning Mr. Chairman and members of the Subcommittee. Thank you for the opportunity to testify on the Texas perspective on planning for Pandemic Influenza.

My name is Dr. David Lakey and I am the Commissioner for the Texas Department of State Health Services, known as DSHS, which is the primary state agency responsible for coordination of pandemic influenza prevention, detection, response and recovery. I became Commissioner on January 2, 2007. Prior to that, I served as an associate professor of medicine, chief of the Division of Clinical Infectious Disease and medical director of the Center for Pulmonary and Infectious Disease Control at the University of Texas Health Center in Tyler. At the UT Center for Bio-

security and Public Health Preparedness, I was the associate director for infectious disease and biosecurity. In addition, I chaired a bioterrorism preparedness committee for 34 hospitals in East Texas and led development of the Public Health Laboratory of East Texas in 2002.

As the state's public health authority, it is our mission to promote optimal health for individuals and communities while providing effective health, mental health and substance abuse services to Texans. Some of these activities range from ensuring essential public health services, such as immunizations to children, tuberculosis prevention and treatment, and food safety regulation to health care safety net services for our neediest Texans, like low income women with breast and cervical cancer or treatment for individuals with mental health illness. Our department also regulates health care facilities and many health care professions.

Integrating Pandemic Influenza Response into All-Hazards Approach

Today, I am here to discuss the major successes and unique challenges that Texas has experienced in preparing for Pandemic Influenza. Texas faces many different emergency situations, ranging from hurricanes, floods, and tornados to infectious disease outbreaks, such as measles. That is why Texas has taken an all-hazards approach by integrating pandemic influenza preparedness and planning into our health and medical response plans. By taking an all-hazards approach, DSHS is building an emergency preparedness infrastructure that can quickly respond to natural, infectious disease and manmade disasters. In a large state like Texas, with very large and small communities, this approach requires working closely with local jurisdictions, health departments and responders. Although influenza pandemics have unique characteristics, response preparations still need to be part of an all-hazards plan. After a pandemic outbreak begins, it is too late to prepare.

First let me outline for you the emergency response structure in Texas and DSHS' primary responsibilities for health and medical preparedness and response.

Public Health and Medical Emergency Support

The Governor's Division of Emergency Management directs the state's role in disaster response: to maintain overall situational awareness and support community response, to provide guidance to local jurisdictions, and to coordinate securing and deploying federal and other resources when state and local assets are insufficient to meet the need. DSHS serves as the primary agency for public health and medical services. Our agency is responsible for coordinating health and medical preparedness and response activities according to the National Response Plan that addresses not only public health and medical services, but also nuclear and/or radiological incidents.

Texas Pandemic Influenza Plan Operating Guidelines

Influenza is always on the watch list, and Texas preparations have been ongoing to get ready for pandemic influenza. In Texas, influenza surveillance activities continue to expand—from identifying Texas illnesses to monitoring global events. Texas began developing its current *Pandemic Influenza Plan* in 2002. The Texas plan, which complements the revised World Health Organization plan and the U.S. plan, includes:

- Guidance to local health departments for working with their community leaders;
- Considerations surrounding allocation and distribution of vaccines and antivirals;
- Updated designs for mass vaccination clinics based on real-time, full-scale exercises;
- Development of information toolkits for health care providers and community leaders.

The plan was developed working in concert with our partners at the local, state and federal levels, including the private sector.

DSHS Responsibilities During an Influenza Pandemic

In Texas, DSHS is the primary state agency responsible for coordination of pandemic flu prevention, detection, response, and recovery, working under the overall framework of the state's emergency management system led by our Governor's Division of Emergency Management. These roles include:

- Developing and maintaining a statewide pandemic flu response plan to provide guidance in preventing, preparing for, identifying and responding to pandemic flu that affects the state;
- Developing and maintaining a statewide pandemic flu surveillance system to detect circulating flu strains;
- Sustaining Texas' ability to rapidly isolate and subtype flu virus;

- Coordinating and supporting training and awareness campaigns for the public related to identifying, preventing and controlling spread of pandemic flu;
- Ensuring timely dissemination of pandemic flu vaccine when it becomes available;
- Organizing attempts to stop, slow, or otherwise limit the spread of pandemic flu by providing guidance to local health departments on activating official response teams, enhancing disease surveillance, collecting specimens and starting interventions;
- Managing and supporting efforts to ensure timely dissemination of Strategic National Stockpile (SNS) resources, including other pharmaceuticals and medical supplies;
- Directing provision of disaster mental health to first responders and those affected.

Recent Successes in Pandemic Preparation

Texas and the Department of State Health Services have achieved some notable successes in our efforts to conduct preparedness and response planning for pandemic influenza.

Strategic National Stockpile (SNS) Technical Assistance Review

Just last week, CDC conducted a technical assistance review of our state plans for the implementation of the Strategic National Stockpile (SNS) plan. While Texas' score is not official, DSHS has been told that it will receive a state level score in the high 90's out of a possible 100. This comprehensive review looked at Texas' readiness and ability to put into action its SNS operations.

CDC Review of Texas Pandemic Influenza Operational Plan

Another recent success was the recognition from the Centers for Disease Control and Prevention (CDC) which provided a review of the six priority areas of the Texas pandemic influenza operational plan. These six priority areas include:

- Antiviral Allocation, Distribution and Storage;
- Communications;
- Surveillance/Laboratory;
- Continuity of Operations;
- Mass Vaccination, and
- Community Containment/Mitigation.

Of these six priority areas, two in particular, Communications and the Antiviral Allocation, Distribution, and Storage Plans were identified as best practices in these areas of preparedness. The DSHS Pandemic Influenza Communication Plan was lauded as being in—depth, detailed and reflected exemplary effort in its development. While the DSHS Anti—Viral Distribution Plan was cited for being well—thought out plans with elements that were exercised and proven to be effective.

Multi-Agency Coordinating Center (MACC)

Another success grew out of the integration of an all-hazards approach to health and medical emergency preparedness. The back-to-back impacts of Hurricanes Katrina and Rita tested the capabilities of DSHS, with federal, state and local partners, to respond to physical and mental health needs resulting from these natural catastrophes. These events led Texas to create the Multi-Agency Coordinating Center (MACC), which provides a state health and medical response across Texas' health and human services agencies during emergencies including pandemic influenza. The MACC has allowed DSHS to better coordinate with state and local partners, in both the public and private sectors, to strengthen the state's public health infrastructure in responding to health and medical emergencies. A state-level pandemic exercise was conducted in mid-August 2007. Lessons learned from that activity and real-life activations were incorporated into MACC emergency operation procedures. After action reports relating to the past hurricanes and recent flooding responses have also led to continued improvement of systems which enhance pandemic preparedness in Texas.

Increased Surveillance Activities

To enhance disease surveillance activities for pandemic influenza, DSHS has instituted procedures and policies for the surveillance and evaluation of cases of Influenza-like Illness (ILI), including a registered sentinel network of primary care providers. This includes working closely with the DSHS Public Health Laboratory to identify both influenza and other respiratory viruses. In addition, DSHS has an ongoing collaborative relationship with the CDC Division of Global Migration and Quarantine, both with training exercises as well as true public health events of concern regarding the potential introduction of communicable infectious agents, including H5N1 avian influenza and tuberculosis. These activities are closely coordinated with CDC and other partners involved with ports of entry and departure, both along

the Texas—Mexico border and other International Ports of Entry at major airports. These measures include strengthening surveillance, laboratory, and hospital response capacity and improving statewide communication about public health and medical threats through the Public Health Information Network (PHIN). The PHIN is an electronic system for quick distribution of specific health and medical information to local health departments, community leaders and medical providers throughout the state. In addition, the PHIN provides video conferencing and distance learning capabilities, along with a mechanism for ensuring the security of health data that is transferred from those members of the network to DSHS.

Laboratory Response Network

Over the past 5 years, Texas has worked to develop a Laboratory Response Network (LRN) across the state. Currently, our state has established 10 high level containment LRN laboratories that can rapidly diagnose infections of significant public health concern. Of these labs, eight can now also diagnose H5N1 avian influenza in about three hours after a sample is submitted to them. This type of infrastructure facilitates a rapid public health response throughout the state and is a critical component in the early identification of a pandemic influenza outbreak.

Some Remaining Challenges in Pandemic Preparation

Size of Texas and its International Border with Mexico

One of the biggest challenges in preparing for pandemic influenza in Texas is reaching all our residents quickly. The size and diversity of Texas results in a wide variety of needs and requires a large number of resources to meet those needs. It is further from El Paso to Houston than it is from El Paso to San Diego, California. Texas has four of the nation's largest cities by population and also some of the most rural and sparsely populated areas in the country. In addition, over half of the U.S.—Mexico International Border is in a part of Texas that covers 32 different counties and four separate Mexican states. Communications between all these different public health agencies is essential. When you consider that over a million legal crossings take place each day along this border, it is a test of the Texas public health system to work in a binational effort with Mexico to identify and prevent the potential for pandemic influenza. Other factors that complicate the disease surveillance activities along the Texas—Mexico border is that cross-border trade more than tripled since 1993, along with rapid population growth on both sides of the border. Added to the challenges represented by the Texas—Mexico border are other points of entry such as sea ports and international airports. Strong public health systems along the Texas—Mexico border and at other designated U.S. points of entry serve not only our state but the entire nation to minimize any potential for spreading pandemic influenza in the United States.

Texas: A Local Control State

Texas is a local control state, and many final decisions about pandemic influenza will be made at the local government level. The DSHS plan was developed with local input to provide a simple, flexible process adaptable for state, regional, and local jurisdictional use. In those areas of the state where there is no local health department, the DSHS regional offices serve as the local health authorities. The goal has been to ensure that Texas continues to build and enhance processes to provide public health planning and response capacity at all levels in all communities. To build local preparedness capacity, DSHS began contracting with local health departments (LHDs) in 2002. DSHS has directed 95% of federal funds to preparedness activities at the local level including direct contracts with local health departments. Separate funding is provided to local governments through two CDC sponsored special initiatives, Cities Readiness Initiative (CRI) and Early Warning Infectious Disease Surveillance (EWIDS).

To be successful locally, it is essential to allow more flexibility for differences in responding to local needs. Maintaining essential public services is a big concern. Hospitals could be inundated; medical staff could be in short supply; police forces may face citizen discontent and other security issues; and keeping citizens supplied with food, clean water, and other basic essentials could become a serious challenge, especially if workers themselves are sick or home caring for loved ones.

Restrictions on Use of Federally-subsidized Antiviral Medications

Antiviral medications can be effective in preventing and treating influenza viruses in a pandemic, especially in reducing the duration of symptoms and some influenza complications. Their use forms one part of a comprehensive approach taken by DSHS to containing pandemic influenza. This approach begins with a strong seasonal flu program to increase vaccination rates, improve surveillance, provide education, and develop best practices for treatment. Planning for antiviral use includes identifying target groups to receive these drugs, allocating and delivering antiviral drugs, communicating critical information, and monitoring the effects of antiviral

drugs. The priority groups to get any available influenza vaccine or limited antivirals during an influenza pandemic may be different from the groups identified for influenza shots during a typical influenza season.

Texas had the opportunity to purchase the antiviral medications Tamiflu® and Relenza® at a deep discount, based on a low federal contract price. The Texas Legislature appropriated \$10 million in general revenue funds in 2007 to purchase additional antivirals for the state supply under the federal contract. This will purchase about 675,000 courses. About 1.5 million courses remain available to Texas for purchase at the federally subsidized price. This remaining amount has been offered to eligible local entities to purchase at the federally subsidized price.

However, there are important drawbacks to purchasing antivirals for stockpiling under this special federal contracting price. There are national policies that prohibit using medications bought on the federal contract for anything but a pandemic declared by the CDC and thus we are not allowed to rotate through the stockpile. Furthermore, since these antiviral medications have a limited shelf life of about five years, our inability to use antivirals purchased under the federal contract for seasonal flu or other illnesses when the fifth year draws close impacts our state's investment in these medications. Other factors include the uncertainty as to whether currently available antivirals will be effective against an emerging, unknown pandemic flu virus. Better and/or less expensive antiviral medications may become available between now and the start of a pandemic. These unknowns and limitations create a challenge in making the case that the purchase of antiviral medications is a good investment.

A Pandemic is Unique

There are differences in health and medical responses required for a hurricane versus a pandemic influenza outbreak. A pandemic is unique in that this is a societal issue, and not just a medical issue. The state and local communities will have to adjust by modifying their normal medical and non-medical responses, such as employing social distancing measures like school and public closures and sheltering in place to counter spread of pandemic influenza. A number of other factors exist making a pandemic influenza response unique. That is why we believe that a multi-faceted, comprehensive approach will better prepare Texas for containing pandemic influenza.

One challenge is preparing for many different response scenarios, including the inavailability of vaccines and antivirals. People will likely need to change their behaviors to reduce illness and death. In the absence of an effective vaccine, "social distancing" will be a key tool in slowing the transmission of a pandemic influenza. "Social distancing" is a term which encompasses such things as school closures, cancellation of public events, working from home, minimizing travel on public transportation, and a range of other steps to essentially keep people away from each other to mitigate spread of the disease. The detailed decisions on such restrictive measures must be made locally. The need for social distancing will take on a greater importance as schools may need to close and activities such as shopping or large-group activities may have to be limited. Local communities might have to figure out how to maintain these restrictive measures for an extended period.

Texas is one of 18 states taking part in Social Distancing Public Health Law Project sponsored by the Association of State and Territorial Health Officials (ASTHO) in collaboration with the Centers for Disease Control and Prevention Public Health Policy Center (CDC). The project's goal is to assist states in assessing their legal preparedness to implement social distancing measures for both declared and undeclared public health emergencies. A careful review social distancing laws as they currently exist in Texas has already been done. We are working with state elected officials, other state agencies, along with private and other public partners to identify gaps, omissions, and potential conflicts between laws and if statutory changes are needed.

Worker safety is another issue that must be addressed. In responding to a pandemic influenza outbreak, the very workers that are responsible for helping to control the outbreak and care for the ill become at risk of being infected. More than that, workers who keep essential services such as food and water in supply are susceptible. For that reason, the federal government and states have purchased antivirals as one tool to help protect first responders, health care personnel and those essential infrastructure workers. Education of infection control practitioners is also critical to assessing potential exposure situations and preventing the spread of the disease in the healthcare setting to other employees and patients. Other worker safety supplies, such as masks, are important for response efforts, but are not something that we would normally stockpile for a typical disaster response.

In pandemic preparations, we must plan for a scenario where 30 to 40 % of the workforce is absent. A key effort will be continuity of operations planning. Planning

for scenarios where such a large number of the workforce is not present represents a challenge for government and also for the private sector. DSHS has been involved in this effort on many fronts, including putting together a business summit and by working with other state agencies to coordinate the human resources policies of Texas state agencies in the event of a pandemic. More work is needed in this area to help educate our businesses and communities of the potential impact of a pandemic and strategies that will help mitigate its impact.

A final factor relating to the uniqueness of pandemic influenza response is the difficulty hospitals will have due to their limited surge capacity, especially in the area of intensive care. Because the pandemic occurs in waves and affects such a broad cross-section of our population, we can anticipate that even a mild pandemic would be a major stress on the medical/hospital system. Hospitals are a critical component of the response system in a pandemic flu outbreak and direct discussions with hospital organizations and their members is necessary to determine how this type of surge will impact the operations of hospitals.

Closing

Despite the complexity and challenges that come with pandemic influenza preparedness planning, DSHS is always working to enhance the public health infrastructure across the state. That includes continued efforts to coordinate assessment and planning with not only our local partners, both public and private, but other neighboring states and Mexican Border States for prevention and containment of illnesses. The goal has been to ensure that Texas continues to build and enhance processes to provide public health response capacity at all levels in all communities. CDC Public Health Preparedness (PHP) funding over the last five years has allowed Texas to build an emergency response infrastructure in those areas where it did not previously exist and to enhance PHP programs in the larger metropolitan areas. As Texas' Public Health Preparedness and Response efforts have evolved, particularly with the threat of pandemic influenza, focus has shifted from building infrastructure to building response capacity in support of a program that has grown in sophistication and complexity. It is my hope that the federal government will give states the flexibility to be able to make the necessary adjustments to meet the diverse needs of its population and the continued support to build and maintain the capacity to protect our state and nation from an influenza pandemic.

Thank you for this opportunity to address you on a subject of great public health importance.

Mr. LANGEVIN. Very good. Thank you, Dr. Lakey.

With that, as I said, it is my intention to recess for about 15 minutes or 20 minutes. We have two votes. We will come back for a very brief round of questions.

Dr. LAKEY. Thank you.

Mr. LANGEVIN. Thank you very much.

The committee stands in recess.

[Recess.]

Mr. LANGEVIN. We appreciate the panel sticking around for a few more minutes, and we will get right to the questions. I will begin with Dr. Cirillo.

In your opinion, are hospitals and major medical centers getting enough federal funding and guidance to prepare for an influenza pandemic?

And how do you propose getting all of the funding resources and guidance that you feel are necessary down to primary care providers?

Dr. CIRILLO. I will be honest with you, Congressman, that there has not been enough money, and the amount of money that it would take to say that we are fully prepared, if we could ever say that, is very significant.

We did calculations in Rhode Island for a year-long pandemic in order to try and have enough medical equipment, supplies and to be able to provide some reimbursement to health care providers

who would come and assist the state, and the price tag for that, for 1 year, was \$550 million.

And those were, you know, rough calculations, but that gives you some sense of the amount of money that it would take to really continue to deliver health care to, you know, an increasingly sick and large number of patients.

I think what we have done is tried to build on those partnerships that we have had through the Hospital Preparedness Program. That has allowed us to try and create common infrastructure, to create common efficiencies with the hospitals.

The challenges that we face, though, are that even if we can stand up alternate care sites and find extra space, the issue of where will the ongoing supplies come from once we get through our initial cash, and where will we continue to find and recruit health care providers—we have discussed the issues of doing, if you will, battlefield promotions.

You know, how can we take medical students even early on in their career and quickly give them some just-in-time training to increase their ability to provide care?

How do we take family members and teach them the basic skills of family health care, to try and allow people to be taken care of at home or at an alternate care site or at a hospital?

So those challenges of resources are still the critical ones that although we can create that infrastructure, when the rubber really hits the road, I think my greatest concern is that the resources that we have will be utilized fairly quickly.

And then it will become increasingly difficult to keep the same standard of care and the challenge of decreasing standards of care or altering them really is something that is very difficult.

Mr. LANGEVIN. Let me ask this question, because it is funding related, and the panel can comment on either the previous question or the current one that I have.

I understand that many of the preparedness grants from HHS, for example, are 1-year grants. Why is this?

And wouldn't it be more efficient to put more multiyear grants out there, which would encourage states and agencies to develop longer-term, more broad-reaching goals?

We will start with Dr. Cirillo, and then if anyone else would like to comment.

Dr. CIRILLO. I think we have tried to encourage our federal colleagues to look at that as an option. I would like to share a very Rhode Island sailing analogy, which is if I decide I want to sail from Newport to the cape, I know where I want to end up.

Along the way, I may have to change and tack with the wind a little bit, but I have a goal of where I want to be in a certain period of time.

And on our level, if we continue to change priorities and change terminology and change strategies every year, it really takes more away from actually being prepared and devotes more time, money and resources to just managing the program, and that is really not what we want to do.

So I think a longer strategy—much as the bills and the programs are authorized for a multiyear basis, we would like to see at the state level that the grants are administered on a multiyear basis

so that we can establish long-term goals, long-term strategies and keep moving toward those in a coordinated fashion.

Mr. LANGEVIN. Any comment from the panel?

Mr. SHULT. If I could maybe bridge the two questions, I agree with all of the previous comments. We have gotten substantial, although now declining, levels of funding to build laboratory capacity in terms of our diagnostic testing, our laboratory networks and developing an emergency response culture.

That needs to be sustained. A lot of that money now is going to sustaining some very highly trained staff where if the money goes away, we are going to be in jeopardy hanging onto them.

So I think Wisconsin has benefitted probably better than some other states in that regard.

I would echo the comment that—well, and then to make up the shortfall, funding essentially comes out of my operating budget in my division and ultimately my public health lab.

It makes it difficult, if we are making decisions on a year-to-year basis, never quite sure how much funding is going to be there, and how much shortfall I am going to have to make up.

So we have enough, we have had an adequate amount to build substantial capacity capability. That needs to be sustained, but it would help us a lot to be able to do this on a multiyear basis so we can set up the long-term goals and maybe shift priorities.

Mr. LANGEVIN. Anyone else?

Dr. CALDWELL. I can tell you that the national county and city health officials are very concerned that we have seen declines of 20 percent or more in the all-hazards preparedness dollars that have gone out to local departments of health—and to know that the pandemic influenza preparedness funding is expected to terminate in August 2008.

You know from your own experience that when federal resources are made available that states and communities will take those resources and match them.

They will do that more readily if they know there is a sustainable commitment over time. And a lot of this has to do with hiring personnel, as you are well aware.

And that is the core part of what we have been trying to do initially, is to build our capacity of professionals to help us with the planning as well as the development of partnership-building and ultimately of exercising and evaluating this.

This is a long-term commitment. The long-term vision is there. And the federal government needs to provide the strength and the foundation to say we are making this a priority in many ways through the passage of certain acts that this is the goal that we have, the public health preparedness and emergencies act, what it is we need to do, and also the resources behind it.

When my county executive sees that there is going to be possibly a termination of funding, he is very uncertain of whether he is also going to be able to match money as well, or start a program and then know that maybe he will have to be fully responsible for it completely, and then not even know whether that may be something that could be implemented.

So therefore, not only in my jurisdiction, but across the country people are wondering, "Well, should we go and make the extra effort or are we going to be stuck?"

Mr. LANGEVIN. Dr. Lakey, any comment?

Dr. LAKEY. I think my comments echo the comments that have already been made. Every year significant effort comes from our agency in the whole grants management process of reallocating the funds.

And having sustainable funding to the local health departments would go a long way in getting them to step up and be a full partner in this. Actually, on the local side, there is a lot of effort that they have to put into every year in this whole grants management project.

I think also, on your first question, I don't think the hospital component is a huge issue. For example, in Austin, a city of 1.3 million, we would expect that we would have 13,000 individuals that would be hospitalized during a pandemic.

And so there are significant preparedness activities that have to take place in the hospitals, and they need the consistent funding.

And they also need to make sure that when that occurs there is some flexibility on how they are going to be able to bill patients and be able to get the ongoing revenue.

If they are taking care of patients in a non-traditional manner on different floors, et cetera, are they still going to be able to keep the billing—be able to keep the financial security of the hospital—during that time period? And that is an issue that I hear from hospitals when I discuss it with them.

Mr. LANGEVIN. Thank you.

The chair now recognizes the ranking member, the gentleman from Texas, for 5 minutes.

Mr. MCCAUL. Thank you, Mr. Chairman.

Well, first I want to thank the witnesses for their patience. I know it has been a long hearing, and we don't control the votes—at least, I have no control over that. And thank you for being here.

You know, the long-term commitment is important on the part of the federal government on an issue that is so important as this one.

I think long term we will have the technology, hopefully, as we heard on the prior panel, to develop the technology for vaccines that could be readily made within a matter of weeks.

But until that time, we have to look at antiviral medications and a whole host of other things to deal with this situation if it happens before that time. We are long overdue for a pandemic outbreak in this country. It has been about 40 years.

First, I wanted to get a comment from the panel on—and I asked this question of the DHS officials, but I would like to get your perspective from a state and local level.

How prepared are we and ready are we in terms of the antiviral stockpile in this nation in the event a pandemic broke out today? And why don't we just go down the panel, starting with you, Dr. Cirillo?

Dr. CIRILLO. I was encouraged to hear, Sir, that at the federal level clearly the production capacity has exceeded what was expected. And that is encouraging to hear.

The federal government had established some federal stockpiles and it sounds like they are meeting those goals, according to Admiral Vanderwagen.

I think the challenge for us is that there is still an expectation that the states were going to participate through a negotiated contract in purchasing antivirals to keep at the state level.

And while from a policy and strategic point of view we agree with that, the challenge is that that is an investment that really is at risk.

And again, I would reference that those medications that we choose to stockpile at the state level are not currently available to be included in the shelf-life extension program.

So if I purchase N95 masks or hand gels, those are items that are really able to be used for lots of different events, and they don't go away. They don't expire.

The decision to invest, you know, scarce resources financially into antivirals—and if we don't have the next pandemic for another 4 years and those expire, I really have lost that investment.

And so that really is a challenge for us. So the decision at the state level of how much financially to invest in antivirals really is the basis of—that is an at-risk investment.

Am I better buying more masks or, you know, investing in something that I know will expire and I may not get any value out of it?

Mr. McCAUL. Dr. Shult?

Mr. SHULT. Just to reiterate some of the comments, I can't speak directly to the antiviral stockpiles, but to point out again or reemphasize the critical need for accurate, very rapid, highly reliable diagnostic testing to make best use of the stockpiles, however they are.

And another element of that is another key role right now for public health laboratories working with the CDC is monitor the emergence of antiviral resistance that we have already seen with one whole class of antivirals.

And this is something that would have to be monitored throughout the pandemic period, which could last 18 months to 2 years.

So however the stockpile sorts out, the laboratories are going to need to have that very rapid diagnostic testing and surveillance that goes along with it.

Mr. McCAUL. That is a good point.

Dr. Caldwell?

Dr. CALDWELL. Yes, it is concerning to me at some level that there is so much emphasis being put on antivirals, which we don't even know are going to work, investing millions upon millions of dollars on that, while at the same time not making a one-to-one commitment for the resources we need to actually get the vaccine or antivirals into people's hands.

And that is where local health departments come in. You know, we are the ones responsible on the ground for accepting the strategic national stockpile. And we have had experience in having moments where we have practiced trying to get medicine to people very quickly.

Let's go back to the 2004 seasonal flu vaccine shortage, where there were delayed shipments and people were anxious and concerned, and the public became extremely vulnerable and worried.

We somehow in Dutchess County were able to give out nearly 6,000 doses in a couple days to our most vulnerable populations. But that is only actually because of the efforts that we had made in emergency preparedness and practicing. We did better with that.

And we need there to be a recognition that the unknown strain, the unknown—hopefully we will be able to develop a vaccine quickly. But the amount of money that you have in antivirals that if they work, maybe—you know, are they going to take 1 day off of the illness, or are they actually going to save lives? We just don't know.

And I think that if you are going to make the commitment into putting dollars into medicines, you need to at least make a one-to-one commitment into putting it into the strategies, the implementation strategies, the practice and the planning at the local level.

Mr. McCAUL. That is a very good point.

Dr. Lakey?

Dr. LAKEY. Thank you. I agree that antivirals are only one component of a comprehensive plan for the state. I think it is an important part of the comprehensive plan and for the state.

I worked this issue quite a bit this last legislative session in Texas. We were offered the ability to buy \$34 million worth of antiviral medicines. It came out of the legislative session with \$10 million, and that was a hard sell.

One of the reasons that it was a hard sell was with ongoing health concerns in the state, spending \$10 million for a medicine that has a 5-year shelf life and the unpredictability of pandemic influenza made a lot of other issues seem more important at the state level than purchasing the antiviral medicines.

I think that the 5-year shelf life played a key role in the difficulty we had in making the case for the state to invest in the antiviral medicines. And so I think that is a key issue that needs to be looked into.

Mr. McCAUL. And, Dr. Lakey, following up on that, can you describe the national policies that prohibit using these medications bought under a federal contract?

Dr. LAKEY. Under the federal contract, it is negotiated at a low rate and with a national subsidy, and with that, we are not allowed to utilize the medicines except for a pandemic, in a pandemic influenza.

We are not allowed to rotate through the stockpile so that we could use so much this influenza season and replace it with additional antivirals that are purchased. Basically it is just put on a shelf and we are not allowed to utilize it except for the pandemic.

And that is where this 5-year shelf life really comes into play.

Mr. McCAUL. That may make some sense to take another look at the contracts so we can fully utilize our resources.

One thing we discussed, Dr. Lakey, yesterday—I wanted you to expand on—is in terms of hospital bed space, the availability, you mentioned a concern of yours in terms of your ability to inspect the hospitals as it relates to CMS's ability to fund.

Can you elaborate on this? And what, if anything, would you recommend we do at the federal level to fix this?

Dr. LAKEY. Sure. The situation is that our agency does initial hospital licensing, initial inspections to hospitals, to allow them to bill Medicaid and Medicare.

We have been told that initial inspections for new hospitals are the last priority, that we are not allowed to do them unless all other types of inspections are done, and basically that is a situation that never occurs.

And so we have multiple hospitals in Texas that are awaiting inspections in order to come up and be able to bill Medicaid and Medicare as part of their business plan that are not allowed to do that at this time.

And so we have 17 hospitals currently sitting in Texas awaiting—and they are ambulatory care centers and smaller hospitals that we can't inspect.

There are other options for the hospitals. They can go through JCAHO accreditation. They can be deemed under a parent hospital so they are part of a feeder system into that hospital.

Or if there is an access-to-care issue—the problem for Texas is we are not an access-to-care state, and so we have offered to use general revenue and other sources in the state to either take care of that backlog or to do the initial inspections.

We have offered to be able to couple them with other type of inspections and then told that we can't do that. And so there are multiple facilities in Texas that we can't bring up because of those issues.

Mr. MCCAUL. I am curious with the other three panelists whether you are experiencing that same problem in your respective states.

Dr. CIRILLO. I don't think we share the same challenge that Dr. Lakey is facing in Texas. I think our greatest challenge in terms of hospitals is the issue of capacity.

And again, within Rhode Island, the hospitals operate on an inpatient basis at greater than 95 percent capacity on every day.

And so when we talk about where would we accommodate surge, again, not just for pandemic—we had the experience in Rhode Island of the Station Nightclub Fire, and that was a challenge to try and despite heroic efforts by first responders and people at hospitals, to create that capacity in a real-time event.

And that really is the challenge, to deal with the unexpected. So my concern on the hospital level is how do we continue to support them in difficult financial times, to invest in preparedness when they are really trying to invest in their day-to-day operation, to remain open.

Mr. MCCAUL. Any comments from the other two?

Mr. SHULT. And again, from a laboratory perspective, we have spent a lot of time working with the clinical labs throughout the state and bringing them up to speed in terms of emergency response, their role in a pandemic and what the pandemic is going to do to them.

We are all going to be affected by this. And they have real concerns as well, similar to what have been echoed here as far as their capacity to respond, keeping in mind they are critical to maintain-

ing day-to-day patient care that has to go on anyhow, much less the complications that are going to arise from a pandemic.

So right now we have been working with them, but they are feeling very much at a loss as to whether they are going to be able to respond adequately to serve the clinical or their clinicians' needs.

Mr. MCCAUL. Dr. Caldwell?

Dr. CALDWELL. Yes, in the state of New York, we are actually cutting back on hospitals and beds, believe it or not, because they feel there is an oversupply, so it is in some ways a reverse problem.

But when you look at, you know, how are we trying to prepare for the large part of our population being sick and very ill, we are thinking that we are going to have to have a lot of people taken care of at home.

And right now, part of our strategy and planning in Dutchess County and many of my colleague counties is to work with our home care agencies and to work with them and build their capacities to develop some unified emergency preparedness home care plans, enabling our residents to know that there will be people available to deliver some medical and nursing care in their homes if they get sick.

Now, are we going to be able to activate hundreds of ventilators, and where are you going to get the staff to activate these ventilators? And I just don't see it being a realistic possibility. I think there is going to be some type of very rationing situation. It is going to be hard.

I mean, we are not going to be taking over hotels. People used to say, "Oh, we are going to take over hotels and put people there." That is not going to happen. The hotels aren't going to want it. Nobody is going to want to go to the hotel, and nobody is going to staff the hotels.

And so we need to look at what already exists in our community, try to think of how people are going to approach the situation, given that it is not just going to be people getting sick. All kinds of things are going to be going on.

There is going to be distribution of food problems. People are going to have trouble getting their food and their water supplies and their other regular medicine.

So I do have one other comment about the previous topic of pharmaceutical stockpile and pharmacies.

Instead of us in Dutchess County sort of going out and buying our own mini-stockpile, what we have done through our relationship-building efforts is work with our local pharmacies, so we have a memorandum of understanding with all the pharmacies in our county to know what is on their shelves.

And should there be an outbreak, they will then immediately inform us of what is on their shelves, so that will be our sort of—rotating many stockpiles, which won't cost us any money.

And of course, they may not have all that we want, but it is at least something that we can have some control over at any time, and it doesn't cost us any money.

As a matter of fact, it is an investment in our continued relationship. While it is not antivirals, it may be something else, like, for

example, some other antibacterial that we may need for some other agent that may come along.

Mr. MCCAUL. That is very creative.

And I appreciate the chair's indulgence. And just in conclusion, I do want to stress again the importance of exercises. I think those are very important. I hope that your partner at the federal level will work with you on those.

And lastly, Dr. Lakey, you mentioned the border, and I think that is an obvious concern on a lot of levels, but certainly from a health standpoint, in terms of who is coming into the country. I think we need to have a better level of control over who is coming into the country.

And certainly, when we had the avian flu outbreak, knowing who is coming over from those parts of the world that could be impacted—and I know that on the science and technology standpoint, there has been some pretty good technology that is out there that could potentially spot if someone who has a high fever, for instance, coming through an airport.

And so I hope that we will be able to make some progress on that level as well.

And with that, I yield back.

Mr. LANGEVIN. I thank the gentleman.

I want to thank the panel for being here today as well as the previous panel. I thank the witnesses for their valuable testimony and the members for their questions.

We obviously have a lot of work to do in this area. We look forward to a continued partnership at the local, state and the federal level to make sure that we get this right and we can protect the American people from both pandemic flu or another public health threat.

Thank you very much again.

The members of the subcommittee may have additional questions for the witnesses, and we ask that you respond expeditiously in writing to those questions.

Hearing no further business, the subcommittee now stands adjourned.

[Whereupon, at 1:17 p.m., the subcommittee was adjourned.]

Appendix I: Letter

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND
SCIENCE AND TECHNOLOGY,
Washington, DC, October 25, 2007.

Hon. JIM LANGEVIN
*Chairman, Subcommittee on Emerging Threats, Cybersecurity, and
Science and Technology, 109 Cannon House Office Building,
Washington, D.C. 20515*

Dear CHAIRMAN LANGEVIN: Thank you for allowing me to testify about pandemic influenza preparedness before the Subcommittee at its hearing on September 26. It was an important opportunity to enhance communication between the federal government and states as we work together to strengthen health and security across the nation.

Please allow me to make two brief clarifications regarding my testimony. I mentioned the percentage of preparedness funding that Texas has directed to the local level including direct contracts with local health departments. That statement should have referred specifically to pandemic influenza preparedness funding. In addition, the percentage of funding awarded for local and regional pandemic preparedness activities was overstated. The correct figure is ninety percent.

Again, I appreciate the opportunity to present to the Subcommittee regarding these issues. Please contact me if I can ever be of assistance.

Sincerely,

DAVID L. LAKEY, M.D.,
Commissioner

Appendix II: Additional Questions and Responses

QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON
EMERGING THREATS, CYBERSECURITY, AND SCIENCE

RESPONSES FROM MICHAEL C. CALDWELL, MD, MPH

Question 1.: What additional resources are needed at the local level to prepare for and respond to pandemic influenza? What is needed at that level—that is not needed at other levels of government or in the private sector?

Effective pandemic influenza preparedness at the local level requires a continued, iterative process of planning, testing the plans either through response to a real event of lesser magnitude or via “tabletop” exercise, identifying gaps and areas needing improvement, achieving those improvements, and re-testing. While this methodology is not unique to the local level, locally it requires reaching out to every community organization, institution, or agency that will be affected by a pandemic to engage them in practical response planning. The breadth and depth of activity required to build and sustain such community engagement, unique to the local level, is a long and labor-intensive effort. It can be accomplished only with a sustained commitment of sufficient funds to pay for the people that do this work. Local pandemic influenza preparedness is not simply a matter of one-time capital purchases of medications, vaccines, or equipment—rather, it requires constructing and sustaining the community response systems that will make a difference in survival rates. NACCHO believes that a return to previously-appropriated levels of funding for state and local public health preparedness (\$940 million in FY05), accompanied by performance and accountability measures that genuinely reflect the local planning, exercising and continuous improvement that is needed, would enable consistent progress. Moreover, it is important to address the funding levels for antiviral purchases and the shelf-life extension problem that now discourages state or local investment.

Question 2.: The best preparation for public health emergencies involves skilled public health workers who plan and exercise their plans for emergency response jointly with local elected officials, police and fire departments, emergency managers, hospitals, physicians, schools, businesses, and other community partners. Please describe how this has occurred in Dutchess County regarding pandemic influenza preparedness.

In Dutchess County, we have prepared and distributed informational materials and have offered trainings to area businesses, schools, faith based organizations and other entities as part of our Pandemic Flu Emergency Preparedness activities. We have organized table top exercises with our area partners, including the local hospitals. Additionally, our regular flu immunization clinics have been used as opportunities to drill the techniques that will be needed in an emergency situation, when medications would have to be distributed to the public in a short period of time. Nine clinics were held in November and December 2006 throughout the county. Each site selected could accommodate large numbers of attendees without traffic problems or long waiting times. Clinic hours were increased over the years and each site had inside waiting areas. Other agencies such as the Sheriff's Department, the Department of Mental Hygiene, Public Works, and the Office for the Aging assisted in mounting these efforts. This type of exercise is being replicated again this year as we run our 2007 flu clinics.

Furthermore, Dutchess County has recruited a local Medical Reserve Corps of over 300 volunteers whoa re been trained to provide assistance with medical care, special needs care, as well as non technical needs. This cadre of citizen volunteers is meant to be fully integrated into the County's emergency planning and response program.

Preparing for a pandemic is part of more comprehensive Emergency Preparedness efforts, looking at multiple scenarios. In Dutchess County, we have also been working on a continuity of operations plan. During a pandemic event, more than 40% of the workforce could potentially be unable to come to work. This plan addresses issues of providing a safe environment, prophylaxis, training and tools needed to perform essential public health functions in our community. Such a plan is critical in a pandemic when the public health and other public resources will be stretched thin providing vaccines and antivirals to the public in a mass clinic or Point of Distribution site.

Question 3.: What can the federal government do to assist city and county public health personnel strengthen and coordinate surveillance at those levels? How do you see information from localities throughout the country, rolling up into a cohesive real-time disease surveillance picture?

Response: Local health department (LHD) involvement in biosurveillance systems development and implementation is critical. LHDs are the traditional entry point for routine disease surveillance and investigation, and function as first responders in a public health emergency. As such, LHDs are keenly aware of the information needed to monitor for public health emergencies and mount response and mitigation activities. LHDs must be actively involved in the definition of data and functional requirements for biosurveillance systems and in the local implementation of such systems. State and federal public health agencies must ensure that LHDs have timely access to any data collected about their local community.

Existing relationships between LHDs and local hospitals and providers should be leveraged for biosurveillance implementation efforts. LHDs have established relationships with hospitals, physicians and other healthcare providers in their communities for disease reporting and preparedness planning and response. As most responses to emergencies are locally managed, it is critical that these existing relationships are maintained and strengthened to ensure rapid response to public health threats. These relationships remain essential even when a state health agency or the CDC initiates the data collection effort, such as with the CDC's implementation of BioSense.⁴ Additionally, over-reliance on biosurveillance data as the only indicator of a public health emergency must be avoided. Electronic biosurveillance systems will not replace astute clinicians and LHD relationships with their clinical communities to detect, monitor and control public health emergencies. Uniform national adoption of an electronic medical record is absolutely essential to eventual development of any fully effective real-time disease surveillance system.

Question 4.: In your testimony, you state “. . .we have seen mixed messages from our federal leadership. There does not seem to be adequate coordination or cooperation between the planners of Health and Human Services and the Department of Homeland Security.” Please provide examples of mixed messages from federal leadership, as well as examples of inadequate coordination and cooperation between HHS and DHS.

HHS and DHS have separate and uncoordinated grant programs for state and local preparedness. Pandemic influenza planning is a major expectation of the CDC grants, but not of the DHS grants for police/fire/emergency management. DHS has undertaken the BioWatch surveillance initiative, but it has not been coordinated with any HHS biosurveillance initiatives, although the responders at the local level are the same.

Question 5.: In your testimony, you state “. . .we have seen clear examples of us being left out of the development of the National Response Plan.” Please provide us with some of these clear examples.

Response: There was no representation of local health departments on any of the 12 workgroups that were formed to fashion the detailed revisions of the National Response Plan.

Question 6.: In your testimony, you state “. . .in the state of New York, we are actually cutting back on hospitals and beds, believe it or not, because they feel there is an oversupply. . .” Who believes there is an oversupply, and on what data are they basing this belief? Please provide data regarding the numbers of hospitals and beds, as well as to what numbers of each the stat is cutting back. What specific impact do you believe this will have if we are to have an influenza pandemic?

⁴BioSense is the national program designed to improve the nation's capabilities for real-time biosurveillance and situational awareness at a time when the vast number of health-related information systems that exist nationally vary in their ability to share data to support immediate biosurveillance needs.

Response: In New York State, the hospital environment has been dominated by mergers and restructuring, which inevitably have an impact not only on the number of beds, but also the types of beds available. This will in turn affect the ability of hospitals to accommodate a surge that would be associated with a pandemic.

Response: New York State has recently undergone an extensive review of its hospital system structure and capacity. The formal review was known as the "Berger Commission" and its detailed report can be accessed at <http://www.nyhealthcarecommission.org/> While some parts of New York State operate at a high hospital bed occupancy rate, many areas of the state do not. The Berger Commission was created to address the concern that overall, New York State is over-bedded by approximately 25 %. The Commission noted that "a fundamental driver of the crisis in our health care delivery system is excess capacity. New York is over-bedded an many hospital beds lie empty on any given day. The statewide hospital occupancy rate has fallen from 82.8% of certified beds in 1983 to 65.3% in 2004, a decrease of 17.5%. Occupancy rates vary by region and are especially low in Western, Northern, and Central regions."

Question 7.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, "The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months" of when the Plan was released—so the deadline would have been October 2006. What are the challenges here? Are you waiting for the Federal government to provide you with guidance and resources?

Response: The initial CDC grant guidance for the first phase (\$100 million) of pandemic influenza funding was released in May 2006. Planning and exercising the full panoply of local resources required for response is a continuous iterative process, as described above, and it certainly takes more than four months. As funding dedicated for state and local pandemic influenza preparedness ends, it will be essential that federal expectations for pan flu preparedness and for all-hazards preparedness be harmonized and realistic within the resources made available.

Question 8.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, "State, local, and tribal law enforcement agencies should coordinate with appropriate medical facilities and countermeasure distribution centers in their jurisdictions to coordinate security matters, within 6 months" of when the Plan was released—so the deadline would have been October 2006. To your knowledge, has any of this coordination taken place? If so, how, and if not, how would you recommend this happen?

Planning and exercising of Points of Distribution for the Strategic National Stockpile has taken place in many jurisdictions with law enforcement involvement for several years now, and most intensively in those that receive Cities Readiness Initiative funding. DHS expectations for law enforcement engagement with medical facilities and countermeasure distribution centers should be directly and explicitly connected to and consistent with HHS expectations for hospitals and health departments.

Question 9.: What roles do associations play in assisting their constituents with emergency and pandemic preparedness?

Response: NACCHO has developed a robust collection of on-line tools and a peer assistance network for local health departments engaged in emergency preparedness. NACCHO also coordinates and disseminates the work of eight local Advanced Practice Centers for Public Health Preparedness, which develop and evaluate cutting-edge preparedness tools and methodologies. We share information on federal actions and provide input to a vast array of HHS and CDC workgroups and advisory groups.

Question 10.: The Government Accountability Office (GAO) says in its report that State, Territorial, Tribal, Local, and other stakeholders need to be involved in providing input to the National Strategy for Pandemic Influenza and its Implementation Plan, especially as the National Strategy evolves. If you were at the White House, how would you ensure this happens?

Response: Local stakeholder representatives should be identified and engaged at the beginning of the federal planning process. They should be engaged in review of early drafts and given enough time to consult meaningfully with their constituents and to provide written responses. While this is not a rulemaking process, the federal authors of the strategy and plan should be required to identify what the stakeholder advice was and explain why it was disregarded or adopted.

Question 11.: As you all know, public health has been identified as one of the critical infrastructures of our Nation. Have you been included in the planning undertaken by the Department of Homeland Security to protect the public health infrastructure? From what you know about this work, how does it affect you in your state and local positions? What more do you think needs to be done in this regard, especially in advance of an influenza pandemic?

Response: NACCHO is a member of the Government Coordinating Council of the Public Health and Healthcare sector (one of 17 identified sectors). This work has no current impact at the local level because the Public Health and Health Care Critical Infrastructure plan is not functional and has no funding behind it.

QUESTIONS FROM THE HONORABLE MICHAEL T. MCCAUL, RANKING MEMBER,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE

Question 12.: At the hearing, Dr. Caldwell testified that most hospitals operate at “95% capacity everyday,” and that New York is actually reducing the number of hospital beds because of “oversupply.”

Please see response to Question # 6 above which references the New York State “Berger Commission.” The detailed report can be located at <http://www.nyhealthcarecommission.org/>

Question 13.: What ability do local hospitals in your states have to accommodate a surge that would be associated with a pandemic?

Response: Local hospitals are expected to have a surge of up to ten percent (10%) over their normal capacity. Most local hospitals in NY are close to that surge capacity.

Question 14.: What type of procedures are in place to increase capacity should a pandemic occur?

The biggest concern for us is what happens when the surge is over the proposed ten percent? What do we do when hospitals are over capacity? Our local hospitals are in the process of developing a plan to address that very question. We need to come up with a model to set up alternate sites of care and that is a huge challenge for our local healthcare systems.

QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON
EMERGING THREATS, CYBERSECURITY, AND SCIENCE

RESPONSES FROM L. ANTHONY CIRILLO, MD

Question 1.: The Implementation Plan for the National Strategy for Pandemic Influenza provided this task, “All Federal, local, tribal, and private sector medical facilities should ensure that protocols for transporting influenza specimens to appropriate reference laboratories are in place within 3 months”—which would have been July 2006. What challenges do you see with executing this task?

Response: The greatest challenges to the development and maintenance of a system to ensure the transport of influenza specimens to reference laboratories is actually support of the labs themselves and the development of a more efficient process for dissemination of the information obtained from testing of influenza specimens. During a pandemic, or even during seasonal flu, the capacity of laboratories to process influenza specimens in a timely manner is limited by the number of staff trained and assigned to this process. Like many other aspects of the healthcare system, the surge capacity of the laboratories is limited. While cross-training of lab personnel occurs, and can help to provide short term support for increased testing demand, it provides only limited increased capacity. Additionally, systems must be developed for the rapid analysis and dissemination of information obtained from testing such as geographic patterns of illness, susceptibility to antiviral medications, appropriateness of match to current influenza vaccine. It is critical that this information be quickly shared with the healthcare and public health sectors for ongoing adjustment of medical and public health interventions during a pandemic.

Question 2.: The Implementation Plan for the National Strategy for Pandemic Influenza states that, “All health care facilities should develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 6 months” of when the Plan was released (deadline: October 2006). Our hospitals and other health care facilities are more than familiar with infection control measures. Can you describe the specific chal-

Challenges in identifying and implementing infection control measures for pandemic influenza?

Response: The challenges to instituting infection control measures at hospitals and other healthcare facilities during a pandemic will be due to a lack of adequate capacity of the healthcare system and the infectious nature of influenza. In order to operate cost-effectively, hospitals today are operating at or near their licensed inpatient bed capacity. While this operational efficiency is financially prudent, it may significantly limit the ability of the hospitals to efficiently segregate patients during a pandemic. Given the increased demand for healthcare services anticipated during a pandemic, it is likely that all existing inpatient bed capacity will be utilized at all times. Attempts at segregating patients with influenza from patients receiving medical services for all other medical conditions may initially be possible, but as the numbers of inpatients continues to surge, the need to provide care quickly, in the next available bed, may very well overwhelm any system designed to segregate infectious from non-infectious patients. An additional challenge during an influenza pandemic will be that people (including patients, staff, and visitors) may be already infected, and contagious, prior to the development of symptoms of influenza. So, even in the best of circumstances, segregation of patients with demonstrated influenza illness will not likely prevent the spread of illness to other clinical areas within a healthcare facility. Given these realities, it is unclear if the expenditure of resources needed to segregate patients will yield much in the way of significant reductions in illness spread.

Question 3.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, "The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months" of when the Plan was released—so the deadline would have been October 2006. What are the challenges here? Are you waiting for the Federal government to provide you with guidance and resources?

Response: Given the worldwide nature of a pandemic by definition, it is appropriate that the overall strategy related to the management of pandemic be developed on a global level. However, while a global strategy for pandemic influenza may be developed through agencies such as the World Health Organization (WHO), the implementation of that strategy will be different based upon the local effect of the pandemic and the availability of supplies, medications, and personnel. Within the United States, there will be an expectation for consistency of care. As such, it is again appropriate that a national approach be taken in responding to a pandemic influenza event. Thus the federal government, especially the Centers for Disease Control and Prevention (CDC), should take the lead in the development of standardized and universal strategies for key aspects of pandemic influenza management. These key aspects include issues such as prioritization of antiviral medication and influenza vaccine distribution and guidance on effectiveness and appropriateness of personal protective equipment (masks, gloves, etc.). After Secretary Leavitt's visit to states during late 2005 / early 2006, the challenge to states at that time was the lack of guidance at the federal level on many of these key issues. Over the past nearly two years, there have now been numerous reports, from various agencies, on many key issues related to pandemic influenza management. As such, the challenge for state and local public health departments is now to continually update and revise pandemic influenza local strategies as guidance continues to be updated at the federal level. While updates in guidance and recommendations are necessary, and should reflect the latest in our understanding of how to mitigate the effects of a pandemic on society, it does require significant resources to continue to update planning documents, and more importantly, communicate these changes to all of the partners involved in pandemic preparedness. Lastly, as plans continue to evolve and change, there is a need for ongoing trainings and exercises to ensure that plans can be effectively implemented which again, requires significant investments of time and money at the state, local, and private sector levels.

Question 4.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, "State, local, and tribal law enforcement agencies should coordinate with appropriate medical facilities and countermeasure distribution centers in their jurisdictions to coordinate security matters, within 6 months" of when the Plan was released—so the deadline would have been October 2006. To your knowledge, has any of this coordination taken place? If so, how, and if not, how would you recommend this happen?

Response: Within Rhode Island (and many other states) coordination of specific functions such as law enforcement /security is accomplished in concert with the

state Emergency Operations Plan (EOP) utilizing the Emergency Support Function (ESF) delegation of functional responsibility. In Rhode Island, the Rhode Island State Police (RISP) serve as the lead agency for coordination of law enforcement planning related to emergency scenarios. The Department of Health serves as the lead agency for pandemic planning within the state by direction of the Governor. The Director of Health, Dr. David Gifford has established the Pandemic Flu Director's Advisory Group, comprised of key state agency directors. The commanding officer for the Rhode Island State Police (or his designee) attends these meetings to coordinate state agency planning for a pandemic. The RISP are also members of the Rhode Island Police Chiefs Association through which additional planning activities have occurred related to pandemic flu. Lastly, the RISP also serve as the law enforcement agency responsible for security evaluations of all medication distribution sites under the federal Strategic National Stockpile (SNS) program. In this capacity, they work together with law enforcement officials in all municipalities in the identification of appropriate facilities for distribution of medications or vaccines during a public health emergency.

Question 5: In your testimony, you described regional interstate coordination in pandemic preparedness, and that the “. . .collaborative effort resulted in a two-day summit and multistate tabletop exercise held to coordinate the interstate response to a pandemic.” Please provide additional information regarding the regional interstate coordination and collaborative efforts you mentioned in testimony, the two-day summit, and the multistate tabletop exercise. What lessons have been observed and learned?

Response: As noted above in Answer #3, after Secretary Leavitt's state visits, the states were charged with developing a comprehensive strategy for responding to a pandemic influenza event. Within the New England region, it was recognized that the geographic proximity of states within the region would necessitate a collaborative approach to pandemic influenza planning. Also as noted above, early on after Secretary Leavitt's visits, there was limited guidance on how to prepare for a pandemic influenza event. Given this lack of national guidance, the six New England states and New York State began a collaborative process to identify best and common practices among the states. At least one representative from each state was assigned to participate in workgroups on the following issues: Antiviral medications, Community Containment, Mass Fatality Management, Laboratory/Illness Surveillance, Personal Protective Equipment (PPE), and Surge Capacity. These groups met by conference call from March through June 2006. The work of these groups culminated in a two-day meeting in Boston, MA on June 29th & 30th. During this meeting, consensus assumptions, positions and planning strategies were identified for many, although not all aspects, of pan flu planning. The key lessons learned from these activities were delineation of common planning assumptions including attack rates of illness, and approaches to school closures and risk communication, especially in mass media markets that traverse state boundaries. Another key lesson learned was the need to integrate planning in the public health / healthcare sector with planning efforts in the emergency management sectors. In order to accomplish this, an exercise was hosted by the Naval War College in Newport, RI in August 2006. The exercise brought together leaders from each state including health care/public health, emergency management, and the Governor's office from each state. In addition, two meetings of the State Directors of Health were also coordinated by the Region I Office of the US Department of Health & Human Services.

Question 6: In your testimony, you mentioned “. . .the disincentives to the purchase of antiviral medications Tamiflu and Relenza due to exclusion from the shelf-life extension program of state health supplies of these medications.” Please provide the Committee with additional information regarding these disincentives, the shelf-life extension program, etc. How do you propose this situation be changed, understanding that the federal government is seeking to ensure that states are preparing for pandemic influenza specifically?

Response: Antiviral medications may have a significant impact on mitigating the effects of pandemic related illness on society. There is however, also the possibility that current antivirals will have little to no effect on the duration or severity of illness. It is this primary uncertainty that makes the purchase of antiviral medications a calculated risk for states in preparing for a pandemic influenza event. Even more important than the development of strategies for stockpiling and distribution in the community, is the fundamental question as to the value of antiviral medications. Historically during seasonal influenza outbreaks, patients who are treated very early on in their illness course have shown a small decrease in the length and severity of illness. However, there is no guarantee that these effects would be seen

during a pandemic influenza event, as the specific virus is currently not known. In testing and treatment of patients infected with H5N1 (Avian Flu), there has been only limited clinical treatment success in reducing illness and mortality. In addition to the uncertainty of the efficacy of antivirals during a pandemic, there is concern about the current policy of the US Food & Drug Administration (FDA) that does not allow for utilization of antiviral medications for clinical treatment if the antiviral medications have reached their expiration date. Even for states who have stored these medications in accordance with acceptable temperature and humidity ranges, there have been no exceptions to the strict expiration date policy. The Shelf Life Extension Program (SLEP) was created to allow for periodic re-verification of the potency of medications or vaccines currently held in federal stockpiles. It is possible to expand the scope of the SLEP program to include the caches of antivirals that states are purchasing for a pandemic influenza event. There would need to be some modifications to the program to allow for the manufacturers to provide samples of each lot of medication produced to the SLEP program for batch verification. As long as states can ensure that locally held caches are kept at appropriate environmental conditions, then the entire manufacturer batch would be eligible for SLEP extension.

Question 7.: In your testimony, you mentioned “. . .it is critical that all federal preparedness programs related to pandemic or other public health emergencies be more closely aligned and coordinated so that we at the state level can more effectively develop an appropriate response to all public health emergencies.” How do you suggest this be accomplished by the federal government?

Response: One of the challenges facing states in their preparedness efforts is the lack of coordination and alignment of federal grant funding goals and objectives. Currently the US Departments of Health and Human Services and Homeland Security are providing funding for emergency preparedness, with a specific focus on pandemic influenza preparedness activities. However, both between, and even within agencies there are gaps in collaboration of grant funding and planning priorities at the federal level. This lack of coordination, especially within HHS, results in grant funding for the same issue, such as pandemic influenza, with conflicting grant deliverables, performance measures, reporting systems, and grant timelines. This lack in coordination at the federal level results in inefficiencies in grant management at the state level attempting to design a single pandemic influenza planning strategy with multiple different “asks” from each grant. Improved coordination must occur at the most senior level of HHS and DHS in order for these gaps in grant planning to occur. Within HHS, the Secretary should establish a single set of priorities and guidance for pandemic influenza preparedness. This single set of priorities and guidance should also be reflected in uniform definitions, performance measures, and timelines for all pandemic influenza grant funding.

Question 8.: What roles do associations play in assisting their constituents with emergency and pandemic preparedness?

Response: The private sector, including professional associations and businesses will play a critical role in the successful response of society to a pandemic event. The ability to incorporate associations such as representatives of hospitals, nursing homes, and healthcare professionals in pandemic influenza event will be crucial in order to muster and coordinated existing healthcare and non-healthcare infrastructure during a pandemic. Just as there is an added inefficiency to coordinated planning between federal agencies, there is a significant benefit to be gained by early involvement of other key stakeholders.

Question 9.: The Government Accountability Office (GAO) says in its report that State, Territorial, Tribal, Local, and other stakeholders need to be involved in providing input to the National Strategy for Pandemic Influenza and its Implementation Plan, especially as the National Strategy evolves. If you were at the White House, how would you ensure this happens?

Response: As has been mentioned above, I believe it is appropriate for a significant portion of the guidance on best practices for pandemic influenza preparedness to be developed at the federal level. However, the process for the development of guidance at the federal level must incorporate the realities of the implementation at the local level. Therefore, it is important that federal policy makers and subject matter experts include representatives of state, local, and tribal entities in the development of guidance and policies regarding pandemic influenza. The input of state, local, and tribal entities is probably most efficiently ensured through the incorporation of representative associations for these groups. Examples of these asso-

ciations would be groups like the Association of State and Territorial Health Officials (ASHTO), the National Association of City and County Health Officials (NACCHO), the National Governor's Association (NGA) and representatives of healthcare professional organizations like the American Medical Association (AMA) and American Nurses Association (ANA). Since these associations and organizations are well recognized as leaders within their respective memberships, they can serve as a conduit of information throughout the development and refinement of guidance and policies related to pandemic influenza.

Question 10.: As you all know, public health has been identified as one of the critical infrastructures of our Nation. Have you been included in the planning undertaken by the Department of Homeland Security to protect the public health infrastructure? From what you know about this work, how does it affect you in your state and local positions? What more do you think needs to be done in this regard, especially in advance of an influenza pandemic?

Response: Initially after state visit of Secretary Leavitt, the public health sector was much more involved in the management of a pandemic influenza event than the emergency management / Department of Homeland Security arenas. However, there has been much recent work by the Federal Emergency Management Agency to improve the coordination of pandemic flu preparedness and response activities. Ongoing efforts related to pandemic flu planning must focus on identifying methodologies to improve the coordination of planning in a "top down" manner, but with inclusion of others as noted in Answer #9. Here in Rhode Island, there has been considerable discussion between the Department of Health and the State of Rhode Island Emergency Management Agency regarding the protection of critical infrastructure and maintenance of society during a prolonged pandemic event.

QUESTIONS FROM HONORABLE MICHAEL T. MCCAUL, RANKING MEMBER,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE

Question 1.: At the hearing, you described national policies that prohibit using medications bought on the federal contract for anything but a pandemic. This makes the procurement of antivirals an "at risk" investment.

Question 2.: How do current federal regulations influence your efforts to stockpile antiviral medications?

Question 3.: What do you see as a practical solution that would reduce the investment risk of procuring antiviral medications while ensuring adequate supplies of these medications are available in the event of a pandemic?

Response: Please refer to Answer #6 above regarding antiviral medications in response to Questions #1—3.

QUESTIONS FROM THE HONORABLE BENNIE G. THOMPSON, CHAIRMAN, COMMITTEE ON
HOMELAND SECURITY

RESPONSES FROM B. TILMAN JOLLY, MD

Question 1.: What is the status of the pandemic influenza exercises that were to be incorporated into the National Exercise Program? How many will there be, when are they occurring, and who all will be involved?

Response: Pandemic Influenza (PI) exercises and the Pandemic Influenza Exercise series (PIX) remain a priority for the National Exercise Division (NED). The first Principal-Level Exercise (PLE) of FY 2008, PLE 1-08, will focus specifically on Pandemic Influenza, and the myriad issues associated with a PI outbreak arriving in the United States. In support of that PLE, two Assistant Secretary-level exercises are being conducted. The first exercise—which has already occurred—was hosted by the State Department in October, and focused on the U.S. response to an influenza outbreak *prior* to arrival in the U.S. This exercise included 21 senior officials from 12 agencies and White House offices. The results will inform and support the Cabinet level exercise in 2008. A similar exercise, also at the Assistant Secretary level, is being developed to cover issues related to an outbreak in the U.S.—and it will also inform and support the PLE. The Homeland Security Council is currently refining the scope of the PLE 1-08 exercise. The exercise is scheduled to be conducted in February 2008.

In order to maximize lessons learned and address issues identified in the conduct of PLE 1-08, the Regional Pandemic Influenza Exercises will occur after that exercise. These exercises will take place in each of the five PI regions identified by the

Department of Homeland Security (DHS), and will involve Regional representation (from state and federal partners) as well as activity at the Headquarters level. The current scope of the Regional PIX focuses on interaction between the Regions and Headquarters, although that may shift depending upon the lessons learned and issues identified during PLE 1–08.

FEMA Regions I and II are co-hosting both a PI workshop and a PI functional exercise in November and December 2007 to examine the regions' response to a PI outbreak at the local level. Further, the Office of Health Affairs will conduct a PI Principal Federal Officials (PFO) workshop in late November 2008 to provide the first test of communications capabilities between Regional and National-level PFOs. Lessons learned from each of these exercises will also be incorporated into the PIX.

Question 2.: Two things result from exercises: (1) the identification of actions necessary to correct problems, and (2) lessons learned. Knowing this, the Department of Homeland Security has created two activities—the Corrective Action Program, and the Lessons Learned Information Sharing system (with information pushed to LLIS.gov). After the pandemic influenza exercises have occurred as part of the National Exercise Program, what plans are there for using the Corrective Action Program and the Lessons Learned Information Sharing system? How does (or will) the Office of Health Affairs work to get the necessary information vetted and included in these programs? What part of the Office of Health Affairs will be staying on top of the situation, ensuring that corrective actions are taken, and that lessons are truly learned—before a pandemic occurs?

Response: The National Exercise Program (NEP) requires the use of the Homeland Security Exercise and Evaluation Program (HSEEP) and the Corrective Action Program (CAP) to identify and resolve major issues from exercises and promotes the use of Lessons Learned Information Sharing System (LLIS) for distribution of lessons learned applicable and appropriate to the broader emergency management community. Any Pandemic Influenza (PI) exercises conducted within the NEP will utilize HSEEP, CAP and LLIS as part of the After Action Report process. (Additionally, exercises conducted outside of the NEP are encouraged to utilize tools provided through HSEEP, CAP and LLIS.) The Department's Office of Health Affairs (OHA) has representatives on the DHS Exercise and Evaluation Steering Committee and has participated in the development of the HSEEP and DHS-specific CAP procedures.

CAP is a formal process and methodology that defines the roles and responsibilities for identification, development, prioritization, tracking, and analysis of corrective actions following exercises or real-world incidents that should receive consideration within the Department or the Interagency dependent upon the issue. It is an overarching program that refers issues to appropriate organizations—such as the Office of Health Affairs—for priority action. The CAP System is a web-based tool that enables Federal, State, and local emergency response and homeland security officials to implement the CAP process.

Since the launch of *Lessons Learned Information Sharing (LLIS.gov)* in April 2004, the Department of Homeland Security has sought to raise awareness of the program, increase membership, and encourage usage among its desired audience of emergency response and homeland security professionals through a coordinated outreach and awareness strategy. These efforts have increased *LLIS.gov* membership to more than 40,000 professionals from all relevant disciplines, levels of government, and all 50 states and territories.

Question 3.: What is the status of the Department of Homeland Security's pandemic influenza implementation plan? Previously, Dr. Runge (the Chief Medical Officer), has referred to this plan in testimony before Congress. We understand that it has been drafted completely, but that it is has not yet been posted to PandemicFlu.gov or the Department's own website. Has the draft plan been circulated throughout the Department? When do you expect that it will be finalized? What is it that personnel throughout the Department are working from to help the Department and the Nation prepare for an influenza pandemic?

Response: The Department's pandemic influenza plan is in final draft form and has been circulated throughout DHS for use in developing component plans. We anticipate being able to revise it based upon a final version of a Federal Strategic Plan, which has been developed by a group led by DHS, and which is now in inter-agency review.

Question 4.: According to the White House, DHS was to have worked with others to complete this action item from the Implementation Plan for the National Strategy

for Pandemic Influenza—by October 2006. The task is, “DOJ, DHS, and DOD shall engage in contingency planning and related exercises to ensure they are prepared to maintain essential operations and conduct missions, as permitted by law, in support of quarantine enforcement and/or assist State, local, and tribal entities in law enforcement emergencies that may arise in the course of an outbreak, within 6 months.” **Why has this task not been completed yet?**

Response: This item was extended because of the requirement for further development of a national quarantine policy and the ongoing interagency work being done on the Federal Pandemic Influenza Strategic Plan and the Federal Pandemic Influenza Border Management Plan. Policy issues surrounding quarantine are within the purview of other parts of the Executive Branch. As these policy issues become more clear, the operational elements can be accomplished.

Question 5.: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by December 2006. The task is, “DHS, in coordination with DOT, HHS, and USDA, shall conduct tabletop discussions and other outreach with private sector transportation and border entities to provide background on the scope of a pandemic, to assess current preparedness, and jointly develop a planning guide, within 8 months.” **Why has this task not been completed yet?**

Response:

The planning guide is under development as part of the broader efforts to complete sector-specific guides for all CI/KR sectors. Meetings with the various transportation modes are in progress. Modes that have completed their Guidelines (evidenced by endorsement by the Sector and Government Coordinating Councils) are: Mass Transit, Highway and Motor Carriers, and Rail. Work with Aviation and Maritime are in the final stages. Completion of the planning document is dependent on Border Policy development and Border CONOPS which have not been finalized by a collection of interagency partners.

Question 6.: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by April 2007. The task is, “DHS and DOT, in coordination with DOD, HHS, USDA, USTR, DOL, and DOS, shall develop detailed operational plans and protocols to respond to potential pandemic-related scenarios, including inbound aircraft/vessel/land border traffic with suspected case of pandemic influenza, international outbreak, multiple domestic outbreaks, and potential mass migration, within 12 months.” **Why has this task not been completed yet?**

Response: This item was extended and will be addressed in the Border CONOPS that will be included as part of the interagency border management plan currently under development pending completion of a Federal Strategic Plan now in interagency review.

Led by OHA, DHS continues to be heavily involved in an interagency effort that is currently finalizing a Federal strategic level pandemic influenza plan. When completed, this plan will effectively outline the roles, responsibilities and possible courses of action of all federal departments and agencies in preparing for and responding to a pandemic. An integral component of the strategic plan dealing with the complex issues involved in attempting to delay the entry of a pandemic through a variety of border management measures, has been completed by a separate interagency working group led by the IMPT and is currently undergoing internal review. There are several complex federal policy decisions involving issues such as screening and possible quarantine of passengers and potential diversion of flights pending, that impact the private sector. Engagement with the private sector has begun, a full review of operational and economic impacts need to be determined in order to finalize both plans. The goal is to have both plans completed prior to a principals level pandemic exercise that has been tentatively scheduled for mid February 2008. Once finalized, the federal strategic plan, incorporating the border management annex, will meet all the performance measures of the referenced action item(s).

Question 7.: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by April 2007. The task is, “DOT and DHS, in coordination with HHS, USDA, and transportation stakeholders, shall develop planning guidance and materials for State, local, and tribal governments, including scenarios that highlight transportation and border challenges and responses to overcome those challenges, and an overview of transportation roles and responsibilities under the NRP, within 12 months.” **Why has this task not been completed yet?**

Response: This item was extended and will be included as part of the inter-agency border management plan currently under development. Additionally, DOT and DHS POCs convened a working group to include transportation stakeholders, HHS and USDA. The group identified multiple documents that provide tailored guidance and planning materials that are available to state, local, and tribal governments as well as transportation stakeholders. Transportation roles and responsibilities are outlined in the NRP Emergency Support Function #1—Transportation Annex. The NRP has been widely distributed to stakeholders. Examples of documents are:

1. The Role of Law Enforcement in Public Health Emergencies (September, 2006); DOJ: Bureau of Justice Assistance; 38 pp. Challenges addressed include: responding to and managing incidents; risks to Law Enforcement to disease; immunization and PPE; protecting the community; Law Enforcement's role during involuntary restrictions, including quarantine; and other subject areas.
2. HHS Pandemic Influenza Plan supplement 9: managing travel-related risk of disease transmission; 16 pp. Challenges addressed include: Engaging community partners; protocols for managing ill passengers at ports of entry; quarantine preparedness at ports of entry; legal preparedness; and others.
3. DHS: Pandemic Influenza: Preparedness, Response, and Recovery; Guide for Critical Infrastructure and Key Resources (June 21, 2006) 84 pp. Challenges addressed include: recommendations for planning, preparedness, response and recovery for businesses (transportation sector is one of the primary CI/KR elements); assessment recommendations on the risks, impacts, and implications of pandemic-related disruptions to international production, supply chain, and goods and personnel movement; border challenges; and others.
4. DOL: Guidance on Preparing Workplaces for an Influenza Pandemic (OSHA 3327-02N 2007); 44 pp. This document provides guidance to all stakeholders to meet the following Pandemic Influenza challenges that directly relate to the transportation sector and border issues: how Influenza Can Spread Between People; classifying Employee Exposure to Pandemic Influenza at Work; How to Maintain Operations During a Pandemic; How Organizations Can Protect Their Employees; The Difference Between a Surgical Mask and a Respirator; Steps Every Employer Can Take to Reduce the Risk of Exposure to Pandemic Influenza in Their Workplace.

Question 8: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by April 2007. The task is, “DOT and DHS, in coordination with HHS, DOD, DOS, airlines/air space users, the cruise line industry, and appropriate State and local health authorities, shall develop protocols to manage and/or divert inbound international flights and vessels with suspected cases of pandemic influenza that identify roles, actions, relevant authorities, and events that trigger response, within 12 months.” **Why has this task not been completed yet?**

Response: This item was extended and will be included as part of the inter-agency border management plan currently under development pending completion of the Federal Strategic Plan now in interagency review.

Led by the IMPT and coordinated by DHS/OHA, an interagency working group has completed a draft pandemic influenza border management plan that will be an integral component to the overall federal strategic pandemic influenza plan. While a draft plan has been completed, there are several complex federal policy decisions that have yet to be resolved. These areas include the screening and possible quarantine and isolation of ill passengers or passengers suspected of being exposed to pandemic influenza; and the possible denial of entry into the US of non-resident aliens during a pandemic. These complex federal policy decisions impact the private sector. Engagement with the private has begun, a full review of operational and economic impacts need to be determined. Interagency groups, in conjunction with and coordinated by sub-PCC and PCCs, continue to work towards finalizing these issues. Once finalized, the federal strategic plan, incorporating the border management annex, will meet all the performance measures of the referenced action item(s).

Question 9: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by December 2006. The task is, “HHS, DHS, and DOT, in coordination with DOS, DOC, Treasury, and USDA, shall develop policy guidelines for international and domestic travel restrictions during a pandemic based on the ability to delay the spread of disease and the resulting health benefits, associated economic impacts, international implications, and operational feasibility, within 8 months.” **Why has this task not been completed yet?**

Response: This item was extended and will be included as part of the inter-agency border management plan currently under development pending completion of the Federal Strategic Plan now in interagency review.

Led by the IMPT and coordinated by DHS/OHA, an interagency working group has completed a draft pandemic influenza border management plan that will be an integral component to the overall federal strategic pandemic influenza plan. While a draft plan has been completed, there are several complex federal policy decisions that have yet to be resolved. These areas include the screening and possible quarantine and isolation of ill passengers or passengers suspected of being exposed to pandemic influenza; and the possible denial of entry into the US of non-resident aliens during a pandemic. These complex federal policy decisions impact the private sector. Engagement with the private has begun, a full review of operational and economic impacts need to be determined. Interagency groups, in conjunction with and coordinated by sub-PCC and PCCs, continue to work towards finalizing these issues. Once finalized, the federal strategic plan , incorporating the border management annex, will meet all the performance measures of the referenced action item(s).

Question 10.: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by February 2007. The task is, “DHS, DOT, and HHS, in coordination with transportation and border stakeholders, and appropriate State and local health authorities, shall develop aviation, land border, and maritime entry and exit protocols and/or screening protocols, and education materials for non-medical, front-line screeners and officers to identify potentially infected persons or cargo, within 10 months.” Why has this task not been completed yet?

Response: This item was extended and will be included as part of the inter-agency border management plan currently under development pending completion of the Federal Strategic Plan now in interagency review.

Led by the IMPT and coordinated by DHS/OHA, an interagency working group has completed a draft pandemic influenza border management plan that will be an integral component to the overall federal strategic pandemic influenza plan. While a draft plan has been completed, there are several complex federal policy decisions that have yet to be resolved. These areas include the screening and possible quarantine and isolation of ill passengers or passengers suspected of being exposed to pandemic influenza; and the possible denial of entry into the US of non-resident aliens during a pandemic. These complex federal policy decisions impact the private sector. Engagement with the private has begun, a full review of operational and economic impacts need to be determined. Interagency groups, in conjunction with and coordinated by sub-PCC and PCCs, continue to work towards finalizing these issues. Once finalized, the federal strategic plan , incorporating the border management annex, will meet all the performance measures of the referenced action item(s).

Question 11.: According to the White House, DHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by February 2007. The task is, “DHS and HHS, in coordination with DOT, DOJ, and appropriate State and local health authorities, shall develop detection, diagnosis, quarantine, isolation, EMS transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between Ports of Entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza, within 10 months.” Why has this task not been completed yet?

Response: This item was extended and will be included as part of the inter-agency border management plan currently under development pending completion of the Federal Strategic Plan now in interagency review.

Led by the IMPT and coordinated by DHS/OHA, an interagency working group has completed a draft pandemic influenza border management plan that will be an integral component to the overall federal strategic pandemic influenza plan. While a draft plan has been completed, there are several complex federal policy decisions that have yet to be resolved. These areas include the screening and possible quarantine and isolation of ill passengers or passengers suspected of being exposed to pandemic influenza; and the possible denial of entry into the US of non-resident aliens during a pandemic. These complex federal policy decisions impact the private sector. Engagement with the private has begun, a full review of operational and economic impacts need to be determined. Interagency groups, in conjunction with and coordinated by sub-PCC and PCCs, continue to work towards finalizing these issues. Once finalized, the federal strategic plan , incorporating the border management annex, will meet all the performance measures of the referenced action item(s).

Question 11.: Please provide us with information regarding the changes in ESF-8 from the National Response Plan to the National Response Framework. What impact will these changes—and any others in other parts of the National Response Framework—have on the pandemic influenza plans you already have in place?

Response: The goals and objectives of ESF-8, and pandemic influenza plans, remain essentially unchanged under the National Response Framework. The need to work within an organized national structure, led by the Secretary of Homeland Security, working in close partnership with ESF-8 and others is still critical.

Question 13.: How does the National Strategy for Pandemic Influenza relate to and work with the National Strategy for Homeland Security?

Response: A detailed analysis of these documents is beyond the scope of the answer to a single question. However, pandemic influenza, particularly severe instances, represents a threat to the homeland in much the same way that other threat scenarios do. These strategic documents work in concert and in concert with other key planning documents.

Question 14.: In his testimony, Dr. Jolly stated that, “. . . DHS is currently leading the development of specific guides for each of the 17 critical infrastructure and key resource sectors using the security partnership model.” Please describe the security partnership model and how it is being applied to develop these guides. What is the status of these guides—when will they be completed? If they are available now, please forward them to the Committee staff.

FACT SHEET

SECTOR-SPECIFIC PANDEMIC INFLUENZA PLANNING GUIDELINES

The Guidelines are the product of collaboration between the Department of Homeland Security's Partnership and Outreach Division (POD) and the 17 Critical Infrastructure and Key Resource (CI/KR) Sectors. The Guidelines are part of an effort to develop Sector-Specific Pandemic Planning Guidelines for all 17 of the Nation's CI/KR Sectors. These Guidelines are an annex to the *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources* (CI/KR Pandemic Influenza Guide), and have been designed to assist owners and operators within each Sector to plan for a catastrophic pandemic.

The Guidelines are the next practical step in the ongoing requirement of the Department of Homeland Security (DHS) to support and facilitate effective pandemic preparedness and partnerships with the public and private sectors. The *Implementation Plan for the National Strategy for Pandemic Influenza* articulates the requirement for these Guidelines in task 9.1.2.1, which specifies:

“DHS, in coordination with Sector-Specific Agencies, critical infrastructure owners and operators, and States, localities and tribal entities, shall develop sector-specific planning guidelines focused on sector-specific requirements and cross-sector dependencies.”

Purpose of Guidelines

- The Guidelines serve as a non-prescriptive reference and a practical tool that business continuity planners can use to augment and tailor their existing emergency response plans to the exceptional challenges specific to a pandemic outbreak.
- It is important to integrate these Guidelines with existing business continuity and emergency response plans and/or the CI/KR Pandemic Influenza Guide's comprehensive framework for pandemic catastrophic planning.

Guideline Development Process within the Sector Partnership Framework

Given the potentially extreme consequences a severe pandemic could have on our Nation's economic and social stability, the importance of strong public-private sector partnerships in our preparedness efforts has never been more important. The POD pandemic support team is eager to work with you to develop practical and useful tools to assist you with pandemic influenza planning.

- The POD pandemic support team worked closely with the Sector-Specific Agency (SSA), Sector Coordinating Council (SCC), and Government Coordinating Council (GCC) of the Sector to develop a concise document that captures the sector-specific planning challenges a sector may face during a pandemic influenza outbreak.

- The team's first step was to work with subject matter experts identified by each sector to learn more about the unique operational and structural characteristics of the sector.
- With that input in hand, the team then developed a draft Guideline and distributed it to the membership of the SCC and GCC for formal review and comment.

Each of the guidelines is being developed within the Sector Partnership Framework (also known as the Sector Partnership Model), which is outlined in the National Infrastructure Protection Plan (NIPP). The goal of the Sector Partnership Framework, including all of its associated structures, partnerships, and information-sharing networks, is to establish the context, framework, and support for activities required to implement and sustain the national CI/KR protection effort.

The framework is the primary organizational structure for coordinating CI/KR efforts and activities. The Sector Partnership Framework encourages formation of SCCs and GCCs as described above. DHS also provides guidance, tools, and support to enable these groups to work together to carry out their respective roles and responsibilities. SCCs and corresponding GCCs work in tandem to create a coordinated national framework for CI/KR protection within and across sectors. The POD Pandemic team has worked closely with representatives of each SCC and GCC in the development, review, and endorsement of each Sector-Specific Guideline. Additionally, as noted above, each SCC and GCC formally jointly reviews and endorses their Sector guideline.

Guideline Development Status Report

The guidelines are being developed with a four-phase guideline development process:

- **Phase One**—Research and Create a Draft Review Guideline: In collaboration with the appropriate SSA/SCC/GCC representatives, the DHS teams will develop for each CI/KR sector a draft Sector-specific Review Guideline.
- **Phase Two**—Formal SSA/SCC/GCC Review and Development: the DHS teams will engage with each sector's SSA and SCC/GCC to formally evaluate, enhance and endorse their sector's draft review guideline.
- **Phase Three**—Workshop: with a sector endorsed Guideline complete a CI/KR Guide and COP-E Update and Sector-specific Guideline Workshop(s).
- **Phase Four**—Distribute Final Approved Guidelines and Post at Websites: after completing reviews and receiving formal approval, DHS will distribute through the SSA and SCC/GCC to the sectors and post on federal websites.

There are 22 guidelines covering all 17 CI/KR Sectors, and there are currently drafts for each of these documents in various stages of development, as noted below. *DHS anticipates posting all 22 guidelines on www.pandemicflu.gov and www.ready.gov in March 2008.*

1. **Banking and Finance**, Phase 1
2. **Chemical**, Phase 2
3. **Commercial Facilities**, Phase 3
4. **Communications**, Phase 3
5. **Dams**, Phase 3
6. **Defense Industrial Base**, Phase 1
7. **Emergency Services**, Phase 1
8. **Energy**
 - a. **Oil and Natural Gas**, Phase 3
 - b. **Electricity**, Phase 3
9. **Food and Agriculture**, Phase 2
10. **Government Facilities**, Phase 1
11. **Information Technology**, Phase 3
12. **National Monuments and Icons**, Phase 1
13. **Nuclear**, Phase 3
14. **Postal and Shipping**, Phase 1
15. **Public Health and Healthcare**, Phase 2
16. **Transportation**
 - a. **Aviation**, Phase 1
 - b. **Highway Motor Carrier**, Phase 3
 - c. **Maritime**, Phase 2
 - d. **Mass Transit**, Phase 3
 - e. **Railroad**, Phase 3
17. **Water**, Phase 3

Question 15.: In his testimony, Dr. Jolly stated that, “. . .DHS is developing a coordinated government-wide planning forum.” Please provide specifics regarding this planning forum. How is coordinated? Which govern-

mental agencies participate? What does the forum produce? How often does it meet?

Response: DHS is working within a construct that is coordinated by the Incident Management Planning Team, within the Operations Directorate. This interagency body is working to develop strategic plans for all threat scenarios. Subject matter expertise from within DHS guides the process, and participants include all departments and agencies involved in preparedness and response for each issue. This group works in various forms every day to developing these plans.

Question 16: In his testimony, Dr. Jolly stated that, “an initial analysis of the response requirements for federal support has been completed.” Please describe this analysis, and highlight its findings (providing the actual analysis is also sufficient to answer this question).

Response:

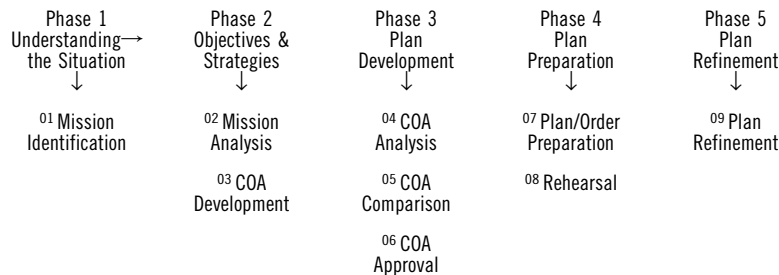
a. The Office of Health Affairs (OHA) in close coordination with the Department of Homeland Security’s (DHS) Incident Management Planning Team (IMPT) has developed a *Federal Pandemic Influenza Strategic Plan*.

b. *The Federal Pandemic Influenza Strategic Plan* is the distillation of over six months of planning development which included an interagency review of the plan by over 53 different Federal Departments and Agencies. Over 2,500 comments were received and integrated into the final draft of this plan. The final draft of this plan is projected to be submitted to the Homeland Security Council (HSC) for review/approval NLT December of 2007.

c. This plan was developed following the five phase process established in the National Planning and Execution System (NPES). The figure below highlights the NPES Incident Decision Making Process that was utilized to develop the plan.

National Planning and Execution System (NPES)

Incident Decision Making Process



Contingency (Deliberate) Planning Process

Figure 1. NPES IDMP Process

d. This process requires extensive analysis during each phase of the plan development. For example, over 30 different guest speakers and 22 separate interagency meetings were conducted during the mission analysis phase of the process.

e. The current final draft of the plan identifies Federal support requirements at the strategic level. This plan is over 50 pages long with hundreds of supporting pages (to include multiple briefings) of supporting analysis. The Federal Pandemic Influenza Strategic Plan is the result of the analysis and provides the Federal response during each of the seven Federal Pandemic Influenza Stages identified in the Pandemic Influenza Implementation Plan.

Question: In his testimony, Dr. Jolly stated that, “. . . a national plan defining the federal concept for coordinating response and recovery operations during a pandemic has been developed and will be undergoing interagency review.” Please describe this national plan. What is the federal concept for coordinating response and recovery operations during a pandemic? What is the status of the interagency review—when do you expect

that it will be completed? (Providing the plan is sufficient to both describe the plan and answer the question regarding the federal concept.)

Response: This national plan provides strategic level guidance that identifies key responsibilities and requirements across the Federal government. The federal concept relies on the construct outlined in the National Response Plan, the National Response Framework, HSPD-5, and other documents. As Secretary Leavitt and others have pointed out, overall response and recovery will also depend heavily on actions at the state and local level, due to the expected nature of a pandemic. The plan has been submitted for interagency review, which is a complex process. We continue to encourage a complete and efficient review process, but cannot predict precisely when this review process will conclude.

Question: In his testimony, Dr. Jolly stated that, “. . .a coordinated federal border management plan has been developed and is currently under review. This process included a wide range of partners.” Please describe this border management plan. Who were the partners that helped to develop this plan? What is the status of the review—when do you expect that it will be completed? Who is conducting this review? (Providing the plan is sufficient to both describe the plan and answer the question regarding the federal concept.)

Response: This border management plan provides strategic guidance for managing issues at our border during a pandemic, and identifies capabilities required to carry out that guidance. Partners included all departments and agencies involved in preparedness for this issue, along with representatives of state, county, and local public health, and public health laboratories. The plan is under review by the DHS Incident Management Planning Team, an interagency body. Wider review is pending review of the broader Federal Strategic Plan, now undergoing interagency review.

Question 19.: What are the five regions to which the pre-designated regional PFOs and deputy PFOs are assigned? Do these personnel physically reside in these regions? If not, why not?

Response:

The five regions to which Principal Federal Officials (PFOs) and Deputy PFOs are assigned:

Region A consists of Standard Federal Regions I and II:
CT, MA, ME, NH, RI, VT, NJ, NY, PR and VI.

Region B consists of Standard Federal Regions III and IV:
DE, DC, MD, PA, VA, WV, AL, FL, GA, KY, MS, NC, SC and TN.

Region C consists of Standard Federal Regions V and VIII:
IL, IN, MI, MN, OH, WI, CO, MT, ND, SD, UT and WY.

Region D consists of Standard Federal Regions VI and VII:
IA, KS, MO, NE, AR, LA, NM, OK and TX.

Region E consists of Standard Federal Regions IX and X:
AZ, CA, HI, NV, AK, ID, OR, WA, AS, GU, MP, FM, MH, and PW.

The PFOs and Deputy PFOs reside in the region to which they are assigned.

Question 20.: In his testimony, Dr. Jolly stated that, “. . .the PFO teams have begun outreach both nationally and in their regions in advance of the more formalized exercise program being developed by DHS.” Please describe these outreach efforts, as well as the more formalized exercise program being developed by DHS. Who is responsible for developing this program? When do you expect that this more formalized exercise program will be implemented?

Response: The PFO teams have been participating in various state, local and regional Pandemic Influenza workshops sponsored by the Association of State and Territorial Health Officials (ASTHO), the National Governors Association, and HHS. The most recent outreach involved observing the CDC Internal Pan Flu Exercise in August 2007 in Atlanta, GA. The Regional PFOs have also taken opportunities to meet with some of the state governors to discuss issues related to PI preparedness and response efforts.

The FEMA National Exercise Program is responsible for planning, coordinating, and developing exercises related to Pandemic Influenza in coordination with DHS Operations Coordination (the Program Manager), the Office of Health Affairs, and the National PFO Team headed by VADM Crea. The Pandemic Influenza PFO Teams are scheduled to conduct an internal exercise on 27 Nov 2007 involving the Regional PFO Teams operating from their pre-designated Joint Field Office locations and communicating the appropriate situational reports to the National PFO

Team at the National Operations Center. The teams will also be given specific exercise scenarios and injects that are specific to their regional Area of Responsibility.

Question 21.: In his testimony, Dr. Jolly stated that, “on an ongoing basis, DHS participates in interagency working groups to develop guidance, including community mitigation strategies, medical countermeasures, vaccine prioritization and risk communication strategies.” Which interagency working groups does DHS participate in? Please provide a comprehensive list.

Response: DHS participates on an ongoing basis on workgroups addressing a list of pandemic issues, including community mitigation, medical countermeasures, vaccine prioritization, and border management, along with other less formal groups that address specific issues as they arise.

Interagency committees that DHS (specifically OHA) participates in include:

- Pandemic Influenza Strategic Guidance Planning Process
- Border Management IMPT Process
- Pandemic Influenza Vaccine Prioritization Interagency Work Group (as co-lead)
- Pandemic Influenza Antiviral Household Prophylaxis Work Group
- Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic Work Group
- State Panflu Operational Plans Workgroup
- DHS Human Capital Pandemic Planning Work Group
- HHS/ASPR PanFlu Risk Management Steering Committee

Question: In answering to a question from Rep. Langevin (During a pandemic, when would the Secretary of Homeland Security lead and when would the Secretary of Health and Human Services lead?), Dr. Jolly stated that, “. . . under the construct, the Secretary of Homeland Security is responsible for overall domestic preparedness and incident coordination at the federal level and would lead the overall federal activities, while the Secretary of Health and Human Services led the health and medical response. . . .” Please describe—using scenarios as you see fit—when the Secretary of Homeland Security and the Secretary of Health and Human Services would execute the responsibilities articulated by Dr. Jolly in his testimony, and lead various efforts during the response to an influenza pandemic.

Response: As stated in my testimony, and consistent with the National Response Plan, the National Response Framework, HSPD-5, and other guiding documents, The Secretary of Homeland Security and the Secretary of Health and Human Services will fulfill these specific duties. During a pandemic, which would likely have wide-ranging and severe effects, the Secretary of Homeland Security would serve as the leader of the federal response, coordinating activities of all departments and agencies working through the ESF structure. The Secretary of the Health and Human Services will fulfill the major responsibility of overseeing the public health and medical response as outlined by RADM Vanderwagen.

Question: How is DHS trying to bring its grants into the same time sequence as the HHS grants? How is it trying to harmonize the DHS and HHS grants? Is DHS trying to do this with the grants put out by any other member of the Executive Branch? If so, which departments and agencies?

Response: In June 2005, DHS and the U.S. Department of Health and Human Services (HHS) established a Joint Grant Program Steering Committee to facilitate the integration of preparedness activities across State and local preparedness programs managed by both Departments. This committee is staffed by key program offices from both Departments, including the DHS Grant Programs and National Preparedness Directorates within FEMA and the Office of Health Affairs in the National Protection and Programs Directorate, and the HHS Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, and the Office of the Surgeon General.

The mission of this grants coordination committee supports requirements outlined in the White House Federal Response to Hurricane Katrina: Lessons Learned report as well as the newly issued Homeland Security Presidential Directive 21: Public Health and Medical Preparedness, which directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to develop and maintain processes for coordinating Federal grant programs for public health and medical preparedness using grant application guidance, investment justifications, reporting, program performance measures, and accountability for future funding in order to promote cross-sector, regional, and capability-based coordination.

Through this committee and ongoing coordination among program offices, DHS and HHS will continue to work with State and local applicants to support and, where possible, integrate preparedness activities regarding programs managed by both Departments. This includes supporting a range of activities that are achieved through collaboration at the State and local level among public safety, emergency management, health and medical communities, and non-governmental entities, such as:

- Developing clear public health emergency plans that delineate who will do what during each stage of the response
- Identifying the specific competencies needed to complete the tasks associated with the operational plan
- Implementing effective training programs that specifically support the competencies related to the public health emergency plan
- Conducting joint exercises to meet multiple requirements from various grant programs
- Engaging special needs populations and/or those who represent them in preparedness planning and exercise activities
- Conducting joint training for local decision-makers (including government administrators, health and medical professionals, and emergency managers) on issues of joint concern, such as pandemic flu preparedness or risk communication

Given that the application periods and allowable activities are frequently driven by statutory provisions, the alignment of application deadlines and award cycles is a longer-term issue that must be carefully considered by both Departments. However, emphasizing a coordinated approach to programmatic activities under the grants, particularly those that may overlap across Departments, is a primary focus of the grant steering committee's work and the guidance development process for all relevant components.

Question 24.: In his testimony, Dr. Jolly stated that “. . .we have plans within our Principal Federal Officials group to exercise within that group and then lead that into a series of leadership level interagency exercises and to culminate in another cabinet-level exercise over a period of time as the schedule develops.” What are these plans? When will the PFO group be exercised? When is the series of leadership level interagency exercise scheduled to occur? When will the next cabinet-level exercise occur?

Response: The plans refer to the PFO Team exercise workshop being conducted November 27, 2007. The PFO Team for Pandemic Influenza Response conducted an exercise workshop on November 27, 2007. It served as an internal communication and information exchange exercise involving the regional teams operating from their pre-designated Joint Field Office locations, and the National PFO operating from the National Operations Center. The findings from this first exercise will be the basis for additional training and exercise venues for the PFO teams.

The FEMA National Exercise Program is working actively with the White House Homeland Security Council's Planning, Training, Exercise and Evaluation Council (PTEEC) Policy Coordination Committee (PCC) on both an Assistant-Secretary Level and Principals-Level Exercise for Pandemic Influenza. The Cabinet level exercise is scheduled for February, 2008.. A series of exercises are expected for development over the next few years. The FEMA National Exercise Program, lead by Mr. Jim Kish, and the PTEEC PCC is developing the schedule and details for the next exercise. Mr. Kish can be contacted at 202 786-9580.

Question 25.: Can the National Biosurveillance Integration System (NBIS) be used to track seasonal influenza now, treating the disease as if it were pandemic influenza? Is this occurring now? If not, what other proxy diseases is NBIS using to continuously stress the System and ensure it will be ready (or as ready as possible) when an influenza pandemic does occur?

Response: NBIS currently tracks seasonal influenza with specific attention to any warning signs of a potential or actual pandemic event. The monitoring, within the Center (National Biosurveillance Integration Center), utilizes subject matter experts and epidemiologic strategies in conjunction with our National Biosurveillance System Group (NBSG) partners in accordance with its biosurveillance mission. Principle responsibility in tracking seasonal influenza and monitoring for pandemic influenza lies with our NBIS interagency partner, Department of Health and Human Services, who is also a member of the NBSG.

NBIS uses the System on a 24/7 basis to track major diseases events on a worldwide basis to proactively maintain a readiness posture. Notification procedures, for routine and urgent issues, are regularly utilized to maintain situational awareness

with senior leadership and key stakeholders within DHS and the interagency partners.

Question: What is the current status of NBIS? How long will it take before you feel that NBIS will be able to function well enough to track the beginnings of an influenza pandemic? What else is necessary to get NBIS to the fully functional state that you envision?

Response: NBIS, as a total, integrative, collaborative system of interagency inputs and surveillance systems with supportive IT structure is expected to reach its Initial Operating Capability (IOC) this January. It is scheduled to reach its Full Operating Capability (FOC) in September, 2008, pursuant to Public Law 110-53. The National Biosurveillance Integration Center (NBIC) is fully operational now with two specific analytic elements: a 24-hour a day 7-day a week Watch Desk manned by U.S. Public Health Service officers located within the Department's National Operations Center and a select group of full-time subject matter experts/analysts including NBIC's first interagency detailee (a senior epidemiologist from the Center for Disease Control). This combined effort provides round-the-clock receipt and assessment of over 350 varied sources of information to track and examine ongoing bio-events occurring globally in multiple domains, and the ability to determine relative significance to homeland security. Via our partner agencies with whom we have Memorandums of Understanding (HHS, DoD, , USDA, DOI, and State Dept) as well as our internal DHS components, the NBIC is capable of receiving and responding to events and tracking information that is currently provided by the primary responsible agencies, as part of this developing interagency system. To reach full functional capability we still require the final integration and testing of the NBIS 2.0 SBU IT System (scheduled for initial operational capability in January 2008), increased integration of existing information streams from MOU agencies, and detailing of Subject Matter Experts from the primary domains of interest—all of which is addressed in the Implementing Recommendations of the 9/11 Commission Act of 2007 (PL-110-53).

QUESTIONS FROM THE BENNIE G. THOMPSON, CHAIRMAN, COMMITTEE ON HOMELAND SECURITY

RESPONSES FROM DAVID L. LAKEY, MD

Question 1: Please describe how the academic centers interact with the State Department of Health in Texas. How can this interaction be improved in advance of a pandemic?

Response: • The Texas Department of State Health Services (DSHS) interacts with academia on public health emergency preparedness issues on several levels.

- DSHS has several forums for communication with the academic health science centers located in Texas. Three members of the DSHS Preparedness Coordinating Council (PCC), which is the Commissioner's statewide advisory committee on preparedness, are from academic health science centers. In addition, several years ago DSHS formed the Academic Senior Advisory Forum on Public Health Preparedness that includes representatives from academic institutions across the state as members. This group, which meets every six months, serves in an advisory capacity to the Commissioner of State Health Services regarding health and medical preparedness.

- DSHS also works collaboratively with the two Centers for Public Health Preparedness in Texas, located at Texas A&M University and at the University of Texas at Houston. Representatives of these institutions work with DSHS to ensure coordination of strategic planning and implementation of activities in order to maximize use of federal funds provided to Texas.

- Following Hurricanes Katrina and Rita, DSHS made a concerted effort to ensure that all 10 of the state's academic health science centers and approximately 100 schools of nursing were connected with and included in their respective local emergency management infrastructures. DSHS has also engaged colleges and universities that have allied ancillary and health practice majors and/or programs, including social work, veterinarian and pharmacist programs.

- During the 2005 response to Hurricanes Katrina and Rita, a remarkable collaboration developed DSHS and the academic institutions. When Houston was designated as the receiving site for Louisiana residents evacuating New Orleans, medical, civic and academic leaders worked diligently to open medical shelters in Houston's two civic arenas; in a short time they established a comprehensive medical triage, treatment and in-patient presence to support medical needs of those Louisiana residents. Similarly, in College Station, Texas A&M's School of Veterinarian Medicine cleared out, cleaned, disinfected, and opened

for human use their large animal hospital. This facility housed several hundred medical evacuees from the Houston—Beaumont area of Texas who left in the face of Rita. In the Panhandle of Texas, Texas Tech University Health Science Center staff and residents established an in-patient treatment facility at the former Reese AFB, while in Tyler, the University of Texas Health Science Center cared for medical special needs persons in the local community college gym. Schools of nursing, pharmacy, mental health and other academic programs contributed significant support to state-wide efforts to assist with medical needs of evacuees.

- The DSHS Regulatory Division has been working with the Executive Chancellor for Health Affairs of the University of Texas System on new ways to enhance DSHS' capacity to respond effectively to emergent public health and medical situations. Current plans include increasing the number UT of School of Nursing Graduate Students working with preceptors in DSHS on specific projects.
- DSHS interaction with Academic Health Centers could be improved in advance of a pandemic by documenting potential response roles and activation plans in the following categories:
 - Diagnostic capabilities and "surge capacity;"
 - Mass dispensing, triage, and care;
 - Emergency-event enhanced surveillance;
 - Emergency hotline support;
 - Just-in-time training;
 - Expert consultation; and
 - Forum for consideration of unique therapies Media resources.

Question 2.: You advocate an all-hazards approach, which includes pandemic influenza, for public health emergency preparedness. Please describe how the unique characteristics of different hazards are addressed by planning efforts. Specifically, how does planning for an influenza pandemic differ from all of the other hazards?

Response:

- DSHS advocates an all hazards approach for public health preparedness because core public health can and should be applied to any type of emergency incident, whether it qualifies as a public health emergency or not.
- Core public health include:
 - Monitoring health status to identify community health problems;
 - Diagnosing and investigating health problems and hazards in the community;
 - Informing, educating, and empowering people to take action about health issues;
 - Enforcing laws and regulations that protect health and ensure safety; and
 - Linking people to needed personal health services and assuring provision of health care when otherwise unavailable.
- In Texas, the responsibility to develop or support emergency response plans is assigned to the Governor's Division of Emergency Management (GDEM). Public health professionals participate in planning initiatives at all jurisdictional levels. Hazard and vulnerability assessment is a key step in the plan development process, and when a health impact is anticipated, DSHS explores a potential response role for public health.
- Since it is anticipated that pandemic influenza will occur in multiple waves of illness, a lengthy, sustained response and recovery operation will be required. It is likely that over the course of the pandemic up to 50 percent of the workforce may be absent due to illness, caretaking responsibilities, fear of contagion, and loss of public transportation or imposition of public health disease control measures. Consequently, DSHS is working in Texas to engage non-traditional public health partners who know most about critical public infrastructure in planning for continuity of business operations.
- Because absenteeism over the course of the pandemic will be high, state employees might be cross trained to provide essential services and functions at state agencies besides their own place of employment. Therefore, continuity of operations planning during a pandemic must address the HR issues that need to be handled uniformly across state agencies.
- Response to most hazards is quick decontamination and recovery. The response to a pandemic influenza outbreak will be to mitigate the overall impact with strategies to reduce mortality and morbidity, to flatten the outbreak curve thereby reducing the peak of illnesses and buy time in order to produce vaccine and to maintain continuity operations over a longer period of time.

- Due to the extended nature of pandemics when compared to disasters of limited duration, like an explosion or 3-day flood, the response to the former is more complex. These may include a huge volume of resources to be managed, potential school closures, along with early warning and public messaging challenges.

Question 3: From the public health perspective, there are certain similarities and differences between disasters and pandemics. Please describe a few of both, and talk about the implications you see for federal support from both the Department of Homeland Security and the Department of Health and Human Services

Response: • Disasters tend to be limited in scope to a certain area while pandemics tend to have widespread geographic impact.

- Disasters themselves tend to have a short duration followed by a variable recovery period. Pandemics tend to last for several months with multiple waves lasting several weeks each. Timing of an interim recovery period for a pandemic is critically short and unpredictable and the overall recovery period may take years.
- In disasters, material loss predominates while in pandemics human loss does.
- Those responding to disasters can count on local material aid and state/federal response. During a pandemic, response is local; state/federal response may be very limited.
- To receive adequate support, the following are needed:
 - Conducting studies to guide preparedness and response scientifically;
 - Funding local laboratories to identify pandemic influenza;
 - Funding sustained efforts at the state and local level;
 - Increasing manpower to control sporadic outbreaks;
 - Suspending federal laws that limit state's ability to get antivirals and vaccines to people, close borders, or otherwise limit state response efforts.
- From a public health perspective, the pressure on the U.S. Department of Homeland Security (DHS) and the Department of Health and Human Services would intensify during a pandemic. Traditional support such as staffing, equipment, and supplies that DHS provides through FEMA and other federal agencies would not be available since the entire nation would be affected at the same time. Public health at the state and local level would have to respond with existing resources and would not be able to expect additional resource support from the federal government.
- HHS would have to consider significant waiver of regulations for health care institutions such as hospitals and nursing facilities. An altered standard of care must be considered since facility and medical staff would be extremely overtaxed. Medical surge temporary facilities would not be able to meet Medicare standards.
- DHS and HHS should consider mechanisms to support the continued re-supply of pharmaceuticals, medical supplies, antivirals, and other infrastructure resources for healthcare facilities. Traditional supply chains will be disrupted. Increased security will be required for manufacturing, warehousing, and transportation of these public health and medical supplies and equipment.

Question 4: How has pandemic influenza been incorporated into the Texas Homeland Security Strategic Plan? How do you think your efforts could be modeled for other states?

Response: • The *Texas Homeland Security Strategic Plan* states that "health related emergencies are a homeland security focus. . ." This plan addresses the importance of optimal detection and rapid response as well as human and animal health surveillance. Texas's Pandemic Influenza Response Plan is found in *Appendix 7 to the Health and Medical Annex H of the Texas State Emergency Management Plan*, which is a companion document to the *Texas Homeland Security Strategic Plan*.

- Strengths of *Appendix 7 to Annex H* which could serve as models for other states include:
 - Assignment of supporting roles for 26 distinct agencies, including two agencies engaged in the state's preparedness planning efforts for the first time, the Office of the Secretary of State and the Division of Economic Development and Tourism within the Office of the Governor.
 - Addition of a clear, strong and significant manpower commitment from the Texas Military Forces to fully support pandemic influenza response and recovery operations.
 - Clear between this plan, which is response to human influenza, and the Foreign and Emerging Animal Diseases (FEAD) Plan, which includes re-

sponse to avian flu. The Texas Animal Health Commission holds primary responsibility for the FEAD plan which includes a supporting role for DSHS.

- Addition of educational efforts to agency stakeholders as a general responsibility for all agencies.

Question 5: Please discuss how improving our efficacy against seasonal flu may reduce risk in the event of a pandemic.

Response:

- Seasonal flu is a significant public health problem that is a major cause of morbidity and mortality annually in Texas: Approximately 36,000 US deaths are attributed to seasonal influenza each year; an estimated 3,000–4,000 Texas deaths annually.
 - Seasonal flu and pandemic flu have several characteristics in common:
 - Given that pandemic flu is likely to emerge as a combination of seasonal flu and avian flu strains, vaccination against seasonal flu may be expected to offer some degree of cross protection against a pandemic flu strain.
 - At the very least, vaccination may avoid a co-infection of seasonal flu on top of a pandemic flu infection.
- Antiviral medications currently being considered for use against pandemic flu have been developed for use against seasonal flu. Rather than simply stockpiling these for use against pandemic flu, their use should be integrated into broader treatment/prophylaxis standards of practice within the health provider community; thereby:-
 - Reducing impact of seasonal influenza on citizens;
 - Recruiting private providers into the overall response effort;
 - Incorporating retail pharmacies into antiviral distribution pipelines, perhaps setting up a “vendor managed inventory” type of stockpile distribution within the network of retail pharmacies;
- Widespread seasonal influenza vaccination of citizens should be a part of any seasonal influenza / pandemic flu response plan. Widespread seasonal flu vaccination needs to be incorporated into standards of practice so that private providers and pharmacies are reimbursed for costs of covering their patients. Seasonal flu vaccination is still consistently underutilized and current vaccine production is not sufficient for national and state needs. Increased doses of seasonal vaccine will not be produced by manufacturers until demand for current production levels is exceeded. Not only will this provide greater seasonal flu protection for the population each year, but also increase vaccine production capacity in case pandemic flu hits this state and nation.
 - Seasonal flu vaccine is expected to provide at least some partial protection against pandemic flu, in addition to reducing the impact of pandemic infection by minimizing risk for seasonal/pandemic flu CO-infections. The last two pandemic flu pandemics have been a result of a resortment process between a novel avian strain (such H5/N1) as combined with a circulating seasonal strain. At least part of the emerging, resorted pandemic strain will have seasonal components for which seasonal vaccination will provide at least partial protection.
- Public health should not be expected to carry the full responsibility for addressing pandemic flu response efforts. A large number of Texans have health care providers and insurance. This existing framework of care should be better utilized in statewide management of seasonal influenza, as well as continuing to serve as primary care and prevention platforms for dealing with pandemic flu. Treatment and prevention of seasonal flu should be incorporated into standards of practice. This will position healthcare providers and the public to deal more effectively with a pandemic.
- Concerns about development of antiviral resistance through routine use of antivirals may be offset by the following:
 - The pandemic strain that emerges will likely have a different sensitivity/resistance pattern than the circulating seasonal strain.
 - Manufacturers will be encouraged to have new antivirals in the development pipeline.
 - Closer surveillance of resistance patterns may document that use of less costly antivirals, such as the M2 agent amantadine, alone or in combination with other medications.
- Strategic surveillance with rapid testing for seasonal/pandemic flu should be in place so that identification of introduction of seasonal/pandemic flu into Texas occurs at the earliest possible moment. Models of disease spread and epidemiologic experience with spread of infection document that early intervention

(control and prevention through targeted use of antivirals and vaccines) will be the major determinant on reducing the effect of seasonal and pandemic flu on morbidity and mortality within the population. The ability to rapidly distinguish between seasonal and pandemic flu strains is of vital importance in this early detection effort.

- The same personal and community precautions that help prevent spread of seasonal flu, such as cough etiquette (for example covering the mouth with a sleeve, rather than a hand); good hand washing / hand sanitation; staying home when ill, and human resources policies that promote influenza prevention in the workplace will help prevent spread of a pandemic strain of influenza. Additional community strategies to mitigate a pandemic are likely to be more accepted and better followed if citizens already take personal, school, and workplace prevention of influenza seriously.

Question 6: What do you think we can do now to address health disparities, and prevent pandemic influenza from disproportionately affecting parts of our population?

- Disparities in public health can be seen in both of the following areas:
 - Persons 65 and older not receiving seasonal flu vaccine: 28.6% of non-Hispanic whites, 49.4% of Hispanics and 54.1% of African-Americans. Minority seniors are almost twice as likely to not receive seasonal flu vaccine. (Source: 2006 BRFSS).
 - Lack of healthcare coverage in adults under the age of 65: 13.9% of non-Hispanic whites, 30.0% of African-Americans, and 50.1% of Hispanics. Hispanics are more than 3 times and African-Americans 2 times as likely to not have health care coverage. (Source: 2006 BRFSS).
 - Addressing these disparities related to influenza prevention could include additional programs for seasonal immunization with a focus on closing the disparity gap. As systems are developed to provide seasonal immunizations, the capacity to deliver pandemic immunizations would increase.
 - Department of Homeland Security has provided Texas with some funding to exercise hurricane evacuation and sheltering for the last 3 years. Texas has studied special needs evacuees, including those along the border area, in a situation without utilities. Through the Governor's Division of Emergency Management and the National Emergency Response and Rescue Training Center, Texas has worked to identify and quantify those individuals who will need special evacuation assistance, special medical assistance. More effort will need to be made through planning and exercising to continue to discover additional requirements needed for extended sheltering and staffing.
 - It is unlikely that enough measures can be put into place to prevent pandemic influenza from disproportionately affecting parts of the population. Health care workers will be disproportionately exposed early on with relatively little warning. Residents in some areas along the international border will be less likely to have access to health departments for information and aid. They may be disproportionately exposed by immigration. Reaching rural and remote areas with screening and surveillance will continue to be a challenge.

Question 7. According to the Implementation Plan for the National Strategy for Pandemic Influenza, "The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required prepare for and respond to a pandemic, within 6 months" of when the Plan was released—so the deadline would have been October 2006. What are challenges here? Are you waiting for the Federal government to provide you with guidance and resources?

Response: • Traditionally, Texas has not waited for federal guidance to define and test actions and priorities. Texas has had a Pandemic Influenza Plan at the Department of State Health Services since 2004. It was updated and posted in October 2005. It has since been renamed the Pandemic Influenza Plan Operating Guidelines (PIPOG). Revisions to the plan have been made to reflect changes in science, federal guidance and available resources and as additional pieces of the plans are developed and tested. DSHS will post revised planning guidelines by the end of 2007. Local health departments have developed plans specific to their jurisdictions. State and local plans are routinely exercised and modified based on after action reports.

- Some of the challenges include:
 - Aligning Texas plans developed prior to receiving federal guidelines takes time.

- With several federal plans and guidelines coming from different agencies, including Homeland Security, Health and Human Services, and Centers for Disease Control and Prevention, determining which federal guidelines take priority can be a challenge.
- Consequently, it is preferable that:
 - A clear line of leadership to the states is established.
 - One set of guidelines which represents the collective guidance of all involved federal agencies be developed.

Question 8.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, “State, local, and tribal law enforcement agencies should coordinate with appropriate medical facilities and countermeasure distribution centers in their jurisdictions to coordinate security matters, within 6 months” of when the Plan was released—so the deadline would have been October 2006. To your knowledge, has any of this coordination taken place? If so, how, and if not, how would you recommend this happen?

Response: • Coordination between law enforcement agencies and local health departments is a key element in countermeasure distribution planning of medication from the National Stockpile. This coordination has happened with varying of success in local jurisdictions in Texas and nationwide. This coordination did not appear to increase substantially as a result of release of this plan. The importance of this coordination and expected results should be communicated and emphasized through law enforcement channels to be effective. This might be done through professional associations as well as licensing bodies.

Question 9.: What roles do associations play in assisting their constituents with emergency and pandemic preparedness?

Response: • Some associations have an advisory role in developing plans and operational guidelines for pandemic preparedness and response. For example, the Texas Medical Association currently has a representative on the Preparedness Coordinating Council, which provides oversight for all preparedness activities. There are also organizations that have been identified in *Annex H: Health and Medical to the State Emergency Plan* as having a responsibility in any statewide public health disaster response. Other public health and medical associations play a key role in helping Texas be better prepared. These organizations are partners with DSHS in increasing the ability for a timely preparedness response to a or natural disaster and include the Texas Hospital Association, the Texas Nurses Association, and the Texas Association of Local Health Officials.

Question 10. The Government Accountability Office (GAO) says in its report that State, Territorial, Tribal, Local, and other stakeholders need to be involved in providing input to the National Strategy for Pandemic Influenza and its implementation Plan, especially as the National Strategy evolves. If you were at the White House, how would you ensure this happens?

• **Response:** States vary in their response planning to pandemic influenza. There are differences in interpretation of federal guidelines. State and federal planning are not synchronized, with the states often planning in advance of the release of federal guidelines. In addition, states do not always coordinate with each other, in part due to substantial differences in governmental structure, law, and demographics.

It would be helpful to include state stakeholders at the beginning of planning processes rather than at the middle or end. The best way to achieve that is to provide multiple vehicles for stakeholders to participate in the process.

Question 11.: As you all know, public health has been identified as one of the critical infrastructures of our Nation.

a. Have you been included in the planning undertaken by the Department of Homeland Security to protect the public health infrastructure?

Response: • Although DSHS has not been directly involved in the planning undertaken by the of Homeland Security (DHS), DSHS works collaboratively with the Texas Office of Homeland Security and with the Texas Governor’s Division of Emergency Management. DSHS provided input on the Texas Homeland Security Strategic Plan 2005–2010.

b. From what you know about this work, how does it affect you in your and local positions?

Response:

- Two documents, the *National Strategy for Pandemic Influenza* (November 2005) and the *National Strategy for Pandemic Influenza implementation Strategy* (May 2006), provided Texas with a general framework for the state response as well as roles and responsibilities for federal agencies. These documents were used to validate the Texas plan that had already been developed and to additional elements to be included.
- DHS will be responsible for coordination of the overall federal response during an influenza pandemic, while the DHS Office of Health Affairs will be leading coordination of efforts that affect state and local policies. This will include implementation of policies that facilitate compliance with recommended social distancing measures, and entry and exit screening for influenza at the borders as they ensure domestic security. Texas has 1,240 miles of international border with many bridges for vehicle and foot traffic to and from Mexico. Many border counties in Texas do not have local health departments. Therefore, surveillance at the points of entry will be critical to Texas during an influenza pandemic. Other initiatives by DHS that affect Texas include the publication of the *Pandemic Influenza Preparedness Response and Recovery Guide for Critical Infrastructure and Key Resources (The Guide)*. Texas has used the Guide for a State-level Pandemic Influenza Exercise. Texas has also participated in the Determined Accord Pan Flu exercise developed by DHS and FEMA.

c. What more do you think needs to be done in this regard, especially in advance of an influenza pandemic?

- DSHS would like to have greater interaction with representatives of federal agencies or the DHS Regional (PFOs) planners during preparedness exercises. All plans have elements that may be subject to “interpretation,” and by having federal representatives present at state-level exercises, some of the ambiguities can be resolved more quickly.

Question 12.: How do current federal regulations influence your efforts to stockpile antiviral medications?

Response:

- Lack of ability to rotate antiviral stock, to implement shelf-life extension program, and limitations on approved uses affected decision-making by the Texas Legislature when deciding on how many state resources could be allocated for purchasing antiviral medications for a state stockpile.
- Supplies provided from federal contracts are restricted to use during pandemic influenza. However, current federal guidelines and packaged labeling do not allow for rotation of antiviral purchased using the federal contract. This creates the potential for waste.
- Federal policy discontinues the Shelf-life Extension Program for antiviral drugs once they are delivered to the states. There is no clear guidance on how long antivirals from the Strategic National Stockpile (SNS) that have expired dates will be viable in state stockpiles that cannot qualify for a Shelf-life Extension Program.

Question 13.: What do you see as a practical solution that would reduce the investment risk of procuring antiviral medications while ensuring adequate supplies of these medications are available in the event of a pandemic?

Response:

- Remove the “*For Government Use Only*” labeling on antiviral packaging to facilitate and allow rotation of stock.
- Similar to smallpox vaccine and medications in the SNS, hold samples from each lot distributed to states for analysis in a Shelf-life Extension Program, thereby allowing antiviral in state possession to remain usable after expiration date.
- Negotiate extension of current federally subsidized contract or a new reduced price to allow more community critical entities to purchase antiviral at a reduced cost.
- Assist with long-term storage rental or adding environmental controls to state owned warehousing and security of storage facilities.

Question 14.: What ability do local hospitals in your states have to accommodate a surge that would be associated with a pandemic?

Response:

- Texas hospitals have developed plans to augment staffing during a pandemic. These include developing databases of available personnel, developing callback

lists, and working with state medical and nursing organizations to identify and recruit individuals who are available during a pandemic.

- In Texas, 65.9 percent of hospitals reported having a database of credentialed clinicians while 52.8 percent reported having a database of other health professionals to contact during a pandemic.

However, there is concern about being able to meet staffing demands over the long term. The ability to provide staffing will be a limiting factor in being able to meet surge demands during a pandemic.

- Currently, availability of resources and equipment to support a surge capacity event varies throughout Texas. Hospitals typically keep 72 hours of inventory in stock. To support resource availability, work group participants report that some hospitals and Regional Advisory Councils are creating or contracting with distributors to create equipment and supply caches. Similarly, a number of hospitals have pre-purchase contracts in place to deliver specified supplies within 72 hours of a disaster in the event communication systems are disrupted.

Question 15.: What type of procedures are in place to increase capacity should a pandemic occur?

Response:

- Most Texas hospitals have the ability to increase bed capacity and supporting physical infrastructure during a pandemic. The majority (59.7 percent) have a bed expansion plan in place and local health departments, city and county governments, and other entities have created plans and processes to open medical shelters if needed. Alternative plans and procedures for increasing physical infrastructure capacity have been developed (discharging patients to make room for disaster victims).
- During Hurricanes Katrina and Rita, human resources were available to provide health and medical care in a mass care environment. Physicians, nurses, allied health professionals, mental health professionals, and others volunteered to provide care.
- DSHS is implementing the Texas Disaster Volunteer Registry, the state's version of the federally-mandated Emergency Systems for Advance Registration of Volunteer Health Professionals (ESAR-VHP), which should be operational this winter. The Registry is being built in collaboration with the state's key medical licensing and regulatory boards and supporting professional organizations, such as the Texas Board of Medical Examiners, the Texas Medical Association and the Texas Osteopathic Medical Association. The Registry will provide: (1) pre-registration of medical/healthcare professional volunteers, as well as supportive lay volunteers; (2) verification of professional and (3) credentialing of professionals—all in any effort to enhance rapid medical response to disasters or public health emergencies.
- During Hurricanes Katrina and Rita, evidence indicates that Texas was able to obtain medical supplies, medications, and durable medical equipment to support patient care.
- The following DoD and VA hospitals are included in and participate regionally in the Texas medical surge efforts:
 - Amarillo VA Health Care System
 - Veterans Affairs Medical Center
 - Veterans Affairs Medical Center-Bonham
 - U S Veterans Hospital
 - Central Texas VA Health Care System
 - Central Texas Veterans Healthcare System—Waco Campus
 - Audie L. Murphy Memorial Veterans Hospital
 - Kerrville VA Medical Center
 - Michael E. DeBakey VA Medical Center
 - William Beaumont Army Medical Center
 - Carl R. Army Medical Center
 - Brooke Army Medical Center

QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN OF THE SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

RESPONSE FROM PETER A. SHULT, PHD

Question 1.: Do the activities and responsibilities of public health laboratories differ when dealing with seasonal influenza versus the more virulent strain expected for pandemic influenza?

Response 1.: The basic diagnostic, networking and reporting activities and responsibilities of the public health laboratory (PHL), as outlined in my testimony document (pages 1—4, *Role of the public health laboratory*), are fundamentally the same in response to either seasonal or pandemic influenza. In the earliest stages of a pandemic we would be trying to detect and identify the novel influenza subtype and differentiate it from seasonal influenza strains and other respiratory pathogens that might be circulating using diagnostic methodologies we currently employ. Results would be immediately shared with our state and local health departments and with the Centers for Disease Control and Prevention (CDC). Furthermore, unusual viral isolates and patient specimens from which they came would be immediately forwarded to the CDC for further characterization as is our current protocol. Finally, we would be interacting with other virus laboratories and rapid influenza testing sites within our states to monitor their results and acquire unusual isolates or specimens that they might encounter for further characterization and expedited delivery to CDC as necessary, similar in the way that we do now. The biggest difference and challenge for the PHL in response to a pandemic would be carrying out these activities during likely periods of reduced staffing (due to personal or family illness, etc.) and significant supply interruptions. This points out the critical need for PHLs and all response agencies to develop and exercise Continuity of Operation Plans.

Question 2.: What additional resources do public health laboratories throughout the Nation—including the territories—need to be able to better address naturally-occurring and intentionally-distributed disease agents that threaten our country?

Response 2.: Largely as a result of Public Health Emergency Preparedness funding from the CDC over the last five or so years, PHLs have been able to build significant, state-of-the-art molecular-based diagnostic testing capability and capacity for the rapid and accurate identification of priority agents of bioterrorism and other significant public health threats. In addition, PHLs have been able to develop strong relationships and working networks with clinical laboratories within their states in order to prepare these laboratories to safely, effectively and cooperatively respond in the event of a public health emergency. The cost of these activities in terms of needed staffing, training, diagnostic equipment and reagents, laboratory security systems, specimen courier systems, emergency communications and electronic data sharing systems, etc. has been great. However, the value to public health of this enhanced laboratory response capability and capacity is undeniable as evidenced by the effective responses, in recent years, to threats such as SARS, monkeypox, pertussis and several nationwide foodborne outbreaks, to name but a few. *Consistent and sustained funding* of PHLs will now be critical to *maintain* the PHL needs already addressed (listed above and in the testimony document) not to mention provide for newer and likely more expensive diagnostic and information and data sharing technologies that will be needed for even more effective response to public health threats in the future.

Question 3.: What sorts of cautions should laboratorians take into consideration regarding the use of rapid diagnostic tests for detecting Influenza A viruses?

Question 3.: There are about 15 different hand-held rapid tests for influenza on the market today. A number of these are simple enough that they are permitted to be performed in the point-of-care setting without laboratory expertise or credentialing. Despite their simplicity, rapid results and relatively low price, these tests have significant limitations:

- In general, the diagnostic sensitivity (ability to detect true positives) of these tests is limited (on average, 70—75% according to the CDC) which means patients with influenza may be misdiagnosed as not having influenza. In some cases this is due to inherent limitations of the test itself or to the type of specimen the test calls for (e.g. throat swab, which is usually not the optimum specimen for influenza, but is recommended for its ease of collection). Furthermore, it is not certain which, if any of these tests will work for detection of a novel, potentially pandemic influenza strain. The result is a patient that might otherwise be treated for influenza may not be.
- A limitation of any diagnostic test including these rapid flu tests is when they are performed during periods of low influenza prevalence (early during a typical flu season or during the earliest stages after the emergence of a novel influenza strain), false positive results often occur. This would be particularly worrisome early on during a pandemic period when false positive results may result in premature triggering of mitigation strategies, unnecessary usage of antivirals and unnecessary concern or panic.

Both of these limitations can be overcome by performing and interpreting these tests in the context of available clinical information indicative of influenza and sur-

veillance information that confirms that influenza is circulating in the community. Also, rapid test sites should be strongly encouraged to confirm suspect (i.e. early or off-season) rapid results with more accurate laboratory testing, which is available at a PHL or larger clinical lab. The PHL should take the lead in identifying and training rapid test sites in proper rapid test usage and interpretation and provide up-to-date influenza surveillance information for appropriate epidemiological context for the test results.

- Another concern is widespread use of rapid tests will interrupt influenza surveillance since these specimens will not come to the PHL for testing. This limitation can be overcome (as demonstrated in Wisconsin and other states) by working with and encouraging rapid test sites to share both specimens for confirmatory testing and their test results data, with minimal inconvenience or financial impact to them.
- Perhaps the biggest concern with widespread usage of these rapid tests is maintaining appropriate biosafety. This is of particular concern for non-laboratorian users of these tests in non-traditional, non-laboratory, point-of-care settings (physician offices, nursing homes, pharmacies, etc) where appropriate facilities, safety devices and personal protective equipment (PPE) may not be available or used. While simple to perform, these tests have steps that can generate infectious aerosols that could infect the user and those in the testing vicinity. These users need basic biosafety training, which can (should) be provided by knowledgeable PHL or other clinical laboratorians.

Question 4.: How have the public health laboratories worked with the Department of Homeland Security to address issues such as bioterrorism, and naturally occurring infectious disease agents such as pandemic influenza? What role has the Integrated Consortium of Laboratory Networks played so far in this regard?

Response 4.: It is my experience in Wisconsin and the opinion of other PHLs that we have had only very limited or indirect interaction with the Department of Homeland Security (DHS). At the level of our PHL association, the Association of Public Health Laboratories (APHL), significant interactions have occurred including:

- Through our national association, APHL, we have established working relationships with Dr. Randy Long and the Integrated Consortium of Laboratory Networks (ICLN). We now have public health laboratorians participating on various subgroups of the ICLN. These subgroups are working on issues such as proficiency testing, accreditation, quality control, methods collection, training, radiological testing capacity.
- APHL has also worked with DHS and DoD on the development of the All-Hazards Receipt Facilities and screening protocols for PHLs for processing unknown environmental samples.
- APHL is also participating in the DHS lead and AOAC facilitated process to evaluate PCR assays for use in autonomous detection systems. **APHL strongly opposes the use of biological and chemical agent detection kits and devices for field testing in the absence of performance standardization, field validation and certified individuals trained in the application of these kits and devices.**

Public health laboratory preparedness and response efforts have been largely (solely?) directed by the CDC at the federal level and by our state health departments and emergency management agencies. The latter, in Wisconsin, has had more direct interaction with DHS. However, PHLs play an integral role in state emergency response planning and exercising of these plans consistent with federal response plans (Pandemic influenza, NRP/NIMS, etc.). As for the Integrated Consortium of Laboratory Networks (ICLN), I think I speak for many PHLs in saying we recognize what the ICLN is and what its basic goals are (this has been presented at a number of professional meetings attended by PHL directors and laboratorians), but we have not been directly affected by this initiative or consulted during its development. However, PHLs have developed (or are in the process of doing so) close working relationships with state and federal agency laboratories within their states responsible for food, animal and water testing during a public health or environmental emergency. Each of these labs (at least in Wisconsin) is part of their own national network in much the same way that the PHL is part of the LRN. For example, our state veterinary diagnostic lab belongs to the National Animal Health Laboratory Network (NAHLN) and our state agriculture/food lab belongs to the Food Emergency response Network (FERN). Our efforts in planning, communication and collaborative response to an emergency with these other laboratories, at this point, has been at the state level with little direct coordination at the federal level apparent to us.

Question 5: In your testimony, you stated that there is a “. . .critical need for accurate, very rapid, highly reliable diagnostic testing to make best use of the stockpiles. . . . Please provide more information regarding this critical need. How much more rapid and reliable do you believe diagnostic testing should be, and how would this testing make best use of the stockpiles?

Response 5: Antiviral stockpiles are a major focus of state and national pandemic preparedness and response efforts. The use of antivirals for prophylaxis and treatment will be a critical adjunct to other community mitigation measures particularly during the early stages and perhaps throughout the first wave of a pandemic in the absence of a vaccine. It is possible if not likely that supplies of antivirals may be limited in a given location. Even if there are sufficient supplies, their mobilization and use will need to be carefully considered and coordinated. The trigger for any pandemic response, including use of the antivirals will require laboratory confirmation that a novel influenza subtype has emerged and is being transmitted among the population. Most state PHLs now have this capability since they have been provided funding from the CDC for resources (staff, diagnostic equipment and reagents, etc)to provide state-of the art, rapid (2-4 hours from specimen receipt), highly sensitive and specific molecular-based diagnostic testing for seasonal and potentially pandemic strains of influenza. These labs also have excellent diagnostic methods for a large number of other respiratory pathogens that might need to be ruled out. Thus, if these capabilities can be maintained and even better tests brought online in the future with adequate funding, a sensitive trigger for pandemic response is available. However, as the outbreak or pandemic progresses and once antiviral stockpiles are distributed to the point-of-care, diagnostic testing and subsequent treatment decisions will be at the level of the clinician. At this point, it would be advantageous to have highly accurate point-of-care testing available to help ensure appropriate use and prevent over- and misuse of the antivirals. As I have pointed out in question 3., this currently isn't the case. Clearly more development in this area is needed. Even with improved point-of-care diagnostics, up to date regional laboratory-based surveillance data, necessary confirmatory testing and antiviral susceptibility testing needs to be made available. This should be among the critical roles for the PHL.

Question 6: A number of testing protocols have been provided to members of the Laboratory Response Network for Bioterrorism, to test for various biological agents. However, there is concern about those situations in which particular agents are not identified or suspected ahead of testing. Further, in the case of pandemic influenza—especially if the virus causing the pandemic does not happen to be H5N1—there will certainly not be any accompanying notes describing the makeup of the virus. How are specimens analyzed before any disease identification has been made (in other words, how do the labs deal with specimens of unknown composition)?

Response 6: Biosafety is a paramount concern in any clinical laboratory and especially in the PHL where we frequently are involved in unknown and unusual outbreak situations. In fact, it is the norm that we do not know what pathogen(s) we might encounter. In addition, we often receive and immediately test specimens from patients from whom we have no clinical or relevant epidemiologic information. We always operate from the premise that the specimen contains the worse possible agent. . . .always! This is the same philosophy that is the underpinning for “Universal Precautions”, familiar to all care givers and laboratorians in safely handling blood and body fluids that might contain bloodborne pathogens. Consequently, all patient specimens or unknown isolates received for further characterization should be initially handled and processed in a biological safety cabinet (BSC) in (at a minimum) a Biosafety Level 2 (BSL-2) laboratory using practices and PPE appropriate to that biosafety level. . . . While impeccable sterile technique is the mainstay of safe handling of the specimen/isolate, the BSC, when used properly, provides a high level of protection (from routine pathogens as well as agents of greater public health concern such as primary agents of bioterrorism, influenza, SARS virus, etc.) for the laboratorian doing the testing and those around him. In the event that we might suspect a patient or environmental specimen, test material referred to us or generated during the testing within our lab contains a pathogen requiring a higher level of biosafety, work would be carried out in our BSL-3, or “containment” laboratory, which provides a much higher level of containment and requires more specialized equipment and a higher level of PPE to protect the facility and better protect the testing staff. Our biosafety protocols are carefully written and rigorously followed and are consistent with guidelines set forth by the CDC.

While I am very confident of the effectiveness of these protocols and of the biosafety expertise within the PHL, I am much less confident when it come to clinical diagnostic labs, particularly those in smaller hospital and clinics, and point-of-care

testing sites (mentioned above). These hospital-based labs will likely be the frontline responders in an infectious disease emergency, whether naturally occurring or intentional. Here is where our concern should really lie and where intensive training efforts should be directed. Indeed, we in Wisconsin and other states have begun these efforts.

Question 7: How are the public health laboratories working with the CDC to “. . . monitor the emergency of antiviral resistance that we have already seen with one whole class of antivirals”? To which class are you referring?

Response 7.: During the 2005-06 influenza season, the CDC announced and published evidence that showed greater the 90% of the circulating seasonal influenza type A viruses tested were resistant to one of the two classes of antivirals available for treatment or prophylaxis of influenza, the adamantanes (amantadine and rimantadine). Results last season were similar. Consequently, use of the adamantanes is no longer recommended. Immediately after these results were reported (in winter 2006), the Wisconsin State laboratory of Hygiene (WSLH) was contacted by the CDC and asked to bring online antiviral susceptibility testing for the adamantanes to provide surge capacity for the CDC to continue to monitor the level of resistance to the antiviral of seasonal influenza and in case a novel subtype emerged. At least 2 other state PHLs have followed suit. Last year these PHLs contributed to the surveillance efforts and stand ready to continue these efforts this year and respond should a novel subtype emerge. While some funding was initially secured (at least in Wisconsin) from CDC to purchase expensive equipment and reagents for this testing, actual PHL antiviral resistance surveillance testing largely has been self-funded. The CDC has also begun surveillance for resistance to the only remaining class of influenza antiviral, the *neuraminidase inhibitors* (*Relenza*[®] and *Tamiflu*[®]). Discussions with CDC are currently underway for some state PHLs to help with this surveillance as well; however, currently only CDC has this capability. The long term goal would be to have the CDC, supported by select PHLs to maintain ongoing surveillance for antiviral resistance among circulating seasonal influenza strains and have this testing available should a novel, possibly pandemic strain of influenza virus emerge. Given the previously mentioned reliance on antiviral for pandemic response, this surveillance will be critical. However, these efforts need to be supported with stable funding.

Question 8: The Implementation Plan for the National Strategy for Pandemic Influenza provided this task, “All Federal, State, local, tribal, and private sector medical facilities should ensure that protocols for transporting influenza specimens to appropriate reference laboratories are in place within 3 months”—which would have been July 2006. What challenges do you see with executing this task? Why has this task has been so difficult to address throughout the country?

Response 8.: In my firsthand experience in Wisconsin and knowledge of some other states, Public Health Emergency Preparedness and other funding from CDC has been used to fund critical specimen transportation to PHLs. Funded activities include development of emergency response and specimen shipping guidelines and protocols, maintaining statewide repositories of critical specimen collection supplies and shipping kits for use by clinical labs and local health departments, training on specimen shipping procedures and regulation, contracting with private couriers (in fact more than one for redundancy) or maintaining the laboratory's own courier, among others. While these activities were originally carried out for response to bioterrorism, they have “all hazards”, including pandemic influenza, applicability. At least in Wisconsin (and I know other states as well), our specimen transport systems and protocols have been frequently and successfully utilized and practiced during a number of recent outbreaks (some quite large) we have been involved in and exercises we carry out with our clinical laboratory partners. This capacity now exists. The challenge, as I see it, will be maintaining this capacity during a pandemic when courier services will be disrupted due to illness or fear of carrying certain specimens (a concern we have had expressed to us by the larger commercial couriers vs. the small private company and HMO or large clinical lab couriers we utilize), specimen collection supplies and shippers may be in short supply, etc. We are currently considering these issues with partners in response and examining ways to provide redundancies for transport, augment stockpiles of critical supplies, prioritize critical testing needs that absolutely require specimens be shipped to my lab and at the same time cover costs. An issue on the national level that has not yet been addressed to my knowledge is how will the state PHL get critical specimens to the CDC, our reference laboratory, given the consequences of a pandemic described above.

Questions 9.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, “The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months” of when the Plan was released—so the deadline would have been October 2006. **What are the challenges here? Are you waiting for the Federal government to provide you with guidance and resources?**

Response 9.: Given the critical role of the PHL in preparedness planning and response to pandemic influenza, working in close collaboration with other national, state and local public health and emergency response partners, their priorities need to be addressed (and funded) and actions defined and exercised. To date, my laboratory has only engaged in relatively limited tabletop exercises with clinical laboratory partners and with local and state public health agencies with minimal involvement with other traditional emergency response partners. Despite their limited scope, these exercises have been extremely valuable in defining the likely obstacles to an effective laboratory and public health response and how these might be overcome and providing valuable and actionable lessons learned. In my opinion (and that of other state PHL colleagues with broader experience with more complex exercises) conducting broader community-based exercises is extraordinarily complex to plan and carryout, expensive and disruptive to day-to-day work activities. This is not surprising given the immensity and diversity of a pandemic’s likely impact and the response needed. I am in favor of our laboratory’s approach in testing parts of the plan (both national and state plans) with limited response partners; however, I acknowledge that larger exercises with more diverse participants to test a specific aspect of the plan (e.g. conducting vaccine clinics, antiviral stockpile mobilization, etc) likely will be needed.

Questions 10.: According to the Implementation Plan for the National Strategy for Pandemic Influenza, “State, local, and tribal law enforcement agencies should coordinate with appropriate medical facilities and countermeasure distribution centers in their jurisdictions to coordinate security matters, within 6 months” of when the Plan was released—so the deadline would have been October 2006. To your knowledge, has any of this coordination taken place? If so, how, and if not, how would you recommend this happen?

Response 10.: This question is really beyond the scope of the laboratory and definitely beyond my experience.

Questions 11.: What roles do associations play in assisting their constituents with emergency and pandemic preparedness?

Response 11.: Speaking only about laboratory-related professional associations [including the APHL, American Society for Microbiology (ASM), College of American Pathologists (CAP), American Clinical Laboratory Association (ACLA), to name a few] it has been my experience that these associations have been very active and effective in assisting their constituents with emergency and pandemic preparedness. Each of these associations’ website is loaded with planning documents, testing recommendations and protocols and links to resources, many of which have been collaboratively developed. Moreover, these associations provide their input to national planning efforts. I have participated in and facilitated a number of very effective working groups among these associations, largely coordinated by the CDC, that have tackled issues related to emergency (including pandemic influenza) preparedness and response including:

- Roles for the large national clinical labs in pandemic response
- Development of testing guidelines
- Impact of new generation point-of-care tests on laboratory diagnosis
- Biosafety issues

The same can be said about numerous public health and clinical specialty associations. Engaging the leadership of these associations in planning efforts and using these associations to reach their thousands of constituents to share information is a highly efficient and effective element of preparedness and response planning.

Question 12.: The Government Accountability Office (GAO) says in its report that State, Territorial, Tribal, Local, and other stakeholders need to be involved in providing input to the National Strategy for Pandemic Influenza and its Implementation Plan, especially as the National Strategy evolves. **If you were at the White House, how would you ensure this happens?**

Response 12.: As an extension of my answer to question 11, relevant federal agencies should be responsible and held accountable for implementation of the National Strategy and for engaging relevant partners (much as CDC has done with

laboratories and state and local public health agencies). Key partners should include professional associations that can ensure content experts are identified (with significant experience in laboratory science and public health, for instance) and state and local input is solicited in the development and implementation of policies and plans. It also needs to be recognized that emergency response in the final analysis will be carried out primarily at the local and state level with support needed from federal resources.

Questions 13.: As you all know, public health has been identified as one of the critical infrastructures of our Nation. **Have you been included in the planning undertaken by the Department of Homeland Security to protect the public health infrastructure? From what you know about this work, how does it affect you in your state and local positions? What more do you think needs to be done in this regard, especially in advance of an influenza pandemic?**

Response 13.: Neither the WSLH nor any other PHL that I am aware of has been included in planning undertaken by DHS to protect PH infrastructure. It is important, however, that DHS and other federal agencies recognize the importance of the PHL and the clinical laboratory networks we oversee within our states for response to pandemic influenza or other public health emergencies. Conversely, we (PHLs and public health in general) need to fully understand the role, authority and expectations of DHS in protecting public health infrastructure, starting with defining public health infrastructure and what the term “protect the PH infrastructure” refers to. I interpret it to mean strengthen and sustain public health (including the PHL) capabilities and capacity now so we are prepared to mount an effective public health response to any emergency such as pandemic influenza. . .and protect public health capabilities and capacity during the response. It is obvious to me that the first steps need to be communication, so that we all can ultimately recognize and understand each other’s roles and expectations, and a commitment to funding this critical response element.

Responses respectfully submitted on behalf of the Association of Public Health Laboratories by:
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QUESTIONS FROM THE HONORABLE JAMES LANGEVIN, CHAIRMAN, SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE

RESPONSES FROM BERNICE STEINHARDT

Question 1.: Regarding the Implementation Plan for the National Strategy for Pandemic Influenza, you state in your report that, “. . .because many of the performance measures do not provide information about the impacts of proposed actions, it will be difficult to assess the extent to which we are better prepared—OR—to identify areas needing additional attention.” **What sort of process do you propose should be used to rectify this situation now?**

Response: In our August 14, 2007, report (*Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, GAO-07-781), we reported that many of the performance measures contained in the Implementation Plan consisted of actions to be completed such as guidance developed and disseminated. Without a clear linkage to anticipated results these measures make it difficult to ascertain whether progress is being made toward achieving the goals and objectives described in the Plan and the National Strategy for Pandemic Influenza.

In our report, we recommended that the Homeland Security Council establish a specific process and time frame for updating the Plan. We further recommended that during this update, the Plan could be improved by including information in the Plan such as a greater use of outcome-focused performance measures.

Question 2.: You state in your report that one of the difficulties with the National Strategy for Pandemic Influenza is that it has not been made clear how it relates to and interacts with others of our National Strategies. **How have other National Strategies have made this clear? How would you recommend this occur now with the National Strategy for Pandemic Influenza?**

Response: Over the past several years, GAO has reviewed several national strategies and we have found that these strategies could have better described how they were linked to the goals, objectives, and activities of other related strategies.

As part of our recommendation to the Homeland Security Council to establish a specific process and time frame for updating the Plan, we stated that the Council's next update of the Plan should more clearly describe the linkages between the Plan with other related strategies and plans.

Question 3.: You state in your report that State, Territorial, Tribal, Local and other stakeholders need to be involved in providing input to the National Strategy for Pandemic Influenza and its Implementation Plan, especially as the National Strategy evolves. How do you propose this should occur? Who should be responsible for ensuring stakeholders are not only invited to provide input, but that their input is indeed incorporated?

Again, in our recommendation to the Homeland Security Council regarding the need to update the Plan, we stated that the update process should involve key stakeholders and incorporate lessons learned from exercises and other sources. Since the Implementation Plan is the responsibility of the Homeland Security Council, it should be up to the Council to not only invite stakeholders to provide input to the next update of the Plan, but to also make sure that the Plan reflects their input. In addition, the agencies that worked with the Council in drafting the Plan, such as the Departments of Homeland Security and Health and Human Services, could hold forums and discussions with their stakeholders and seek their input during the update process.

QUESTIONS FROM THE COMMITTEE ON HOMELAND SECURITY

RESPONSES FROM RADM W. CRAIG VANDERWAGEN, MD

Question 1.: The Assistant Secretary for Preparedness and Response has a unit that deals with exercises. The Office of the Assistant Secretary for Preparedness and Response has also reached out to the Department of Homeland Security regarding the use of the Lessons Learned Information Sharing system. **How is HHS using the system? How are personnel in the Office of the Assistant Secretary of Preparedness and Response working with those in the Office of Health Affairs, the National Exercise Program, and other programs at the Department of Homeland Security, to combine efforts and data?**

Response: The Training, Exercise and Lessons Learned Team (TE&LL) in the Office of the Assistant Secretary for Preparedness and Response (ASPR), as appropriate, maximally employs the Department of Homeland Security's (DHS) tools and systems as prescribed in HSPD-8 to manage HHS training activities, exercises, and lessons learned.

The TE&LL Team represents HHS at the Exercise and Evaluation Sub Policy Coordinating Committee (PCC) (formerly the Plans, Training and Exercise PCC of the Homeland Security Council). Within this forum HHS liaises with DHS and the National Exercise Program, and all other Departments and agencies. This body meets bi-weekly and offers an excellent forum for interdepartmental communications.

The TE&LL Team represents HHS on the Executive Steering Committee of the National Exercise Program (NEP), and collaborates frequently with DHS on submitting joint exercise proposals (Pandemic Influenza Exercise Series). HHS also sits on the TOPOFF 4 Executive Steering Committee, and participates in all Principal Level Exercise and Senior Official Exercise activities. DHS acts as the executive agent for managing all of the preceding committees.

HHS participates in all principal National Exercise Schedule (NEXS) conferences and meetings.

HHS maintains five blanket purchasing agreements (BPAs) with many of the same vendors that DHS utilizes for managing their HSPD-8 activities. This leads to better synergy and alignment between HHS and the HSPD-8 tools and activities. With help from contract support, HHS is actively moving all of its major training, exercise, and lessons learned paper-based systems to the HSPD-8 electronic based system.

A standing weekly call is held between the Assistant Secretary for Preparedness and Response and the DHS Office of Health Affairs Acting Assistant Secretary/Chief Medical Officer to coordinate efforts and activities.

At HHS' Strategic Readiness Plan (SRP) Roll Out in August 2007, multiple DHS programs were invited to participate along with their leadership (Corrective Action Program, National Exercise System directors). At the SRP Roll Out the Department formally adopted the HSPD-8 tools into its training, exercise, and lessons learned management processes.

Some components of HHS have achieved initial integration with DHS's *Lessons Learned Information Sharing (LLIS.gov)* system. For example, the Centers for Disease Control and Prevention (CDC) Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), Division of State and Local Readiness (DSLRL) has partnered with *LLIS.gov* to develop the CDC DSLR "Channel" on *LLIS.gov*. Channels are secure areas of *LLIS.gov* dedicated and customized to the preferences of a specific community of interest, organization, or jurisdiction. The CDC DSLR has written into its grant guidance that *LLIS.gov* is the official repository of State and local jurisdictions' exercise schedules. To date, CDC DSLR grantees have uploaded more than 80 exercise schedules to the *LLIS.gov* Channel. Additionally, the Channel is used as a shared workspace and information sharing forum for federal, State, and local health stakeholders.

Question 2.: Please provide us with information regarding the changes in ESF-8 from the National Response Plan to the National Response Framework. What impact will these changes—and any others in other parts of the National Response Framework—have on the pandemic influenza plans you already have in place?

Response: The text for the ESF#8 Annex currently contained in the National Response Framework is the same language HHS submitted to DHS for the National Response Plan and supports the HHS/ESF#8 effort to prevent, protect, respond, and recover from all domestic response activities. There is no impact on pandemic influenza planning. The text was updated to reflect recent legislative changes impacting ESF#8. This included the following:

- In the event of a public health emergency the Secretary of HHS shall assume command and control, when appropriate, of Federal emergency public health and medical response assets that have appropriate MOUs in place, except for members of the Armed Forces, who remain under the authority and control of the Secretary of Defense.
- The Secretary of HHS, through the Office of the Assistant Secretary for Preparedness and Response (ASPR), coordinates national ESF#8 preparedness, response, and recovery actions.
- Updated to reflect the transfer of the National Disaster Medical System (NDMS) from DHS to HHS.

Question 3.: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by July 2006. The task is, "HHS shall improve the speed at which it performs mortality surveillance through the 122 Cities Mortality Reporting System within 3 months." Why has this task not been completed yet?

Response: Since the release of the National Strategy for Pandemic Influenza Implementation Plan, much has been accomplished to realize the U.S. Government's pandemic preparedness and response goals of: (1) stopping, slowing, or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic and mitigating disease, suffering, and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society.

Although we have realized progress in expanding disease surveillance abroad, critical gaps remain with respect to "real-time" disease detection and clinical surveillance in the United States. As part of its national influenza surveillance effort, the CDC currently receives weekly mortality reports from 122 cities and metropolitan areas in the United States. This information helps the CDC track trends in disease spread, identify severely affected populations, and monitor the impact of influenza on health. One of the limitations of this system, however, is an approximately 2-week lag in obtaining data. BioSense is a national program intended to improve the Nation's capabilities by conducting nearly real-time clinical disease surveillance. Of the nearly 6,000 hospitals in the United States, only 700 hospitals are currently engaged in some stage of implementation for sharing data with the BioSense program.

Question 4.: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by October 2006. The task is, "HHS, in coordination with DHS, DOT, DOS, DOC, and DOJ, shall develop policy recommendations for aviation, land border, and maritime entry and exit protocols and/or screening and review the need for domestic response protocols or screening within 6 months." Why has this task not been completed yet?

Since the release of the National Strategy for Pandemic Influenza Implementation Plan, much has been accomplished to realize the U.S. Government's pandemic preparedness and response goals of: (1) stopping, slowing, or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic and mitigating disease, suffering, and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society.

Once an influenza pandemic reaches the United States, the primary focus is safeguarding the health of Americans. The U.S. Government is working to enhance the Nation's ability to detect and respond early and effectively to a pandemic. To better identify the first cases of pandemic influenza in a community, the U.S. Government has provided resources to State and local health departments to increase the number of sentinel providers and improve laboratory detection at public health laboratories. The U.S. Laboratory Response Network (LRN), which includes State public health laboratories, is prepared to conduct initial testing of suspected human infection with H5N1 within 24 hours of receipt. To ensure that suspected cases can be promptly confirmed and treated, the Federal Government is working with industry partners to develop rapid diagnostic tests to quickly discriminate pandemic influenza from seasonal influenza or other illnesses.

Question 5: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by *January 2007*. The task is, “HHS, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall develop plans for the allocation, distribution, and administration of pre-pandemic vaccine, within 9 months.” **Why has this task not been completed yet?**

Allocation

Medical countermeasures have little utility if they cannot be delivered quickly to those in need, yet the logistical challenges of rapidly allocating, distributing, and administering countermeasures to 300 million Americans are substantial. Although we have made significant investments in distribution capacity since 2002 through the Strategic National Stockpile, State and local grant programs, and the Cities Readiness Initiative, much work remains. Guidance and resources have been provided to State, local, tribal, and territorial governments to facilitate completion of distribution plans for medical countermeasure stockpiles. Recipients of pandemic influenza supplemental funding are required to complete and exercise these plans.

Countermeasure allocation and distribution is important for preparing our Nation for pandemic influenza and other naturally occurring infectious diseases, as well as for chemical and nuclear attacks. In the future we may be faced with the need to prioritize scarce medical resources during a major disaster. The pandemic efforts could well serve as a template for allocating and distributing life-saving countermeasures against other threats. The ongoing guidance development process for prioritizing and deploying countermeasures during a pandemic represents our first steps in addressing this complex ethical and logistical challenge.

One major goal of the U.S. pandemic influenza vaccination program is to vaccinate all persons in the United States who choose to be vaccinated. An interdepartmental working group led by HHS developed and prepared a draft report leading to guidance that analyzed and established prioritization tables of different functional population groups and accompanying rationale for the allocation of pre-pandemic and pandemic influenza vaccines at the onset and during an influenza pandemic with a CDC severity index of 5. This report is distributed currently for public comment through Dec. 31, 2007 (See <http://www.aspe.hhs.gov/panflu/vaccinepriorities.shtml>). Final guidance is expected in early 2008.

The draft guidance is firmly rooted in the most up-to-date scientific information available, and directly considers the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination. Information considered by the working group included rigorous scientific assessments of pandemics and pandemic vaccines, national and homeland security issues, essential community services and the infrastructures and workforces critical to maintaining them, and the perspectives of state and local public health and homeland security experts. Historical analysis of the influenza pandemics of 1918, 1957, and 1968 and their effects provided valuable insights to this draft guidance. Ethical considerations presented by an ethicist who served on the working group and by academic ethicists also were important to the working group process and deliberations.

A formal decision-analysis process also was undertaken that considered the objectives of a pandemic vaccination program and the degree to which protecting population groups (defined by their occupation, age, and health status) contributed to meeting those objectives. Based on this process, groups that ranked highest were

frontline public health responders, essential health care workers, emergency medical service providers, and law enforcement personnel. Among the general population groups, infants and toddlers ranked highest.

It is recognized that vaccine supply to meet this goal will likely not be available all at once, but rather, develop at varying rates depending on both vaccine characteristics (antigen required) and production capacity. Given that influenza vaccine supply will increase incrementally as vaccine is produced during a pandemic, allocation decisions will have to be made. Such decisions should be based on publicly articulated and discussed program objectives and principles. The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy.

One of the most important findings of the working group analysis, and the strongest message from the public and stakeholder meetings, was that there is no single, overriding objective for pandemic vaccination and no single target group to protect at the exclusion of others. Rather, there are several important objectives and, thus, vaccine should be allocated simultaneously to several groups. Each of the meetings came to the same conclusions about which program objectives are most important:

- Protecting those who are essential to the pandemic response and provide care for persons who are ill,
- Protecting those who maintain essential community services,
- Protecting children, and
- Protecting workers who are at greater risk of infection due to their job.

In addition to these, the important Federal objective of maintaining homeland and national security was factored into the guidance.

General guidance includes the following:

- The need to target vaccine to maintain security, health care, and essential services will depend on how severe the pandemic is, as rates of absenteeism and the ability to supply essential products and services will differ between more and less severe pandemics. As a result, groups targeted for earlier vaccination will differ by pandemic severity.
- Allocation of pandemic vaccines to States will be in proportion to the State's population.
- Whereas States should follow the national guidance, they will have some flexibility in defining the target groups and implementing the guidance to best fit their local situations.
- Within the parameters of the guidance, a small proportion of each State's vaccine allocation may be maintained at the State level for distribution based on the specific needs of that jurisdiction.
- In past pandemics, groups at increased risk for serious illness and death have differed by age and health status. Because the high-risk groups in the next pandemic are not known, this guidance will be reassessed and may be modified at the time of the pandemic.
- Guidance on pandemic vaccine allocation and targeting will be re-assessed periodically to consider the potential impacts of new scientific advances, changes in vaccine production capacity, and advances in other medical and public health measures.

Guidance for targeting vaccination was developed in a structure that defines target groups in four broad categories—people who: (1) protect homeland and national security, (2) provide health care and community support services, (3) maintain critical infrastructure, and (4) are in the general population. Within categories, vaccination target groups are clustered into *levels*. In general, all groups within a category and level will have the same priority for vaccination. Within a category, levels are listed in descending order of priority for vaccine. Levels across categories are not necessarily comparable in terms of vaccine prioritization.

Allocation and targeting of vaccine integrating categories occurs in *tiers*. By design, groups in a tier (cutting across categories) are vaccinated simultaneously unless vaccine supply is so limited that sub-prioritization is needed. Finally, groups in vaccination tiers differ depending on *pandemic severity*, defined as severe, moderate, and less severe as described in the Pandemic Severity Index.

Distribution/Administration

During 2007, HHS/CDC with HHS/BARDA developed plans in consultation with other federal government departments including DHS, State and local governments and domestic influenza vaccine manufacturers for distribution of pre-pandemic and pandemic influenza vaccines from the domestic manufacturer distribution centers to points of distribution (PODs) within States for the near (<18 mos.) and long term. On August 15–17, 2007 CDC in coordination with HHS/BARDA, DHS, the States of Ohio and Arkansas, and one of the domestic influenza vaccine manufacturers con-

ducted a pandemic influenza vaccine training exercise to test the communication and actual shipment of vaccine from the manufacturer to State points of distribution according the HHS plan for pandemic vaccine distribution. During the exercise, an influenza pandemic event from HHS to the vaccine manufacturer and the States and the need for shipment of pandemic influenza vaccine to the States was communicated effectively, and mock containers of vaccine were successfully transported overnight from the vaccine manufacturer to the PODs of the two States.

Question 6: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by *April 2007*. The task is, “HHS, in coordination with DHS, DOT, DOS, DOD, air carriers/air space users, the cruise line industry, and appropriate State and local health authorities, shall develop en route protocols for crewmembers on-board aircraft and vessels to identify and respond to travelers who become ill en route and to make timely notification to Federal agencies, health care providers, and other relevant authorities, within 12 months.” **Why has this task not been completed yet?**

Response: If a pandemic begins outside the United States, and international containment efforts fail, the U.S. Government has planned a series of layered border measures that may be implemented incrementally during a severe pandemic to slow the entry of a pandemic virus into the United States while allowing the flow of goods and people. These border measures during the early stages of a severe pandemic may include flight restrictions from affected regions, issuance of health guidance to travelers intending to enter the United States, health screening of travelers before departure, en route, and on arrival to the United States, as well as public health measures to limit onward transmission of the disease.

We are working closely with our neighbors Canada and Mexico to establish a common North American approach to delay the arrival and impact of a pandemic. One of the objectives of the pandemic planning efforts in the Security and Prosperity Partnership is the development of the North American Plan for Avian and Pandemic Influenza. This trilateral plan, now being finalized, establishes a framework for coordinated, trilateral actions regarding communication, responses to avian and pandemic influenza, border monitoring, and critical infrastructure protection. Developed as part of the Plan is a concept of operations for responding to aircraft inbound to North America that are carrying passengers potentially infected with the pandemic virus. This approach is currently being shared with other aviation partners around the world. U.S. Quarantine Stations, located at ports of entry and land-border crossings where international travelers arrive, will play an important role in delaying the introduction of pandemic influenza into the United States and helping to limit its spread. The number of quarantine stations in the United States has more than doubled since 2004, expanding from 8 to 20 locations, with quarantine stations in Dallas and Philadelphia added this past year.

Response 7.: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by *April 2007*. The task is, HHS, in coordination with DHS, shall review and approve State Pandemic Influenza plans to supplement and support DHS State Homeland Security Strategies to ensure that Federal homeland security grants, training, exercises, technical, and other forms of assistance are applied to a common set of priorities, capabilities, and performance benchmarks, in conformance with the National Preparedness Goal, within 12 months.” **Why has this task not been completed yet?**

HHS provided interim assessments to the respective State Health Officials and their Governor’s Chief of Staff. Each draft interim assessment contained jurisdiction-specific feedback as well as general feedback from the participating federal departments.

Question 8: According to the White House, HHS was to have completed this action item from the Implementation Plan for the National Strategy for Pandemic Influenza—by *April 2007*. The task is, “HHS, in collaboration with State, territorial, tribal, and local health care delivery partners, shall develop and execute strategies to effectively implement target group recommendations, within 12 months.” **Why has this task not been completed yet?**

Response: At the beginning of a pandemic, the scarcity of vaccine will require the limited supply to be prioritized for distribution and administration. The Federal Government has begun a process to revise previous interim guidance for Federal, State, local, tribal, and territorial planners on groups to target for earlier access to pandemic vaccines. The U.S. Government has sought input from influenza experts,

State and local public health officials, homeland security experts, ethicists, private sector stakeholders, and the public in developing this guidance.

Question 9.: In his testimony, Dr. Vanderwagen stated that, “. . .there was a transfer of responsibility to the ASPR from the Assistant Secretary for Health for pandemic planning and coordination within HHS.” **What does this transfer entail? Why did the transfer occur? What are the implications for this transfer?**

Response: The Pandemic and All-Hazards Preparedness Act (PAHPA), Public Law No. 109–417, established the position of the Assistant Secretary for Preparedness and Response (ASPR) and designated the ASPR as the principal advisor to the Secretary on all matters related to public health and medical emergency preparedness and response. Under PAHPA, the ASPR office assumed responsibility for leadership and coordination of public health and medical preparedness and response activities within HHS, including planning and coordination of activities related to pandemic influenza.

Prior to the transfer, the Assistant Secretary for Health (ASH) was responsible for leading pandemic influenza planning and served as the lead HHS contact to the Homeland Security Council (HSC), while the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) executed all initiatives. The transfer brings all pandemic influenza activities, from planning to execution, under one umbrella; ASPR is now also the HHS pandemic influenza lead contact to the HSC.

ASPR’s pandemic influenza activities include overseeing the advanced research, development, and procurement of qualified medical countermeasures and qualified pandemic or epidemic products through the Biomedical Advanced Research and Development Authority (BARDA). ASPR also administers pandemic preparedness and response efforts through the National Disaster Medical System (NDMS) and the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR–VHP), and coordinates closely with the Medical Reserve Corps (MRC).

The consolidation of the Department’s public health and medical preparedness and response efforts under ASPR will ensure a unified, integrated approach in preparing for and responding to the public health and medical effects of natural and man-made disasters, including pandemic influenza. Through ASPR, the Department will be better able to coordinate interagency activities between HHS, other Federal departments, agencies, and offices, and State and local officials, as well as private sector entities, responsible for emergency preparedness and the protection of the civilian population.

Question 10.: During the hearing, Dr. Vanderwagen discussed with the Members of the Committee on Homeland Security various aspects of the Strategic National Stockpile, including the purchase and stockpiling of antiviral medications. In answering a question put forward by Rep. Pascrell about letters of inquire from Congress (that went to Secretary of Health and Human Services Leavitt—one letter from the House Republican leadership in June, one letter from the House Democratic leadership in August, and one from Senator Thad Cochran in September), Assistant Secretary Vanderwagen stated that two of these letters had been responded to by the Department of Health and Human Services. **When were these letters sent, and to whom? Has the third response to Senator Cochran been made as well? Please attach copies of all of these letters when answering this question for the record.**

Copies of the following letters are enclosed:¹

Representative Boehner Letter dated June 21 / Reply dated November 6
 Representative Hoyer Letter dated August 1 / Reply dated November 26
 Senator Cochran Letter dated September 11 / Reply dated November 26

¹See attachments below.

A-41-007 07-004 Post-Office Secretary for Letters 212-180-790 1-025 P 05/07 P-115
JUN-21-2007 10:30 PROGRAM, KIM SWANER 002 205 2683 TO: 002 003 7044 P-076

Congress of the United States
Washington, DC 20518
June 21, 2007

OFFICE OF THE SECRETARY
OF THE SECRETARY OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
OF THE SECRETARY OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Dear Mr. Secretary:

We appreciate your continued leadership in working to ensure our nation is prepared against the very real threat of a pandemic influenza. President Bush has rightfully made our nation's preparedness against this inevitable threat a high priority. Rest assured we have and will continue our efforts to ensure that your Department's needs are met so we can address this critical national need.

We are very concerned, however, by reports that the Department of Health and Human Services has approximately \$2.5 billion in unobligated funds for the implementation of the National Strategy for Pandemic Influenza (NSPI).

In particular, we are concerned about the slow progress in completing key elements of the Department's preparedness plan. One of the most notable of those elements is the planned stockpiling of antivirals, which is one of the primary components of the NSPI and our nation's first line of defense at the onset of any future pandemic influenza outbreak here in the United States. And yet, the planned antiviral stockpile remains incomplete despite the fact that ample resources are available now to put that part of the plan firmly in place.

We are aware that of the \$2.5 billion in unobligated funds, approximately \$400 million remains to develop an advance antiviral treatment to combat avian influenza. We respectfully request that you act expeditiously to complete the stockpile with existing antivirals that have shown to be effective, and then work to develop the next generation of advance antivirals, which could take five years or more to develop. Please provide us with your specific plans, including timelines, for doing so. We look forward to receiving a response at your earliest convenience.

John Boehner
Rep. John Boehner
Rep. Roy Blount
Rep. Roy Blount
Rep. Adam P. Brown
Rep. Adam P. Brown
Rep. Bob Chabers
Rep. Bob Chabers
Rep. John Conaway
Rep. John Conaway
Rep. Tom Cole
Rep. Tom Cole
Rep. David Dreier
Rep. David Dreier

cc: Tim Watters, OIG
Rob Portman, OIG

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20491

NOV - 6 2007

The Honorable Jfm. Boehner
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Boehner:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$1.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 28 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable Jim Boehner - Page 1

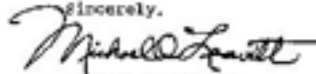
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Salenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the co-signers of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20492

ADV - 6 2007

The Honorable John Carter
U.S. House of Representatives
Washington, DC 20514

Dear Mr. Carter:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.6 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2009. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable John Carter - Page 2

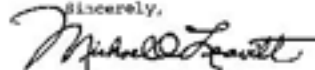
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the cosigners of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20512

NOV - 6 2007

The Honorable Adam Putnam
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Putnam:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.6 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 30 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable Adam Putnam - Page 3

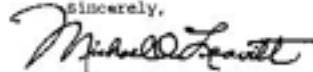
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the cosigners of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael G. Leavitt

Michael G. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20037

AJCV - 6 2007

The Honorable Kay Granger
U.S. House of Representatives
Washington, DC 20515

Dear Ms. Granger:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$1.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable Kay Granger - Page 2

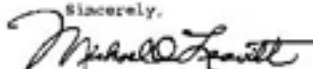
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the signers of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

HCY - 6 277

The Honorable Roy Blunt
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Blunt:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2008 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$1.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable Roy Blunt - Page 2

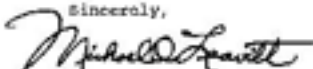
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the co-sponsors of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, DC 20201

NOV - 6 2007

The Honorable David Dreier
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Dreier:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.5 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable David Dreier - Page 2

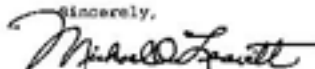
Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the cosigners of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael C. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20491

NOV - 6 2007

The Honorable Tom Cole
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Cole:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$1.6 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 13 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

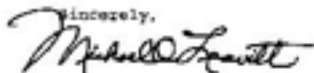
The Honorable Tom Cole - Page 2

Based on a review of the antiviral research and development pipeline, HHS science, medical and procurement experts now project that contracts for new antivirals will likely be awarded after full year appropriations are enacted for FY 2008. In addition, based on HHS negotiations with companies currently in progress, we expect to achieve favorable pricing, shelf-life and other considerations for the government by accelerating our planned purchases of Relenza and Tamiflu. Therefore, it is likely we will use currently available appropriations to make these stockpile purchases over the next few weeks.

It remains critical that Congress appropriate the full \$470 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the co-signers of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,

Michael O. Leavitt

Congress of the United States
Washington, DC 20515

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August 1, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Secretary:

It has come to our attention the Department of Health and Human Services (HHS) has approximately \$2.5 billion in unobligated funds for the implementation of the National Strategy for Pandemic Influenza (NSPI). We understand a large portion of those funds are contractually committed, however, we are concerned about the slow progress of completing the stockpiling of antivirals because it is one of the primary components of our nation's first line of defense at the outset of any future pandemic influenza outbreak in the United States.

As you are aware, the NSPI has outlined a plan to purchase enough antivirals to treat at least 25 percent of the U.S. population during a pandemic, which equals 81 million courses of treatment. To date, HHS and the States have only purchased a combined 51 million courses of antivirals, which is enough to treat only about 15 percent of the population.

Public health experts estimate a pandemic of even relatively low severity could potentially cause 90,000 U.S. deaths if appropriate interventions are not made. However, it seems that by not expeditiously completing the antiviral stockpile, the Administration and HHS are gambling that an influenza pandemic will not occur in the near future - notwithstanding the H5N1 virus continues to spread around the world and the toll of human lives lost due to H5N1 continues to rise.

The failure to prepare for a pandemic influenza outbreak represents a failure to safeguard the welfare of the American people. We have only to remember the catastrophic events of Hurricane Katrina and its terrible toll on human life to recognize the importance for strong preparation and implementation of disaster plans at the federal level. Therefore, with the remaining unobligated and uncommitted funds, we respectfully request you to make progress toward the completion of purchases of antivirals for our stockpile in a swift and expeditious manner.

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The Honorable Michael O. Leavitt
August 1, 2007
Page Two

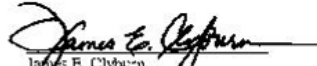
In lieu of an undeveloped vaccine, which even if developed the experimental vaccine would not be available in sufficient quantities at the outset of an influenza pandemic, it is imperative we do all we can to obtain an adequate supply of antivirals, our only treatment available to combat an influenza pandemic.

We appreciate your comprehensive consideration of this request.

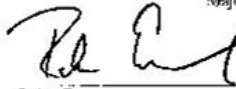
Sincerely,



Steny H. Hays
Majority Leader



James E. Clyburn
Majority Whip



Rahm Emanuel
Democratic Caucus Chairman



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20515

NOV 3 6 2007

The Honorable Steny Hoyer
House of Representatives
Washington, D.C. 20515

Dear Mr. Hoyer:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the Federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable Steny Hoyer - Page 2

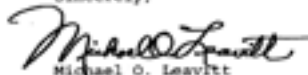
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It remains critical that Congress appropriate the full \$870 million requested for FY 2008 so we can carry out all the actions in our pandemic preparedness plan, including development of new antiviral medications. It would be short-sighted to rely upon only the medications currently available. We must be prepared for a pandemic for today, and for the future.

I am sending the same response to the cosigners of your letter.

Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20491

NOV 26 2007

The Honorable James Clyburn
House of Representatives
Washington, D.C. 20515

Dear Mr. Clyburn:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

The HHS Pandemic Influenza Plan called for a stockpile of enough antiviral drugs for 25 percent of the population. HHS has purchased approximately 38 million courses of antiviral drugs and plans to complete the federal portion of the stockpile in FY 2008. HHS also remains committed to the advanced development of new and better influenza antiviral drugs as this is a key component of the HHS pandemic preparedness strategy. The emergence of drug-resistant virus strains has already obviated one of the two classes of antiviral drugs that we have to use against H5N1 viruses. Completing the stockpile of currently available antiviral medications that work today, and developing new ones that will work in the future, are equally critical components of our pandemic preparedness plan.

The Honorable James Clyburn - Page 2

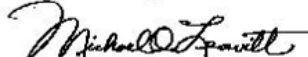
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Michael O. Leavitt



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 26 2007

The Honorable Rahm Emanuel
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Emanuel:

Thank you for your letter expressing interest in the status of HHS pandemic preparedness activities. We appreciate the funding Congress has provided to HHS for pandemic preparedness through two FY 2006 emergency appropriations bills.

As of October 2007, HHS has obligated approximately \$3.8 billion in pandemic influenza funds and has unobligated balances totaling \$1.8 billion. HHS has already made commitments for the use of these funds or has plans to obligate the funds in FY 2008.

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The Honorable Rahm Emanuel - Page 2

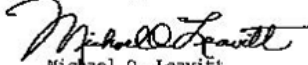
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Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt

09/11/07 15:56 FAX 202 224 8450

THAD COCHRAN
MEMPHIS

United States Senate RECEIVED
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CONSERVATION
COMMITTEE ON
RULES AND
ADMINISTRATION

September 11, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, #615 F
Washington, D.C. 20201

Dear Secretary Leavitt:

I am pleased with the steps the Department of Health and Human Services has taken in preparing the United States for an outbreak of pandemic influenza. However, it has come to my attention that to date, the Department and individual states have purchased a combined 51 million courses of antivirals, which is enough to treat only about 15 percent of the population. The National Strategy for Pandemic Influenza (NSPI) outlines a plan to purchase enough antivirals to treat at least 25 percent of the U.S. population during a pandemic influenza, which means 83 million courses of treatment need to be stockpiled.

Public health experts estimate that a pandemic of even relatively low severity could potentially cause 90,000 deaths if appropriate precautionary measures are not put in place. It is also clear that the H5N1 virus continues to spread around the world and that the toll of human lives lost due to H5N1 continues to rise. Therefore, in lieu of a vaccine that has yet to be completely developed, and knowing that even the experimental vaccine would not be available in sufficient quantities at the outset of an influenza pandemic, I urge you to designate any unobligated funds under NSPI towards the completion of purchases of antivirals for the stockpile.

I appreciate your attention to this matter.

Sincerely,


THAD COCHRAN
United States Senator

TC/wc



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20515

NOV 26 2007

The Honorable Thad Cochran
United States Senate
Washington, DC 20515

Dear Senator Cochran:

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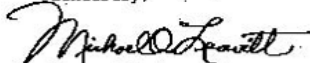
The Honorable Thad Cochran - Page 2

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Thank you for your support in preparing the nation to combat an influenza pandemic.

Sincerely,



Michael O. Leavitt

Question 11.: In his testimony, Dr. Vanderwagen stated that, “. . . gaps exist in respiratory protection.” **Please expand upon this statement. What are these gaps? How would HHS like to see these gaps filled?**

Response: HHS has done an assessment of the need for respiratory protection devices based on Pandemic Severity 5 (PS-5) pandemic. Current and near-term guidance documents and recommended practices were used as guides to assess the need. This assessment covers the needs for all segments of the US population (health care, public safety, business, and general public). Based on this assessment the need for N95 respirators is 5.3 billion and surgical masks is 26.9 billion. An evaluation was also done of the US market for these items and the surge capacity of the US manufacturing base. The need exceeds the market numbers by about 10-fold. HHS is currently working on strategies to address these gaps and the responsibilities of government, health care, business, and the general public for specific portions of the gap. While it is clear stockpiling and increasing domestic production

will be part of any proposed solution, it is premature to give specifics to the solution to be proposed.

Question 12.: In his testimony, Dr. Vanderwagen stated that, “. . . gaps. . . exist in how we can make community mitigation even more effective potentially using the expanded production capability in antivirals to perhaps use antivirals in a prophylactic mode as opposed to a pure treatment mode. . .” **Please provide more information regarding the use of antivirals in a prophylactic (as opposed to pure treatment) mode. Is HHS putting this forward as policy at this time? Aside from using antivirals prophylactically, how else does HHS envision making community mitigation even more effective?**

Antiviral drug use will be an important component of a pandemic influenza response. While current antiviral drug use strategies and stockpiled assets are targeted primarily for treatment of persons with pandemic illness, expanded antiviral drug production has allowed additional new strategies to be considered. In February 2007, the U.S. Government released community mitigation guidance for mitigating the impact of a pandemic. This community mitigation strategy includes antiviral medications for treatment of ill persons and if sufficient supply exists, for prophylaxis for household contacts of an ill person. Mathematical models of the potential effects of community mitigation illustrate the additive effects that antiviral prophylaxis offers in reducing disease transmission.

An interagency working group, with representatives from State, local and tribal public health agencies, considered scientific issues, ethics and values, and perspectives of stakeholders in developing draft guidance on antiviral use strategies and stockpiling. A draft guidance, which was developed by this working group led by HHS and is under public review, provides guidance for the use of influenza antiviral medications assuming that effective community mitigation measures will reduce pandemic illness by one-half.

Draft guidance on antiviral use was based on goals of the U.S. national pandemic response which are to slow the spread of pandemic disease, reduce impacts on health, and minimize societal and economic disruption. The working group recommended the following strategies and settings for antiviral use to meet these goals:

- Containing or suppressing initial pandemic outbreaks overseas and in the U.S. with treatment and post-exposure prophylaxis (PEP) among individuals identified as exposed to pandemic influenza and/or geographically targeted prophylaxis for geographic areas where exposure is thought likely to occur;
- Reducing introduction of infection into the United States early in an influenza pandemic by post-exposure prophylaxis of exposed travelers as part of a risk-based policy at U.S. borders;
- Treatment of persons with pandemic illness who present for care early during their illness and would benefit from such treatment;
- Prophylaxis of critical health care workers, emergency service personnel, and workers with unique roles maintaining critical infrastructures for the duration of community outbreaks;
- Post-exposure prophylaxis of household contacts of persons with influenza illness as a component of community mitigation; and
- Post-exposure prophylaxis of workers in the health care sector with limited patient contact, of persons with compromised immune systems who are unable to be protected by vaccination, and of persons living in closed settings such as nursing homes and prisons if a pandemic outbreak occurs at that facility.

Antiviral drugs stockpiled by the Department of Defense and by some private sector businesses will protect military and critical support capabilities and employees, respectively, and contribute to maintaining essential societal and economic infrastructures. We recognize that shipment or use of antiviral medications for purposes beyond those in the labeled indication, which may include use for prophylaxis rather than treatment, would require consultation with the Food and Drug Administration, and either an Investigative New Drug exemption or an Emergency Use Authorization.

This draft guidance is based on consideration of scientific, behavioral, and logistical issues, as well as societal values. Further discussions with stakeholders and the public are underway as part of a transparent process and to move forward in addressing implementation issues. Rapid implementation of these strategies during a pandemic will pose substantial challenges. Planning should include defining occupational target groups and developing approaches to ensure appropriate targeted prescribing and dispensing of antiviral drugs for both treatment and post-exposure prophylaxis. Periodic reassessment of antiviral drug guidance will be important based on scientific and technological advances and surveillance for antiviral re-

sistance. Strategies also need to be continuously reviewed as a pandemic occurs and progresses to take into account the characteristics of the virus and epidemiology of disease in regard to control measures.

Consistent implementation of the social distancing measures included in the Community Mitigation Guidance is important to produce reductions in disease transmissions within and among communities. HHS is working with public health agencies in every State to incorporate community mitigation in their pandemic planning activities. It is also important that State planners are aware of any potential adverse consequences due to these interventions and take actions to minimize the negative impact of these strategies. To enhance individual and community adherence to these community mitigation measures, HHS is providing guidance to State planners to encourage continued work with the private sector, public health, education, and community-based and faith-based organizations to address feasibility concerns, develop clear and appropriate public messaging, and minimize any adverse consequences associated with implementation.

In addition and complimentary to social distancing, another key countermeasure among those used to mitigate an influenza pandemic in a community setting is the usage of masks and respirators. In some workplaces, employers will not be able to eliminate the risk of exposure to pandemic influenza for all employees and respirators will be an important component of protecting these employees and allowing them to perform essential work. Respirators are used to reduce an employee's exposure to airborne contaminants. Respirators are designed to fit the face and to provide a tight seal between the respirator's edge and the face. A proper seal between the user's face and the respirator forces inhaled air to be pulled through the respirator's filter material and not through gaps between the face and respirator. Respirators must be used in the context of a comprehensive respiratory protection program, (see OSHA standard 29 CFR 1910.134, or www.osha.gov/SLTC/respiratoryprotection/index.html).

Question 13.: In his testimony, Dr. Vanderwagen stated that the engagement of state and local governments, businesses, individuals and families “. . . in the gap filling process needs to be active and needs to be present. We have started that process here in the last couple of months, and have met with business interests, public health interests, medical interests in Seattle, in Raleigh.” **How have all of these entities been engaged? What has been done to start this process? Please include, but do not limit, information regarding the activities in Seattle and Raleigh.**

The purpose of the meetings in Seattle and Raleigh was to present modeling efforts we had undertaken to determine the requirements for certain types of material during a pandemic. We discussed antivirals, face masks and N95 respirators, and ventilators. The participants included a broad range of stakeholders to include emergency response, public health, health care and private sector. We discussed the magnitude of the need and how the various stakeholders could work together to fill the gaps. A consistent message from the stakeholders was that they are willing to be active partners with the Federal government but more specific guidance is needed. Since these initial meetings in Seattle and Raleigh, there have been subsequent meetings with a broad range of stakeholders to continue the discussions about shared responsibility for meeting the needs for antiviral medications as well as masks and respirators. Specific guidance is being developed.

More broadly, HHS and other Federal agencies recognize that the private sector has an important role to play in preparing for, responding to, and recovering from a pandemic. The private sector owns and operates over 85 percent of the critical infrastructure in the United States, and therefore represents an integral part of our society because of the critical goods and services that it provides. Moreover, it touches the majority of our population on a daily basis, through employer-employee or vendor-customer relationships. For these reasons, it is essential that the U.S. private sector be engaged in preparedness and response activities for a pandemic. In the event of an influenza pandemic, businesses and other employers will play a key role in protecting employees' health and safety as well as limiting the negative impact to the community, economy, and society.

Since November 2005, HHS has produced numerous tools for businesses of all types and sizes to assist them in planning for a pandemic. Several checklists have been produced that include information for businesses in general (*Business Pandemic Influenza Planning Checklist*), as well as *Planning for U.S. Businesses with Overseas Operations*, *Health Insurer Pandemic Influenza Planning Checklist*, and *Travel Industry Pandemic Influenza Planning Checklist*. State governments, local governments, and thousands of businesses and employers in this country and worldwide have used the checklists to improve their pandemic planning efforts. In coordi-

nation with other Federal agencies, other tools for businesses have been developed and distributed for use, including:

1. *Guidance on Preparing Workplaces for an Influenza Pandemic*: guidance and recommendations on infection control in the workplace, including information on engineering controls, work practices, and personal protective equipment, such as respirators and surgical masks.
2. *Guidance for Protecting Workers against Avian Flu*: information for protecting employees who may have been exposed to avian influenza.
3. *Cover Your Cough*: flyers and posters showing ways to reduce transmission of respiratory illnesses.
4. *Stopping the Spread of Germs at Work*: basic precautions for protecting employee health.
5. *Quick Cards for Employees to Protect Yourself from Avian Flu*: general precautions and specific information for poultry employees, laboratory employees, animal handlers, food handlers, and healthcare workers.
6. *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers*: information and tools helpful to healthcare planners.

Over the last year, HHS and other agencies have conducted an extensive outreach effort to the private sector, particularly critical infrastructure businesses. In the last year, more than 150 presentations, workshops, and fora have been conducted and attended by thousands of key stakeholders from critical infrastructure entities (e. g., healthcare operations, banking and finance entities, operations centers, retail operations, transportation and trucking operations, supply warehousing operations, grocery and food suppliers, and supply distributors) as well as businesses of all types. These information sharing sessions have provided practical action-oriented information to identify essential functions and critical planning elements and to assist businesses in protecting the health of employees and in maintaining continuity of business operations during a pandemic.

In addition, the CDC *Community Mitigation Guidance* includes specific planning recommendations for aligning business practices with public health protection interventions. The document provides clear steps an employer can take to potentially slow the spread of pandemic influenza, help keep workplaces safe, and reduce the number of people who become sick. All of these tools listed above are posted on www.pandemicflu.gov.

Question 14.: In his testimony, Dr. Vanderwagen stated that “the last purchase to fill out the 81 million treatment courses for [antiviral medications] will occur in fiscal year 2008.” **When exactly in fiscal year 2008 will this purchase be made?**

Due to business reasons including possibilities of price increases, VA and HHS/BARDA renegotiated contracts with Roche for the purchase of Tamiflu® antiviral drug for Federal and State pandemic antiviral drug stockpiles. Purchases of 12.6 million treatment courses of Tamiflu (Roche) and Relenza (GSK) for adults and children are expected by HHS in November 2007 with delivery to the SNS by the end of calendar year 2007 to reach the 50 million treatment course goal of influenza antivirals for the federal pandemic stockpile.

Question 15.: **How is HHS trying to bring its own grants (to the public health, health care delivery, and other health-related communities) into better alignment and the same time sequence? How is HHS trying to bring its grants into the same time sequence as the DHS grants?**

The Department of Homeland Security grants cycle is dependent upon when their annual appropriations bill is signed into law, which causes variability in the date that awards are released each year. However, DHS grant awards have historically been released earlier in Federal Fiscal Year (FY) than the Department of Health and Human Services (HHS) cooperative agreement awards, which have been released in late August or early September. HHS is currently exploring several options that will better align the HHS awards with the DHS grants, and enable States to engage in better strategic planning across preparedness programs and among emergency responders.

Question 16.: **What is the reasoning for HHS disallowing the states to rotate antivirals through their stockpiles? What plans does HHS have for when the antivirals in the Federal and state stockpiles expire?**

HHS has no role or policy in the rotation of influenza antiviral drug stocks in State stockpiles. These matters are between the States and the manufacturers that must be conducted in accordance with FDA guidelines. Since 1985 DoD with FDA have practiced a Shelf Life Extension Program (SLEP) for large federal stockpiles

of some pharmaceutical products including licensed influenza antiviral drug products, which are kept under strict environmentally controlled conditions and tested continuously with validated testing procedures. FDA and DoD do not have the resources or the legal authority to conduct a SLEP for State stockpiles. Alternatively, HHS encourages the manufacturers of influenza antivirals to submit product stability data that support longer expiration dating. To that end, Roche submitted in November 2007 data to FDA for consideration of 7 year expiration dating for Tamiflu®, which is licensed currently for 5 years expiration.

Question 17.: How is HHS using real-world situations (such as this year's influenza season) to optimize its surveillance, health care delivery, and other mechanisms to better prepare for pandemic influenza? What role do programs—such as the National Immunization Program—play in greater-than-normal activities designed to not just address seasonal influenza but prepare for a pandemic?

CDC has approached planning for the 2007-2008 influenza season by utilizing some of the paradigms originally developed for pandemic response. This season, in anticipation of new “drift” strains circulating in the U.S., CDC leadership convened a task force to enhance surveillance systems and explore contingency plans in the event of a severe influenza season. This approach is using lessons learned and methods from pandemic planning and exercises to address the following areas:

Enhanced surveillance

- Communications to State health departments to expedite reporting.
- Active solicitation of viral specimens from partner laboratories for monitoring of genetic drift in circulating strains.
- Pilot “super sentinel” sites established for daily reporting of outpatient illness and testing.
- Vaccine effectiveness evaluation
 - Literature review/analysis of scientific data from previous seasons with sub-optimal vaccine match.
 - Active dialogue with public health officials in partner countries and Department of Defense on recent vaccine effectiveness analyses
 - Collaboration with research partners to expedite vaccine effectiveness for upcoming season on existing platforms.
- Strategies for use of countermeasures
 - Performed assessment of supply and surge production capability of manufacturers of antiviral medications and rapid influenza test kits.
- Mitigation
 - Working groups formed to develop strategies for community guidance and health care system recommendations in the event of a severe influenza season.
- Immunization:
 - Pilot test in progress with preparedness grantees to measure data collection for vaccine administration in public clinics (the pilot test will be completed December 31, 2007).
 - Promotion of novel State approaches to rapid and nontraditional vaccination methods, e.g., drive-through vaccination.
- Health Communications
 - Broadened annual flu communications to emphasize use of antiviral medications, respiratory hygiene, and infection control.
 - Aggressive promotion of vaccination during National Influenza Vaccination Week by CDC Director and subject matter experts through more than 50 media interviews, popular and scientific publications, campaigns with industry partners, “new media” avenues such as webinars and MySpace, and revised CDC flu web site.
- Exercises

The Pandemic Influenza Cooperative Agreement for the 62 state, local, territorial, and tribal nations requires grantees to develop and implement a program to assess capabilities for non-pharmaceutical interventions, medical surge, and use of seasonal influenza clinics to exercise mass prophylaxis capabilities. As administrator of the cooperative agreement, CDC

- developed and distributed to grantees a tabletop exercise kit on school closures
- provided supplemental guidance on use of seasonal influenza clinics under circumstances that approximate those expected during an influenza pandemic
- gathered and analyzed data from exercises
- is working with grantees to identify and address gaps in state and local preparedness and response.

Question 18.: Please describe the BioSense program. What is its role in picking up on outbreaks, epidemics, and pandemics? How does/will BioSense interact with the National Biosurveillance Integration System (NBIS)?

Description of BioSense

BioSense is a national program intended to improve the nation's capabilities for conducting near real-time biosurveillance, further enabling health situational awareness efforts through access to existing data from healthcare organizations across the country. The primary objective is to expedite response coordination among Federal, State, local public health and healthcare organizations by providing each level of public health access to the same data, at the same time. Consequently, if a bioterrorism event or a disease outbreak occurs, every level of public health will be able to see healthcare data from their community in near real-time.

BioSense functionalities include:

- Line lists of data anomalies found by automated statistical testing to facilitate rapid screening for new outbreaks;
- Time series graphs to determine the likely importance of data anomalies and monitor disease trends;
- Line lists and patient detail views to examine data at a granular level; and interactive maps to display count data both over geographic area and time.

The Role of BioSense

BioSense provides the ability to assess the impact of an outbreak or other public health event and the healthcare system's ability to react to it. The role of BioSense in providing health situational awareness supports public health efforts not only during outbreaks, epidemics, and pandemics but in catastrophic events as well.

Examples of how BioSense is being utilized include:

- The recent California Wildfires—The BioIntelligence Center (BIC) provided the California Commissioner of Health regular reports of BioSense data reflecting the prevalence and trends of respiratory illnesses and burns in the areas affected by the fires. California's Commissioner of Health wrote a letter to Dr. Gerberding highlighting the utility of BioSense and the reports provided.
- The Influenza Module—a new component of the BioSense application, displays relevant flu data from BioSense alongside traditional influenza surveillance data sets from the Influenza Division at CDC. The success of the initial prototype resulted in the program receiving a SAS Award and prompted a plan to make the Influenza module scalable and accessible to local and State public health departments. The Influenza Module data are presented in a variety of formats, allowing simultaneous views of multiple data sources and facilitating simpler comparisons. The Influenza Module will improve the ability of public health officials at local, State, and national levels to monitor influenza activity across the nation and in their State and to provide health situational awareness of influenza. State public health officials, State influenza surveillance coordinators, and CDC epidemiologists will be the first groups with access to the new tool.
- Regular Flu Exercises—BioSense is used in these preparedness exercises throughout the year. The after-action evaluations and summaries further inform the optimal role for BioSense in outbreaks, epidemics, and pandemics.
- Ongoing collaboration enhances communication between the BIC and local, State, and Federal public health. Utilizing BioSense data, the BIC has communicated with public health regarding events such as:
 - A norovirus outbreak at a DoD base in South Carolina
 - An influenza outbreak at several hospitals in one region of Texas
 - An influenza outbreak at several hospitals in one region of Missouri
 - A rash outbreak at a single hospital in Ohio
 - A possible outbreak of meningitis at a single hospital in Indiana
 - Identifying a potential cholera outbreak and discovering there was a cholera drill at a single hospital in Illinois
 - A respiratory outbreak at a DoD base in South Carolina.

In each of these collaborations, the local/State public health departments were appreciative of the information and support. Potential future collaborations were discussed in each of these events.

Collaboration with DHS and NBIS

In collaboration with the Department of Homeland Security (DHS) and the National Biosurveillance Integration System (NBIS), a BioSense Analyst from CDC has begun a detail with DHS. This work will help build a bridge between the surveil-

lance efforts of BioSense and NBIS and will define how the programs will work together in the future.

- Create summary reports of human health status by geographic region and disease category. The format and frequency for these is considered under development. The reports are both for information purposes and to provide substance upon which to base the refinement of specification requirements for the NBIS concept of operations as well as for other health indicator information sources.
- Serve as a human health domain expert for dialogue and interactions regarding population health threat events of interest. This includes providing a social network bridge for reaching back to other human resources and information systems at CDC.
- Maintain a log of identified issues and requirements that are relevant to enhancing the surveillance collaboration between CDC and DHS/NBIS.
- Update and summarize a comprehensive needs assessment report at least every two weeks to inform next steps in the refinement of the CDC/DHS biosurveillance interaction. Considerations will include emergency as well as non-emergency situational awareness information needs, communications, organizational implications, and other relevant identified factors.

BioSense contributes to biosurveillance by providing jurisdiction-specific access to data for users outside CDC; a consolidated and cross-jurisdictional national view of data for Federal users; and daily monitoring and analysis.

- Users at various levels (local, State, and Federal public health, as well as individual facilities) have simultaneous access to several streams of surveillance data, presented in a common user-friendly interface. The ability to simultaneously access several data types, including non-Federal hospitals and Federal (VA and DoD) outpatient clinics, contributes to system utility.
- Federal users include staff from the CDC Division of Emergency Preparedness and Response (DEPR), other CDC programs, and the Directors Emergency Operations Center (DEOC).

BioSense data are analyzed at three levels of aggregation. Counts, aggregated by week, are used to track longer-term trends in community levels of diseases, especially seasonal influenza and gastrointestinal disease, and to provide context for other analyses.

The CDC BioIntelligence Center (BIC) provides a team of analysts who assist users outside CDC, monitor data from a national and cross-jurisdictional viewpoint, and support the DEOC in preparedness exercises. BIC staff answers questions and provides assistance to users outside CDC to assist them in making best use of the BioSense System. The staff examines the BioSense application each day, and performs additional analyses for trends and statistical increases in disease indicators of concern, paying special attention to diseases and geographic areas with known outbreaks. Finally, BIC staff participate in BioSense application quality control and enhancement efforts.

Question 19.: Aside from the potential of H5N1 to cause an influenza pandemic, other strains may also be cause for concern. **What other strains is HHS tracking that it believes may also cause an influenza pandemic? Does HHS believe H3N2 to be of particular concern over other strains? Is the CDC involved in tracking the increasing prevalence and spread of H3N2? When did the CDC begin tracking H3N2? If the CDC did not pick up on the spread of H3N2 (particularly in Central and South America) on its own, who alerted the CDC as to this threat?**

The WHO collaborating laboratory at CDC tracks human and animal influenza in humans, and USDA/SEPRL tracks in animals, especially birds. Among non-human influenza strains, particular attention is being paid to the H7 and H9 avian subtypes, because these both have been shown to cause infections in humans.

H3N2 is a human influenza virus that first appeared in 1968 with the pandemic Hong Kong flu. This influenza virus subtype virus has been tracked annually globally by WHO and within the U.S by CDC since its emergence in 1968 and, along with type A/H1N1 virus and type B influenza virus, is capable of causing seasonal epidemics. For this reason, these three strains are monitored closely by the WHO Global Influenza Surveillance Network in which the WHO Collaborating Center at CDC plays a major role. The CDC regularly receives reports and viruses from Central and South America as part of its ongoing surveillance efforts the results of which are combined with other data collected globally to select the appropriate strains to be included in the annual influenza vaccine.

QUESTIONS FROM THE HONORABLE MICHAEL T. MCCAUL, RANKING MEMBER
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE

Question 20.: At the hearing you briefly discussed the current State of vaccine production technology. **Could please elaborate by answering the following questions?**

Key medical countermeasure goals of the HHS Pandemic Influenza Plan are to establish national pre-pandemic influenza vaccine stockpiles for 20 million persons in the critical workforce for administration at the onset of an influenza pandemic and to provide pandemic influenza vaccine to every American within six months of the isolation of a pandemic influenza virus strain. The first stage of the pandemic medical countermeasure program involves investment during 2006–07 into the expansion of vaccine manufacturing capacity (egg- and cell-based), the advanced development of new cell-based vaccines, antigen-sparing technologies, the establishment and maintenance of pre-pandemic vaccine stockpiles, and vaccine manufacturing infrastructure building of existing domestic facilities to produce pandemic vaccines. Building upon the foundation laid down during the initial stage activities is the second stage of the pandemic medical countermeasure program to be implemented in 2008-09.

- In June 2007, HHS awarded \$132.5 million to sanofi pasteur and MedImmune for the retrofitting of existing domestic manufacturing facilities of U.S.-licensed biologicals for pandemic influenza vaccine production to increase domestic egg-based influenza vaccine production capacity and for warm base manufacturing operations. Concept facility design plans were submitted in September 2007, and detailed facility design plans are expected in December 2007 by these two manufacturers. Later in FY08 a solicitation for proposals to build and validate new domestic facilities for the manufacturing of cell-based influenza vaccines is anticipated.
- In January 2007, HHS awarded three contracts totaling \$132.5 million to GlaxoSmithKline, Novartis, and IOMAI for the advanced development of H5N1 influenza vaccines using antigen-sparing techniques towards U.S. licensure and expanded domestic vaccine manufacturing surge capacity. U.S. clinical trials were initiated in Sept. 2007 for evaluation of the safety, immunogenicity, and cross-reactivity of egg-based inactivated H5N1 vaccines using the companies' proprietary adjuvants with the likelihood that U.S. licensure of one influenza vaccine with adjuvant will be sought in 2008. Additional funding (\$95 million) may be needed for one company depending on the successful completion of Phase 1 trials by the end of 2007.
- In May 2006, HHS added five contracts for over \$1 billion to GlaxoSmithKline, MedImmune, Novartis (formerly Chiron), Solvay, and Dynport (with Baxter) to the cell-based influenza vaccine program that had awarded sanofi pasteur a contract previously in April 2005 (\$97.1 million) for support of advanced development of cell-based influenza vaccines towards U.S. licensure and expanded domestic vaccine manufacturing surge capacity. HHS provided additional funding (\$201.3 million) on Oct. 12, 2007 to the contract with Dynport Vaccine Company, due to the Contractor's high performance and decision to utilize non-wild type pandemic influenza virus strains to manufacture pandemic influenza vaccines. U.S. clinical studies (Phase 1 to 3) of cell-based seasonal influenza vaccines began in the fall of 2007 for these manufacturers with the likelihood that U.S. licensure of two cell-based influenza vaccines will be sought in 2008. In July 2007 groundbreaking of a new cell-based influenza vaccine manufacturing facility in North Carolina occurred by one of these contracted manufacturers. An estimated \$133 million funding may be needed in FY08 for another manufacturer to conduct Phase 3 clinical studies. These contracts are expected to enable domestic production of 240+million courses of cell-based pandemic vaccine within six months of influenza pandemic onset by 2011.
- HHS issued a Request for Proposals (RFP) on Oct. 19, 2007 for the advanced development of next generation recombinant influenza vaccines towards U.S. licensure that may shorten the timeline for production and release of pandemic influenza vaccine.
- Using HHS Strategic National Stockpile (SNS) funds, HHS awarded two contracts totaling \$164 million in Fall 2005 to purchase approximately 2.7 million courses of H5N1 clade 1 bulk vaccine from sanofi pasteur and Novartis (formerly Chiron). With funding from the December 2005 supplemental, HHS awarded three contracts for \$207 million in November 2006 to procure 3.7 million vaccine courses of H5N1 clade 1 and 2 bulk vaccine from sanofi pasteur, Novartis, and GlaxoSmithKline. Recognizing that the H5N1 virus continues to

evolve, this purchase included both clade 1 and clade 2 vaccine. The term “clade” refers to the genetic variants (antigenic drift) of an influenza virus strain. The first licensed H5N1 vaccine, which was developed and manufactured by sanofi pasteur, was supported by HHS and was licensed by the FDA in April 2007. Additional task orders from these contracts were issued in August 2007 for the manufacturing of at least 5.6 million vaccine courses of H5N1 bulk vaccine at a cost of \$415.8 million. These H5N1 vaccines, manufactured during the fall of 2007, were matched against three circulating strains (subclade 2.1, 2.2 and 2.3) of H5N1 influenza viruses. As of October 30, 2007, HHS has obligated \$2.3 billion out of the \$3.2 billion allocated for pandemic vaccine-related activities. The total number of H5N1 vaccine courses in the national pre-pandemic influenza vaccine stockpile will be 13 million by Dec. 2007.

Question 21.: How quickly (once a flu strain is identified) can a vaccine be manufactured based on current egg-based production methods?

The manufacturing production cycle for domestic egg- and cell-based inactivated pandemic influenza vaccines is estimated at 20–23 weeks from the availability of a pandemic influenza virus isolate to lot release and shipment of pandemic influenza vaccine from manufacturers to points of distribution within States. Alternatively, the manufacturing production cycle of next generation recombinant pandemic influenza vaccines may be 5–12 weeks post pandemic onset; however, development of these vaccines is further behind cell-based influenza vaccines and with considerably less infrastructure, integration, and manufacturing capacity. HHS expects to award contracts in FY08 for advanced development of next generation recombinant influenza vaccines.

Question 22.: What is the status of faster, cell-based technology?

First we note that, although cell-based technology is likely to be preferable for a variety of reasons, it has not yet been demonstrated that cell-based technology will be able to generate equal or larger numbers of vaccine doses faster than egg-based technologies.

In May 2006, HHS funded five contracts for over \$1 billion to GlaxoSmithKline, MedImmune, Novartis (formerly Chiron), Solvay, and Dynport (with Baxter) for the cell-based influenza vaccine program that had awarded sanofi pasteur a contract previously in Apr. 2005 (\$97.1 million) for support of advanced development of cell-based influenza vaccines towards U.S. licensure and expanded domestic vaccine manufacturing surge capacity. HHS provided additional funding (\$201.3 million) on Oct. 12, 2007 to the contract with Dynport Vaccine Company, due to the Contractor’s high performance and decision to utilize non-wild type pandemic influenza virus strains to manufacture pandemic influenza vaccines. Two Phase 3, one Phase 2, and one Phase 1 clinical studies in the U.S. using cell-based seasonal influenza vaccines from four manufacturers began in the fall of 2007 for these manufacturers with the likelihood that U.S. licensure of two cell-based influenza vaccines will be in sought in 2008. In July 2007 groundbreaking of a new cell-based influenza vaccine manufacturing facility in North Carolina occurred by one of these contracted manufacturers. These contracts are expected to enable domestic production of 240+ million courses of cell-based pandemic vaccine within six months of influenza pandemic onset by 2011. The total funding for advanced development of cell-based influenza vaccine development reached \$1.3 million during this reporting period.

We note that the manufacturing production cycle of next generation recombinant pandemic influenza vaccines may eventually be accomplished in 5–12 weeks post pandemic onset. However, development of these next generation vaccines is further behind cell-based influenza vaccines and with considerably less infrastructure, integration, and manufacturing capacity. HHS expects to award contracts in FY08 for advance development of next generation recombinant influenza vaccines.

