

**BEYOND READINESS: AN EXAMINATION OF THE
CURRENT STATUS AND FUTURE OUTLOOK OF
THE NATIONAL RESPONSE TO PANDEMIC
INFLUENZA**

HEARING
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HOUSE OF REPRESENTATIVES
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CONTENTS

	Page
STATEMENTS	
The Honorable Bennie G. Thompson, a Representative in Congress From the State of Mississippi, and Chairman, Committee on Homeland Security:	
Oral Statement	1
Prepared Statement	2
The Honorable Peter T. King, a Representative in Congress From the State of New York, and Ranking Member, Committee on Homeland Security:	
Oral Statement	3
The Honorable Paul C. Broun, a Representative in Congress From the State of Georgia:	
Prepared Statement	3
The Honorable Stephen F. Lynch, a Representative in Congress From the State of Massachusetts:	
Prepared Statement	4
WITNESSES	
PANEL I	
Ms. Jane Holl Lute, Deputy Secretary, Department of Homeland Security:	
Oral Statement	5
Prepared Statement	7
Mr. William Corr, Deputy Secretary, Department of Health and Human Services:	
Oral Statement	10
Prepared Statement	12
Ms. Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office:	
Oral Statement	16
Prepared Statement	17
PANEL II	
Ms. Colleen M. Kelley, President, National Treasury Employees Union:	
Oral Statement	46
Prepared Statement	48
Mr. Richard G. Muth, Executive Director, Maryland Emergency Management Agency:	
Oral Statement	51
Prepared Statement	54
Dr. Mark B. Horton, M.D., M.S.P.H., Director, California Department of Public Health, and State Health Officer:	
Oral Statement	60
Prepared Statement	62
Dr. Thomas A. Farley, M.D., New York City Department of Health and Mental Hygiene:	
Oral Statement	68
Prepared Statement	70

IV

APPENDIX

	Page
Questions From Chairman Bennie G. Thompson of Mississippi for Ms. Jane Holl Lute, Deputy Secretary, Department of Homeland Security	85
Questions From Chairman Bennie G. Thompson of Mississippi for William Corr, Deputy Secretary, Department of Health and Human Services	98
Questions From Ranking Member Peter T. King of New York for William Corr, Deputy Secretary, Department of Health and Human Services	101
Questions From the Honorable Michael T. McCaul of Texas for William Corr, Deputy Secretary, Department of Health and Human Services	101
Questions From Chairman Bennie G. Thompson of Mississippi for Ms. Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office	102
Questions From Ranking Member Peter T. King of New York for Ms. Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office	102
Question From Chairman Bennie G. Thompson of Mississippi for Ms. Colleen M. Kelley, National President, National Treasury Employees Union	103
Questions From Chairman Bennie G. Thompson of Mississippi for Mr. Richard G. Muth, Executive Director, Maryland Emergency Management Agency	103
Questions From Chairman Bennie G. Thompson of Mississippi for Dr. Mark B. Horton, Director, California Department of Public Health	103
Questions From Chairman Bennie G. Thompson of Mississippi for Dr. Thomas A. Farley, New York City Department of Health and Mental Hygiene	104

BEYOND READINESS: AN EXAMINATION OF THE CURRENT STATUS AND FUTURE OUT- LOOK OF THE NATIONAL RESPONSE TO PANDEMIC INFLUENZA

Wednesday, July 29, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The committee met, pursuant to call, at 2:00 p.m., in Room 311, Cannon House Office Building, Hon. Bennie G. Thompson [Chairman of the committee] presiding.

Present: Representatives Thompson, Harman, Jackson Lee, Cuellar, Carney, Richardson, Kirkpatrick, Luján, Pascrell, Cleaver, Green, Himes, King, Rogers, McCaul, Dent, Bilirakis, Olson, and Cao.

Chairman THOMPSON. The committee on Homeland Security will come to order.

As a matter of housekeeping, our reporter is in a building where a suspicious package has been identified and security will not let anyone out of the building. But they are watching us on an in-house station doing the reporting and unless they have to evacuate the building, rest assured, a transcript of this hearing will take place. But you can understand the sensitivity of the security, and that is why our recorder is not present at this point. However, as indicated, we will continue with the hearing.

The committee is meeting today to receive testimony on “Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza.”

I would like to thank our witnesses for appearing before us today. Today’s hearing will review this Nation’s state of preparedness for an influenza pandemic.

In April 2009, the Centers for Disease Control and Prevention reported two cases of respiratory illness in children caused by a virus. Those two cases, which occurred less than 4 months ago, were the first confirmed instances of H1N1 flu within the United States.

By late June, U.S. health officials estimated that there had been more than 1 million infections in the United States. According to the World Health Organization, this virus is travelling the world with unprecedented speed. There have been confirmed cases on every continent except Antarctica. While this may be troubling, there is no need to panic in the face of this pandemic.

So far, the disease has been mild in most people and treatments are available. But many scientists and public health officials are predicting that the virus will surge in the fall. It is that resurgence which we must be ready to meet. The Centers for Disease Control and Prevention estimates that as many as 40 percent of the U.S. population could become infected with H1N1 over the next 2 years.

The good news is that a vaccine is currently under development, and over the last 4 years, Congress has provided approximately \$8.6 billion for pandemic planning efforts. But unfortunately, despite this amount of funding, according to GAO there are still major gaps in pandemic planning and preparedness efforts. Among the major gaps is the failure to plan for additional bed space and medical supplies.

Additionally, GAO determined that leadership roles and responsibilities for an influenza pandemic need to be further clarified, tested, and exercised. Given this country's recent experience with disasters, it is hard to believe that there are those who underestimate the importance of plans and drills. Our children are taught in school what to do in a fire drill. They are not taught to wait until a fire starts, yell instructions, and hope everybody makes it to the exit. We teach them that planning and practice increases their chance of survival. That elementary school lesson still applies.

Finally, we need to understand that the emergency preparedness and response community and the health care community have always shared resources during crises and disasters. These formal and informal partnerships may be strained during a pandemic. Increased drills and exercises will strengthen these relationships, decrease uncertainty, and improve response and recovery.

I want to thank our witnesses and look forward to their testimony today. The Chair now recognizes the Ranking Member of the full committee, the gentleman from New York, Mr. King, for an opening statement.

[The statement of Chairman Thompson follows:]

PREPARED STATEMENT OF CHAIRMAN BENNIE G. THOMPSON

JULY 29, 2009

In April 2009, the Centers for Disease Control and Prevention (CDC) reported two cases of respiratory illness in children caused by a virus. Those two cases, which occurred less than 4 months ago, were the first confirmed instances of H1N1 flu within the United States. By late June, U.S. health officials estimated that there had been more than 1 million infections in the United States.

According to the World Health Organization, this virus is travelling the world with "unprecedented speed". There have been confirmed cases on every continent except Antarctica.

And while this may be troubling, there is no need to panic in the face of this pandemic. So far, the disease has been mild in most people and treatments are available. But many scientists and public health officials are predicting that the virus will resurge in the fall. And it is that resurgence which we must be ready to meet.

The Centers for Disease Control and Prevention estimates that as many as 40 percent of the U.S. population could become infected with H1N1 over the next 2 years. The good news is that a vaccine is currently under development and over the last 4 years Congress has provided approximately \$8.6 billion for pandemic planning efforts. But unfortunately, despite this amount of funding, according to GAO there are still major gaps in pandemic planning and preparedness efforts.

Among the major gaps, is the failure to plan for additional bed space and medical supplies. Additionally, GAO determined that leadership roles and responsibilities for an influenza pandemic need to be further clarified, tested, and exercised. Given this

country's recent experience with disasters, it is hard to believe that there are those who underestimate the importance of plans and drills.

Our children are taught in school what to do in a fire drill. They are not taught to wait until a fire starts, yell instructions, and hope everybody makes it to the exit. We teach them that planning and practice increases their chance of survival. That elementary school lesson still applies. Finally, we need to understand that the emergency preparedness and response community and the health care community have always shared resources during crises and disasters. These formal and informal partnerships may be strained during a pandemic.

Increased drills and exercises will strengthen these relationships, decrease uncertainty, and improve response and recovery.

Mr. KING. Thank you, Mr. Chairman. Thank you for holding this hearing. As you indicated, this is a very serious issue.

Apparently, the consensus is that the H1N1 flu is going to return, and possibly it could be more severe than the first go-around. I don't have a very long opening statement, but one, I would like to acknowledge the presence of Dr. Tom Farley, who is the newly-appointed commissioner of the New York City Health Department and congratulate him for the job he has done in less than 2 months, coming in right at the peak of the flu season in New York.

I also would like to stress some questions I will be asking during the question-and-answer session.

One is on the issue of the vaccine. I met with Secretary Lute the other day on this as to what the prospects are for having a vaccine. Almost as importantly is the educational process that will go to the public. Already there are rumors going around that the vaccine could be more harmful and that it is dangerous to kids, and what is going to be done to stop those rumors when they start and what can be done to convince the public that, in fact, this vaccine is expected to work and certainly will not be dangerous, especially to young children.

Also, the issue, since DHS is obviously a new Department, and as far as I know, this is the first health crisis that has affected the country since DHS was started. Secretary Lute, have you looked back to see lessons learned, how effective the Department was, how close the coordination was with HHS, whether or not it was synchronized, and what, if any, improvements are necessary for the future. Also on the issue for our employees, TSA, CBP in particular, and what will be done to protect them as they are doing their job. What are the appropriate procedures for them?

With that, I look forward to the testimony, Mr. Chairman. Thank you for the hearing.

Chairman THOMPSON. Thank you.

Other Members of the committee are reminded that under committee rules, opening statements may be submitted for the record.

[The statement of Hon. Broun follows:]

PREPARED STATEMENT OF THE HONORABLE PAUL C. BROUN

JULY 29, 2009

Thank you, Mr. Chairman.

I'd like to welcome our witnesses here today. I'm pleased the committee is meeting to review and assess the status of H1N1 readiness efforts to prepare for and respond to pandemic influenza.

As a doctor, I am particularly troubled with the Federal Government's lack of concern for the protection of Federal employees' health. I'm sure that you know that I offered amendment earlier this year that would have allowed any TSA employee to wear a protective facemask in the event of a pandemic or public health emer-

gency. I was disappointed that this important amendment was defeated on a party line vote.

I am particularly concerned by what seems to be a lack of progress in this area, due in part because of the defeat of my amendment. I believe that it is absolutely essential that the employees on the front lines be able to protect themselves by taking extra precautions if they feel it is in the best interest of their personal health. The Department needs to adopt a policy immediately to permit its employees to take precautionary measures to protect their own health.

I am specifically interested in hearing our witnesses' thoughts on protective equipment measures such as face masks, and what the strategy is to protect screeners and other personnel at the border and around the country. I'd like to quote my colleague Congressman Stephen Lynch who said, "In my opinion it is unconscionable that our workers have been denied the use of certain PPE [personal protective equipment] items—such as N-95 and surgical masks, gloves, and hand sanitizer—and even threatened for attempting to protect themselves from a communicable disease."

I hope our witnesses can convince my colleagues of the importance and seriousness of this issue and that we can work together in a bipartisan manner to fix it soon.

Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman THOMPSON. Without objection, a statement provided to the committee by Representative Lynch of Massachusetts addressing the subject matter covered by today's hearing will be inserted into the record at the appropriate point.

[The statement of Hon. Lynch follows:]

PREPARED STATEMENT OF THE HONORABLE STEPHEN F. LYNCH

JULY 30, 2009

I'd like to thank Chairman Thompson for allowing me to submit a statement for the record for today's hearing.

As Chair of the House's Federal Workforce Subcommittee, I have monitored closely the Department of Homeland Security's (DHS) response to the outbreak of the H1N1 virus. DHS employs approximately 225,000 Federal workers who are charged with the tremendous job of keeping the American public safe, including 52,000 Customs and Border Patrol (CBP) employees, 50,000 Transportation Security Administration (TSA) employees, and 17,200 Immigration and Customs Enforcement (ICE) employees. I feel it is my responsibility to ensure the health and safety of these Federal employees—especially those on the front-line.

In addition to the on-going emergency preparedness efforts to secure the public's safety, it is essential that Federal agencies implement adequate and uniform worker policies that protect the very employees who will be called upon to respond in the event of an emergency. Without such policies, not only is the health of front-line employees being put at risk, but the health of their families and the general welfare of the public are also placed at risk. In short, the Federal Government cannot ably respond to emergencies if the very personnel needed as part of that response are themselves compromised.

I have been troubled by the apparent reluctance on the part of DHS to address the voluntary use of personal protective equipment (PPE) amidst the H1N1 flu outbreak. In my opinion it is unconscionable that our workers have been denied the use of certain PPE items—such as N-95 and surgical masks, gloves, and hand sanitizer—and even threatened for attempting to protect themselves from a communicable disease. Further, it is alarming that DHS has not yet distributed written guidance on the voluntary usage of protective gear to its own employees during a public health emergency.

These front-line Federal workers—many of whom work well within 6 feet of individuals who could be known or suspected to have the H1N1 virus—deserve to be reassured that their employer—which in this case is the Federal Government—has done everything possible to guarantee their health while on the job.

Mr. Chairman, I thank you for holding this timely hearing, and look forward to working with you to ensure that our Federal workforce's needs are addressed as our Government prepares for the possibility of a larger influenza outbreak this fall and winter.

Chairman THOMPSON. I welcome our first panel of witnesses. Our first witness is Dr. Jane Holl Lute, Deputy Secretary of the Department of Homeland Security. As Deputy Secretary, she is responsible for the operation of our newest Federal department and the operational coordination of Federal, non-Federal, and private sector agencies when the Nation is confronted with events that threaten our homeland. She was confirmed by the Senate in January 2009 and brings to the Department over 30 years of military and senior executive experience in the U.S. Government.

Welcome, Dr. Lute.

Our second witness is Mr. William Corr, the Deputy Secretary of the Department of Health and Human Services. As Deputy Secretary, he is responsible for the operations of the largest civilian department in the Federal Government. Mr. Corr has extensive management and health care policy experience, including work for Congress. I welcome him back to the Hill today.

Our third witness is Ms. Bernice Steinhardt, Director of Strategic Issues at the Government Accountability Office. She has studied a number of different health policies and strategic issues, and has been responsible for producing many of the reports about pandemic influenza and related issues for our committee.

We thank all of you for being our witnesses and for your service to the Nation and for being here today.

Without objection, the witness' full statements will be inserted in the record. I now ask each witness to summarize their statement for 5 minutes beginning with Secretary Lute.

**STATEMENT OF JANE HOLL LUTE, DEPUTY SECRETARY,
DEPARTMENT OF HOMELAND SECURITY**

Ms. LUTE. Mr. Chairman, Ranking Member King, distinguished Members of the committee, it is an honor to appear before you this afternoon with my colleagues to discuss the Department of Homeland Security's preparation for a possible resurgence of H1N1 this fall.

I have to say it is nice to appear before Congress to discuss something other than myself. As fun as that confirmation process was, I am happier to be on these sides of the issue.

In the months since I have been in office, it has been readily apparent how important the relationship between this committee and the Department of Homeland Security is. Like all important relationships, we won't always get it quite right. But, Mr. Chairman and Ranking Member King, Members of the committee, I hope you all know that Secretary Napolitano and I are committed to collaborating with you as we work to make the United States of America a safer place. We want and need your support, your ideas, your direction, and the American people deserve your oversight.

While I recognize that this proceeding is focused on H1N1, I think it is important to contextualize H1N1 within the spectrum of threats that Department of Homeland Security negotiates and navigates every day.

Secretary Napolitano and I often think about our jobs in the context of managing the supply chain of trouble. Now, I am sure there is a more sophisticated way to express it, but I am from New York, so it seems to be a vivid representation of the challenges we face.

Trouble, it will come as no surprise to this committee, comes in many forms; whether it is a time bomb, or tornado, a computer virus created by man, or a pandemic virus created by Mother Nature. Trouble has suppliers, facilitators, purchasers, producers, distributors, and customers. These perilous products move through multiple channels before they reach our shore, and it is the job of the Department of Homeland Security to understand the supply chain of trouble and identify opportunities along the way to gather information, intelligence, interdict, redirect, and stop trouble before it reaches our shores and our communities, and to do this in a way that is not only consistent with but that honors our cherished principles of civil rights, executive authority, and the important laws that guide our privacy and liberty.

Just as threats have multiplied and evolved, the Department of Homeland Security's mission to lead the American effort to protect itself must adapt to the new supply chains of trouble that deliver, not just bombs and bullets, but botnets, and now we know, pandemics.

Nontraditional threats like H1N1 cannot be stopped by magnetometers or guns or fences. Indeed, H1N1, as the Chairman has noted, is already here. In fact, it is ever present around the world.

While we lack a complete understanding of what this fall will look like, we are planning for the worst. The outbreak of H1N1 this spring offered an unparalleled window into the state of our critical pandemic response capabilities and readiness. In some areas we excel. In other areas, frankly, as this committee has noted, we still have work to do.

As with all aspects of the Department's work, Secretary Napolitano has asked me to supervise the staff members responsible for coordinating lessons learned and ensure that the Department is ready for whatever the fall may bring. While the Secretary may be the principal Federal official for domestic incident management, she is not the sole Federal official.

The Department of Health and Human Services, I am deeply honored to be testifying with my HHS colleague, Deputy Secretary Corr this afternoon, who has a leading role to play in mounting a response to H1N1, as does the Department of Education and others, as does Congress.

Indeed, congressional leadership on this issue has been of particular importance. The \$47 million Congress provided to DHS for pandemic influenza preparedness in fiscal year 2006 has already proven its worth. With that funding, we have been able to build the foundation of our pandemic preparedness, including stockpiling of personal protective equipment and antiviral drugs for DHS employees and supporting pandemic influenza workshops.

Our role is to coordinate and assist the larger Federal response. We are working with the White House, National security staff and our Federal interagency partners to finalize the Federal strategic implementation plan for the 2009 H1N1 flu. This plan is being revised to reflect the lessons that we learned this spring.

Internally, we are finalizing our own operational plans to provide direction to DHS components to ensure that our mission-essential

functions are maintained while protecting our workforce in the face of a sustained or worsening outbreak.

While final touches to formal plans are being made, the overall coordination for this incident began months ago. At the start of the current outbreak of H1N1, the National Operations Center was fully activated to fulfill its role on interagency coordination, and they were assisted in this by the Office of Health Affairs which coordinated with HHS to help manage requests for information from a variety of stakeholders.

We have been actively engaged with our Federal, State, and local and Tribal partners throughout the H1N1 outbreak, and we are working with others under the direction of President Obama who hosted a H1N1 summit 3 weeks ago for State and local leaders and stakeholders. This summit focused on lessons learned from the response so far. We are helping the private sector to plan for a pandemic. DHS began providing extensive guidance to private sector partners several years ago. Challenges have arisen and we are adapting in view of the experience gained.

The health and safety of our workforce is one of our highest priorities, and we will continue to ensure that our front-line employees receive guidance on personal protection that is based on the best science available. We learned from the H1N1 flu that we have to have more guidance in place, and we have worked in that direction.

There are a number of other efforts throughout the Department that I detailed in my statement for the record.

Every day, Secretary Napolitano and I wake up thinking about how we can find new points on the supply chain of trouble and to interdict that trouble before it makes its way to the United States. H1N1 is no different. We will be prepared and we will be ready.

Thank you again for this opportunity to testify. I will be happy to answer your questions.

[The statement of Ms. Lute follows:]

PREPARED STATEMENT OF JANE HOLL LUTE

JULY 29, 2009

Chairman Thompson, Ranking Member King, and Members of the committee: Thank you for this opportunity to discuss National efforts to respond to the H1N1 flu outbreak, and what the Department of Homeland Security (DHS) is doing to prepare Americans for the effects of pandemic influenza in the future.

The outbreak of H1N1 this past spring presented us with an early opportunity to evaluate our capacity to respond to a potential pandemic influenza. As we ready for the possibility that the H1N1 influenza may worsen, we must take advantage of what we learned from our earlier experience with this flu.

Secretary Napolitano has asked me to lead internal coordination of the Department's response to H1N1. Our efforts within DHS are many, but we work in close coordination with the Department of Health and Human Services, the Department of Education, and the many other agencies that are contributing to the preparedness of our Nation. I am pleased to testify alongside my colleague, Deputy Secretary Corr, from HHS. We must, and are, acting in unison to ensure the entire Nation has the highest level of preparedness possible.

OVERVIEW OF PANDEMIC PREPAREDNESS AND PLANNING WITHIN DHS

Before speaking about current and future activities of DHS, I would like to touch briefly on the past leadership that has allowed us to reach our current readiness state.

Specifically, I would like to acknowledge the \$47.3 million that Congress allocated to DHS for pandemic influenza preparedness in fiscal year 2006. The recent outbreak of H1N1 made the importance of this funding even more evident. With that funding, the Department was able to build the basis of our pandemic preparedness foundation. For example, DHS conducted exercises (including intradepartmental pandemic influenza tabletops and workshops), purchased personal protective equipment (PPE) for DHS employees, and stockpiled antiviral medications for employees.

DHS is currently working with White House National Security Staff and our Federal interagency partners to finalize the Federal Strategic Implementation Plan for the 2009 H1N1 flu. The draft H1N1 Implementation Plan is being revised to reflect the many policy and strategic decisions that have been made, lessons learned from the initial response, and an overarching goal to mitigate the impact of H1N1 on society and the economy.

At the same time, the Department is finalizing the DHS 2009 H1N1 Operational Plan, which will be completed within the coming weeks. This plan will provide the necessary direction to DHS components to ensure that the Department's mission-essential functions are maintained while protecting our workforce in the face of a sustained or worsening outbreak.

The Secretary and I are committed to the timely finalization of both the inter- and intra-agency pandemic flu plans.

INCIDENT COORDINATION

While final touches to formal plans are being made, overall coordination for this incident began immediately as Secretary Napolitano carried out her responsibilities as the Principal Federal Official.

At the start of the current outbreak of H1N1, the Department's National Operations Center (NOC) was fully activated in order to provide direct support to the Secretary as well as to fulfill its role of interagency coordination. The NOC was ably assisted by the Office of Health Affairs (OHA), which coordinated with HHS and helped to manage requests for information from a variety of stakeholders, including our own DHS components, Federal interagency partners, State and local officials, the private sector, and Congress.

To further facilitate incident coordination, DHS recently established Regional Coordination Teams to serve as an additional resource for the Federal Government, States, and local communities. The teams are designed to provide a regional link to our Federal partners; identify and respond to critical needs; identify and help reconcile regional issues; and coordinate with safety and health officials to protect Federal workers. The teams are charged with facilitating Federal interaction with our State and local partners in a pandemic where, unlike in many site-specific natural disasters, the affected population is spread across the entire Nation.

STATE, LOCAL, TRIBAL, AND TERRITORIAL OUTREACH

The Department of Homeland Security has been actively engaged with our Federal, State, local, territorial, and Tribal partners to prepare for our national response to an influenza pandemic. DHS offices and components have worked closely with partners to share information that is most critical to preparedness plans. During the initial H1N1 outbreak in the spring, DHS' Office of Intergovernmental Programs held daily information calls and posted daily status updates to fusion centers through the Homeland Security State and Local Intelligence Community (HS-SLIC) network. Given the overwhelmingly positive response that this outreach and engagement received, DHS will continue to use all mechanisms at hand come this fall, including, but not limited to, the Homeland Security Information Network, and the Homeland Security State and local intelligence community, in order to distribute critical information.

Three weeks ago, following President Obama's direction and leadership, DHS, HHS, and the Department of Education hosted a summit for State and local leaders and stakeholders. The summit discussions focused on lessons learned from the initial wave, including DHS areas of focus such as continuity of operations planning, front-line employee protection, and public and private sector roles in the national response. The summit's multiagency approach was very well-received. It allowed the Federal Government to convene key leaders and underscore how critical it is for local communities to coordinate activities among and between officials from the public health, emergency management, education, and public and private sectors.

CRITICAL INFRASTRUCTURE AND PRIVATE SECTOR PREPAREDNESS

This history of past efforts and coordination proved beneficial during the H1N1 outbreak. Prior to the outbreak, DHS had published the "Pandemic Influenza Pre-

paredness, Response and Recovery, Guide for Critical Infrastructures and Key Resources” to provide guidance to our Critical Infrastructure and Key Resource (CIKR) partners. In addition, with the help of our interagency partners, DHS completed specific pandemic influenza plans for all 18 of the CIKR sectors. Important components of the final plans and overall pandemic preparedness issues were highlighted, and will continue to be highlighted, in a series of web seminars led by DHS representatives. DHS is also coordinating with CIKR partners through the Government Coordinating Councils (GCC) and Sector Coordinating Councils (SCC).

Across DHS, we are engaged with various private sector organizations, associations, and businesses to more broadly ensure their access to, and understanding of, pandemic preparation tools, resources, and guidance.

While this guidance has been useful to our stakeholders, challenges arose because the H1N1 virus presented itself in a way that differed from some assumptions made in previous pandemic flu planning materials. Because of this, DHS and the Centers for Disease Control and Prevention (CDC) continue to work together to provide updated guidance that can best help CIKR and private sector partners maintain operations through the trials of a pandemic influenza.

For example, our CIKR and Private Sector Offices are jointly participating in outreach with CDC, bringing together representatives from several major international corporations. The initial workshop focused on efforts to help private sector partners better prepare to meet their essential functions in a pandemic environment. Additional outreach is planned by both the National Protection and Programs Directorate and the Private Sector Office.

Furthermore, to anticipate the impact of H1N1 on critical infrastructure and private sector businesses and organizations, the DHS National Biosurveillance Integration Center has partnered with the National Infrastructure Simulation and Analysis Center within the DHS Office of Infrastructure Protection to present mathematical modeling of the virus’ expected spread and infrastructure impact informed by the best available epidemiological information about the virus. We will use this data to help guide our policy decisions as well as our preparedness and planning activities.

PROTECTING THE DHS WORKFORCE

As I mentioned earlier, DHS had personal protective equipment on hand for use by employees, specifically those who perform certain tasks that may place them at increased risk of exposure. Components with employees who may be at risk include the U.S. Coast Guard (USCG), U.S. Immigration and Customs Enforcement (ICE), U.S. Customs and Border Protection (CBP), and the Transportation Security Administration (TSA). For example, TSA has shipped PPE to every airport hub, to Federal Air Marshal Special Agent in Charge offices, and to Office of Inspection field locations. Additionally, PPE is pre-positioned at 120 DHS locations and field offices Nation-wide.

The Department has also stockpiled two types of antivirals, oseltamivir (Tamiflu®) and zanamivir (Relenza®), dedicated to DHS workforce protection. These medications are stored in a pharmaceutical warehouse, fielded across the Operational Workforce sites, and are prepared to be deployed as necessary. In addition, the USCG purchased courses of antivirals through Department of Defense stockpile channels. Overall, DHS has on hand approximately 540,000 courses of antivirals targeted for its mission-essential workforce.

The health and safety of our workforce is one of Secretary Napolitano’s and my top priorities, and we will continue to ensure that our front-line employees receive workforce protection guidance based on the best science available. DHS follows CDC guidance and OSHA standards on personal protective equipment, including when to use masks and respirators, and updates that guidance as new guidance is released. We learned from the H1N1 flu emergence that we needed to have more guidance in place. Looking forward, we are involved in intra-agency and interagency efforts to develop coordinated workforce protection guidance. There is no question that this continues to be a priority area for DHS.

OTHER CURRENT AND ON-GOING H1N1 ACTIVITIES

The Department will continue to conduct stakeholder outreach, strategize and plan, and work with our interagency partners to help the Nation become as prepared as possible for any future pandemic. Additional on-going activities of DHS offices and components include the following:

- OHA is working with the CDC, HHS, and the Department of Veterans Affairs on guidance to Federal departments on prioritizing their employees for vaccines as well as on vaccine distribution strategies for Federal employees.

- OHA continues to stockpile antivirals and PPE. OHA is also developing policies and guidance for the use of antivirals and PPE by DHS employees, based on CDC guidance, as well as working with all components on communication programs, education, and training in order to protect our workforce.
- The Office of Public Affairs is working with the White House, HHS, and other agencies on overall pandemic communication strategies.
- The Regional Coordination Teams are beginning training and outreach to State and local officials.
- Department leadership, under my supervision, meets weekly to review key preparedness timelines and strategies, identify gaps, and design solutions.
- FEMA, in coordination with HHS, has drafted a Comprehensive Preparedness Guide (CPG) specifically for pandemic influenza. This CPG will be published in the next few weeks to provide operational direction to State, local, and Tribal jurisdictions relating to their pandemic planning.
- NBIC is maintaining constant, real-time, dynamic biosurveillance.
- The NOC is coordinating efforts that will allow the U.S. Government to maintain a common operating picture of the current status of H1N1 influenza outbreaks during the fall waves.

Again, thank you for the invitation to discuss these important issues and for your continued willingness to work alongside the Department to provide leadership in protecting and ensuring the security of our homeland.

Chairman THOMPSON. Thank you for your testimony.

I now recognize Deputy Secretary Corr to summarize his statement for 5 minutes.

**STATEMENT OF WILLIAM CORR, DEPUTY SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. CORR. Thank you, Mr. Chairman, Congressman King, and Members of the committee, it is a pleasure to be here today to give you an update on the activities of the Department of Health and Human Services. It is certainly a pleasure to appear with Deputy Secretary Lute, my colleague with DHS, and certainly with Ms. Steinhardt, we have great respect for the work that GAO does and take it very, very seriously.

Secretary Sebelius and all of us at HHS deeply appreciate the leadership that the Congress has shown in providing the resources in the supplemental appropriations bill to give us the flexibility to begin targeting our resources as we need to for this H1N1 outbreak.

While the headlines and the 24-hour news updates may have quieted down, this virus has not gone away and we cannot let up for one moment. In concert with our partners at Homeland Security and throughout the administration, we are doing everything possible to monitor and respond to this virus. The Department's concentrated and considerable efforts are not about raising alarms, they are about being being prepared. This is a very serious virus capable of causing severe disease and death, and it is essential that we have a coordinated and clear strategy to combat it.

Going forward, we will work closely with the White House, with the Department of Homeland Security, and all of our Federal inter-agency partners to focus our health efforts around four areas.

First is surveillance, to learn as much as we can about the virus, how it is changing and how it is spreading.

Second, mitigation to encourage people to do what they can do. Each citizen has things that they can do in home and in their schools and their neighborhoods, to deal with the potential surge on our medical infrastructure, and to provide appropriate medical countermeasures.

Immunization is the third leg which involves laying the groundwork for a potentially large-scale campaign to distribute vaccine.

Last is communication, providing clear and accurate information to State and local governments and to the public.

I would like to, Mr. Chairman, very quickly try to summarize some of the main activities. There are many, but I will highlight them and then be available for any questions that the committee might ask.

As noted, the virus has now reached every State in the United States. As of July 24, there were over 43,000 confirmed cases; 5,000 hospitalizations; and 302 deaths. Going forward, CDC will be reporting in a different way, reporting on the number of hospitalizations and deaths and a good deal of information about the virus itself, how we are tracking it, where the flu is occurring and what the impact is on disease and on hospitalization.

This virus usually causes a self-limited disease that gets better without treatment, but it also can cause severe illness and even death. Infants, children, and those with underlying health conditions appear to be most vulnerable to severe disease.

The CDC is working closely with the World Health Organization and the Pan American Health Organization and ministries of health from around the world to continue characterizing the virus as it spreads. To today, we have observed rapid, early season increases in flu cases in the southern hemisphere, evidence of increased burden on the health care system, and extended school closures in some locations. We are working aggressively to monitor for evidence of change in the virus and whether it is becoming more virulent and transmittal.

All of this information will allow us to make decisions as we go forward here in the United States.

On May 22, Secretary Sebelius announced \$1.1 billion of funds for vaccine development and manufacturing that includes clinical trials that will give us further information about safety and the optimal dose that is needed for the protective immune response that we desire. She also has announced \$884 million to secure ingredients, including the antigens which are the key components of vaccine and adjuvant so that we will have vaccine available, if needed.

The studies are underway now with the vaccine, and we anticipate limited quantities of the vaccine in the next several months. Today, a special meeting of the CDC's advisory committee on immunization practices is occurring, and they will be considering many subjects and are one of our many advisory committees that we are relying upon for scientific and public health expertise.

One of the recommendations will be on the age and risk groups that are recommended for vaccination. To help communities prepare for an increase in cases this fall, HHS, Homeland Security, and the Department of Education conducted a summit on July 9 involving State, local, Tribal, and Federal officials to discuss lessons learned, best practices, and to discuss preparedness priorities. At the summit, Secretary Sebelius announced the availability of \$350 million in supplemental funding that will be made available both to State, local, and territorial health departments as well as to hospitals for preparedness.

At the summit, we sent a strong message to our partners that they must be ready to begin an immunization program this fall when the licensed vaccine is anticipated to be available, but the decision to do a vaccination program has not been made yet and will be made in the near future.

Before an immunization campaign begins, our scientific and public health experts will learn everything we can about the vaccine, its safety and efficacy, as well as the status of the spread of the virus as we make decisions. We have also purchased antivirals and other needed products. We have begun our effort to educate the public as, Congressman King pointed out, and I know that all of the Members of the committee are deeply concerned about so that the public has as much information as possible on how they can protect themselves.

We have provided some school guidance, and will be providing extensive guidance to schools about how they should consider their activities as they enter into the school year.

We are working with Federal, State, local, and Tribal partners to develop a community-based set of interventions. Mr. Chairman, if I may say in closing, we will also make every endeavor to keep this committee and other key committees of the Congress fully informed about our actions, what we know, as well as what we do not know. Thank you, Mr. Chairman.

[The statement of Mr. Corr follows:]

PREPARED STATEMENT OF WILLIAM CORR

JULY 29, 2009

Good afternoon Chairman Thompson, Ranking Member King, and Members of the committee. I am Bill Corr, Deputy Secretary at the U.S. Department of Health and Human Services (HHS). I am pleased to have this opportunity to update the committee on HHS' activities related to the 2009-H1N1 influenza outbreak. Several HHS agencies, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), play key roles in our preparations for and response to pandemic influenza.

We appreciate the quick action of Congress in recently providing \$1.85 billion in immediately available resources and an additional \$5.8 billion contingency emergency appropriation for pandemic influenza preparedness and response, of which we have notified you that we plan to immediately access \$1.825 billion. The Congress has provided sufficient flexibility within the appropriation for HHS to target its responses and resources as the situation evolves. Immediate activities will include providing funding to States for important planning necessary if a 2009-H1N1 immunization program is implemented this fall; funding to hospitals for preparation activities given a likely surge in patients during the flu season; purchasing additional vaccines, syringes, and needles; and providing support for monitoring, diagnostics, and public health response capabilities.

Mr. Chairman, we at the Department are proud of what we've done so far to protect the American people. While the headlines and 24-hour news updates may have quieted down, this virus has not gone away, and we have not let up. In concert with our partners at the Department of Homeland Security and throughout the administration, we are doing everything possible to monitor and respond to this virus.

It has been our goal to build the national infrastructure necessary to mount a scalable and flexible response to a novel influenza virus. This has included developing pre-pandemic vaccines for viruses with pandemic potential; Federal and State stockpiling of key medical countermeasures, such as antiviral drugs; and conducting exercises to practice accessing and distributing materiel from the stockpiles.

With the strong support of Congress, and working with Governors, mayors, Tribes, State and local health departments, the medical community, and our private sector partners, the administration has been actively building on the preparations that have been underway for several years for an anticipated influenza pandemic

to ensure the Nation is ready for the H1N1 virus scenarios that may develop over the next few months. From the outset, we have said that medical science will lead the way, and we are preparing action plans based on the best scientific information available.

I want to be clear: The Department's efforts are not about raising alarms or stoking fears. They are about being prepared. This is a serious virus capable of causing severe disease and death, and it is essential that we have a clear and coordinated strategy to combat it.

With that in mind, HHS is currently working with the White House and our Federal interagency partners to focus and galvanize our efforts around a National Framework for 2009–H1N1 Influenza Preparedness and Response that is based on four pillars: Surveillance, mitigation, immunization, and communication.

Surveillance entails learning as much as we can about whether and how the virus is changing and spreading in the rest of the world, so that we have a clearer idea of how the virus will present in the United States during the fall flu season. Mitigation means encouraging people to do basic things at work, at home, in schools, and in their neighborhoods to help stop the spread of the virus; managing a potential surge in demands on our medical infrastructure; and providing appropriate medical countermeasures to infection. Immunization involves laying the groundwork for a potentially large-scale campaign to distribute an H1N1 vaccine and prioritize its use. And communication means providing clear and accurate information to State and local governments and to the public, which is essential during an outbreak.

Each of the efforts I will describe this morning fits into this framework.

Since the first 2009–H1N1 influenza patient in the United States was confirmed by laboratory testing at CDC on April 15, 2009, the virus has reached every State in the United States. On April 26, 2009 HHS issued a Nation-wide Public Health Emergency Declaration and declared that the emergency justified emergency use of several products. On that and the following day FDA issued four Emergency Use Authorizations (EUAs) in response to requests by CDC. An EUA allows the use of an unapproved product or use of an approved product for an unapproved use in an emergency declared as justifying such use. These authorizations allowed for the emergency use of certain antiviral medications, in vitro diagnostic devices, and respiratory protection products. A fifth EUA for a diagnostic panel for laboratory screening followed.

As of July 24, 2009 CDC reported 43,771 confirmed and probable cases in the United States, with 5,011 hospitalizations and 302 deaths. However, most cases are not tested and confirmed and CDC estimates that there have been more than 1 million cases of novel H1N1 flu in the United States to date. Since the exact number of persons ill with 2009–H1N1 flu is likely to be much higher than individual case counts indicate, Friday, July 24, 2009, was the last day that CDC is providing individual confirmed and probable cases of novel H1N1 influenza. CDC will continue to report the total number of hospitalizations and deaths each week, and to use its traditional surveillance systems to track the progress of the novel H1N1 flu outbreak. These systems work to determine when and where flu activity is occurring, track flu-related illness, determine what flu viruses are circulating, detect changes in flu viruses and measure the impact of flu on hospitalizations and deaths in the United States. The World Health Organization (WHO) reported 94,512 confirmed cases on July 6, 2009. For similar reasons, earlier in July the World Health Organization announced that it would stop issuing its global tables showing the numbers of confirmed novel H1N1 flu cases for all countries.

This virus usually causes a self-limited disease that gets better without treatment, but it can also cause severe illness and even death. Infants, children, and those with underlying health conditions appear to be most vulnerable to severe disease.

CDC staff worldwide are collaborating with WHO, the Pan American Health Organization (PAHO) and ministries of health to study characteristics of the 2009–H1N1 virus, including: The severity and transmissibility of H1N1 illness; population-based rates of mild and severe illness; risk factors for severe disease; impact on the health care infrastructure; and rates of transmission in households and communities in the Southern Hemisphere. These activities will better prepare the Nation and other Northern Hemisphere countries when we enter flu season in the fall.

To date, we have observed rapid early season increase in flu cases in the Southern Hemisphere, evidence of increased burden on health care systems and extended school closures in several locations. We also are working aggressively to monitor for evidence of changes in the 2009–H1N1 virus itself, whether the virus is becoming more virulent or transmittable.

Efforts are underway to develop a vaccine against this new virus. NIH plans to invest more than \$200 million in influenza research, including research on the

2009–H1N1, this fiscal year. Over the years, NIH has built a substantial infrastructure of research centers, intramural and NIH-supported extramural laboratories, highly trained personnel, and clinical research networks to rapidly conduct research on new pandemic viruses, such as 2009–H1N1 influenza. This established infrastructure enabled intramural researchers on the NIH campus, researchers at medical centers throughout the country in pre-existing NIH research networks, such as the Centers of Excellence in Influenza Research and Surveillance (CEIRS) and Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), as well as industry partners and individual NIH grantees to act quickly to study the 2009–H1N1 influenza virus. In addition, NIH has been working with the biotechnology and pharmaceutical industries to speed development of new influenza vaccines, diagnostic tools, and anti-influenza drugs.

On May 22, 2009 HHS Secretary Sebelius announced that \$1.1 billion of funds previously appropriated for such purposes would be used for vaccine development and manufacturing. This includes resources for the clinical trials that are being carried out through NIH and through the manufacturers in collaboration with the FDA, CDC, and ASPR. On July 13, Secretary Sebelius announced that the Department will commit an additional \$884 million to secure additional ingredients, including antigens and adjuvants, needed to manufacture the H1N1 vaccines. The Biomedical Advanced Research and Development Authority (BARDA) within ASPR has contracted with five vaccine manufacturers for the purchase of these bulk vaccine components. In addition to clinical trials conducted by the manufacturers, NIH will use its longstanding vaccine clinical trials infrastructure, notably the network of Vaccine and Treatment Evaluation Units, to conduct clinical studies to confirm safety and determine the optimal dose needed to induce a protective immune response. The five manufacturers who already produce U.S.-licensed seasonal vaccine are also conducting their own 2009–H1N1 influenza vaccine trials under contract with HHS. These studies are just beginning to get under way and will be carried out over the next several months. We anticipate that limited quantities of a vaccine may be available by mid-October.

NIH and its industry partners have been developing several other kinds of influenza vaccines, for example, DNA vaccines, in which harmless influenza genetic sequences are injected directly into a person to stimulate an immune response against the proteins coded for by these genetic sequences. Studies are underway to evaluate how well these candidate antiviral drugs block the 2009–H1N1 influenza strain and to screen other compounds for activity against the virus. However, because these “next-generation” vaccines will require additional safety and efficacy testing before they can be deployed, they are unlikely to reach the public before the vaccines that are currently being produced.

Today a special meeting of CDC’s Advisory Committee on Immunization Practices (ACIP) will take place in Atlanta to follow up on issues related to planning for a 2009–H1N1 immunization campaign should it become necessary. Meeting topics include 2009–H1N1 epidemiology in the United States and internationally; implementation planning; vaccine development and formulations; communications; and ACIP Workgroup recommendations on age/risk groups recommended for vaccination.

To help communities prepare for an increase in 2009–H1N1 influenza cases in the fall, HHS, the Department of Homeland Security, the Department of Education and the White House held the H1N1 Influenza Preparedness Summit at NIH on July 9, 2009 for Federal, State, local, and Tribal officials to build on and tailor States’ existing pandemic plans, share lessons learned and best practices, and discuss preparedness priorities.

At the summit, Secretary Sebelius announced the availability of \$350 million in supplemental funding. These funds will be available to State, local, and territorial health departments to bolster their response activities to the 2009–H1N1 influenza pandemic, including: Addressing planning gaps; preparing for a potential mass vaccination campaign; meeting the information needs of the public, health, and educational professionals to support their decision-making; implementing strategies to reduce people’s exposure to the 2009–H1N1 virus; supporting laboratory testing; preparing hospitals and the health care community; and improving influenza surveillance and investigations.

At the summit we sent a strong message to our State, tribal, and local partners that they must be ready to begin an immunization program by mid-October, when the first licensed vaccine is anticipated to be available. Before an immunization campaign begins, we will review what we know about the vaccine, its safety and efficacy, as well as the status of the pandemic to determine if an immunization program should proceed.

Vaccines are not the only tools we have in our response armamentarium. Other 2009–H1N1 response efforts include the use of antiviral drugs and mitigation efforts, such as social distancing.

The 2009–H1N1 influenza virus is currently sensitive to the antiviral drugs oseltamivir (Tamiflu®) and zanamivir (Relenza®). (Although cases of resistance to oseltamivir have been detected in some 2009–H1N1 virus isolates, they are currently rare.) When it became apparent that 2009–H1N1 was spreading within the United States, HHS released 25 percent of the States' pro rata share of antiviral drugs and personal protective equipment, to help the States prepare to respond to the outbreak. Thirteen million regimens of antiviral drugs have been purchased and are scheduled to be delivered to replenish the CDC's Strategic National Stockpile (SNS) by the end of September 2009. An additional 400,000 regimens of antiviral drugs from the SNS were delivered to Mexico in response to an official request for assistance in combating the 2009–H1N1 influenza outbreak. Additionally, HHS recently announced plans to provide 420,000 treatment courses of oseltamivir to PAHO to fight the 2009–H1N1 virus in Latin America and the Caribbean.

CDC and other HHS agencies continue to educate the public on ways to prevent infection, including frequent hand washing, staying home from school or work if ill, and coughing and sneezing into your elbow instead of your hands.

School guidance is an area of particular concern because children are one of the groups at greatest risk of illness with this particular strain of influenza and are transmitting the virus at high rates. HHS is working with Federal, State, local, and Tribal partners to develop a comprehensive public health guidance package to inform decisions about a range of interventions applicable to school settings. Our goal, if possible, is to keep schools open and safe for students, faculty, and staff, but we will also advise communities to be prepared for the possibility of school closures, particularly if the virus were to change or become more severe. It will include decision-making guidance about how to choose combinations of interventions most applicable to the local situation and acceptable to the community.

HHS is also working with Federal, State, local, and Tribal partners to develop a more general set of community-based interventions applicable in a wide range of settings. HHS will develop tools and materials to make the recommendations specific to various settings, and is establishing a technical assistance cadre to provide one-on-one consulting.

To assist in preparing communities for increased health care demand, HHS is increasing the level of engagement with health care providers by convening stakeholder meetings to develop guidance and/or tools; providing tools and templates for local community planners; facilitating or supporting the development of clinical and triage protocols; and providing other technical assistance to partners and Federal agencies.

Additionally, HHS will continue to evaluate community mitigation guidelines. As the outbreak progresses, we will continue to assess all guidelines to ensure that they are appropriately based upon the available science.

Please be assured that we will continue to communicate with you. We will tell you what we know when we know it, and we will also inform you when we don't know. To that end, we continue to work with our State, local, territorial, and Tribal partners to best prepare our communities to respond effectively to the formidable public health and medical challenge that 2009–H1N1 influenza presents to us all.

I would like to conclude by making two important points. First, we are all in this together. While the steps the Department and other agencies have taken will help engage the American people and ensure they are prepared, it's important for every family, business, and school to prepare its own household and business plan and think through the steps they will take if a family member, co-worker, or student contracts the H1N1 flu. This is a responsibility that we all share as parents, neighbors, co-workers, and community members.

The second point is that, while the H1N1 pandemic presents a tremendous challenge, it has also brought a valuable opportunity that has helped us accelerate our work to improve the entire public health system; raise awareness about the basic steps people can take to stop the spread of germs and disease and the value of seasonal flu vaccine; and identify the strengths and weaknesses in our prevention and preparedness systems. The application of these lessons will be invaluable.

We have made tremendous progress over the years in preparing for a flu pandemic. Congress has provided strong leadership and support for these efforts. We look forward to working with you to continue the progress we have made to ensure that our Nation is prepared for any public health threat.

I would be happy to answer any questions.

Chairman THOMPSON. Thank you for your testimony. We will get into some of the meat of it after opening statements.

I now recognize Director Steinhardt to summarize her statement for 5 minutes.

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

Ms. STEINHARDT. Thank you, Mr. Chairman, Mr. King, and other Members of the committee. We appreciate the opportunity to be here today to talk about the work that we have done at your request over the last 3 years, to assess the Federal Government's planning and preparedness for a pandemic influenza. When we started, a pandemic was a possibility. Today, it is a reality. As it has turned out, we have been fortunate so far that the pandemic has not been severe. The big question that we face is whether it will stay that way or whether the virus will become more virulent this fall or winter. In any case, we know we have to be prepared for that.

So how well-prepared are we? Clearly we are benefiting from the groundwork that has been laid over the last few years. We have a National pandemic strategy and implementation plan developed by the Federal Government. All 50 States and the District of Columbia, as well as many local governments and private companies have their own pandemic plans as well. But the work we have done suggests that there is more that the Federal Government can and should do to fill in the gaps in the Nation's readiness.

This afternoon I would like to focus on the most important of these gaps that our work has shown.

First, the leadership roles in the pandemic, the who-is-in-charge question, have not been clearly worked out and tested, as you pointed out earlier, Mr. Chairman. Under the National plan, the Secretaries of Homeland Security and Health and Human Services are supposed to share leadership responsibilities along with the system of Federal coordinating officials, principal Federal officials, and the FEMA administrator. But there has never been a National exercise to test how these roles will work together, a point of particular importance now that we have new leaders in these positions. In 2007, we recommended that the two Departments undertake this kind of exercise, but that has not been done.

Second, the National plan, which was intended to be a 3-year plan, is now over 3 years old and it needs to be updated, particularly in light of the experiences of the last few months. But there are no provisions for updating the plan or even reporting on its progress. Two years ago we recommended that the Homeland Security Council establish a process for updating the plan that would also involve key stakeholders, like State and local governments, and would incorporate lessons learned from exercises and other sources. That still has not been acted on.

Third, the Federal Government could be doing a better job of sharing its expertise and coordinating its decisions with other levels of government and the private sector. There have been a number of mechanisms developed for this purpose, but they could be used even more. The critical infrastructure coordinating councils, for example, bring together private sector leaders from the 18 crit-

ical infrastructure sectors with officials from DHS and other Federal and State agencies to develop plans to protect critical infrastructure in major emergencies, including a pandemic flu.

But at the time of our 2007 review, private sector members told us they were still looking for clarification about the respective roles and responsibilities of the Federal and State governments in areas like State border closures and vaccine distribution. We recommended then that DHS make greater use of the coordinating councils to have these kinds of discussions and help resolve some of these issues, but it is not clear to us that this has been happening.

Finally, there needs to be a greater degree of accountability to ensure that Federal workers are protected in the event of a pandemic.

Under the National pandemic plan, agencies are supposed to develop operational plans to protect their employees and to maintain essential operations and services. But based on our survey of the major agencies, progress on these plans appear to be very uneven with several agencies reporting that they were still in the early stages of planning. Yet there is no mechanism to monitor agency planning and no provision for agencies to report on their progress. As a result, we recommended that the Homeland Security Council ask DHS to take on this monitoring and reporting role, and we suggested that the Congress might want to consider requiring DHS to report to the Congress as well as to the White House.

In closing, I want to observe that the last few months have given us real-life experience with some of the issues that are raised by a pandemic flu, but all of this experience will be for naught if we don't incorporate its lessons into our planning for the future. As our work suggests, there are still significant gaps and we should be addressing them now while time is still on our side.

Thank you very much.

[The statement of Ms. Steinhardt follows:]

PREPARED STATEMENT OF STATEMENT OF BERNICE STEINHARDT

JULY 29, 2009

GAO HIGHLIGHTS

Highlights of GAO-09-909T, a testimony before the Committee on Homeland Security, House of Representatives.

Why GAO Did This Study

As the current H1N1 outbreak underscores, an influenza pandemic remains a real threat to our Nation. Over the past 3 years, GAO conducted a body of work, consisting of 12 reports and 4 testimonies, to help the Nation better prepare for a possible pandemic. In February 2009, GAO synthesized the results of most of this work and, in June 2009, GAO issued an additional report on agency accountability for protecting the Federal workforce in the event of a pandemic. GAO's work points out that while a number of actions have been taken to plan for a pandemic, including developing a national strategy and implementation plan, many gaps in pandemic planning and preparedness still remain.

This statement covers six thematic areas: (1) Leadership, authority, and coordination; (2) detecting threats and managing risks; (3) planning, training, and exercising; (4) capacity to respond and recover; (5) information sharing and communication; and (6) performance and accountability.

What GAO Recommends

This statement discusses the status of GAO's prior recommendations on the Nation's planning and preparedness for a pandemic. Key open recommendations con-

cern the need to exercise the shared Federal leadership roles for a pandemic, address planning gaps at all levels of government and in the private sector, and monitor and report on agencies' plans to protect their workers.

INFLUENZA PANDEMIC.—GAPS IN PANDEMIC PLANNING AND PREPAREDNESS NEED TO BE ADDRESSED

What GAO Found

- Leadership roles and responsibilities for an influenza pandemic need to be clarified, tested, and exercised, and existing coordination mechanisms, such as critical infrastructure coordinating councils, could be better utilized to address challenges in coordination between the Federal, State, and local governments and the private sector in preparing for a pandemic.
- Efforts are underway to improve the surveillance and detection of pandemic-related threats, but targeting assistance to countries at the greatest risk has been based on incomplete information, particularly from developing countries.
- Pandemic planning and exercising has occurred at the Federal, State, and local government levels, but important planning gaps remain at all levels of government. At the Federal level, agency planning to maintain essential operations and services while protecting their employees in the event of a pandemic is uneven.
- Further actions are needed to address the capacity to respond to and recover from an influenza pandemic, which will require additional capacity in patient treatment space, and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines.
- Federal agencies have provided considerable guidance and pandemic-related information to State and local governments, but could augment their efforts with additional information on school closures, State border closures, and other topics.
- Performance monitoring and accountability for pandemic preparedness needs strengthening. For example, the May 2006 *National Strategy for Pandemic Influenza Implementation Plan* does not establish priorities among its 324 action items and does not provide information on the financial resources needed to implement them. Also, greater agency accountability is needed to protect Federal workers in the event of a pandemic because there is no mechanism in place to monitor and report on agencies' progress in developing workforce pandemic plans.

The current H1N1 pandemic should serve as a powerful reminder that the threat of a pandemic influenza, which seemed to fade from public awareness in recent years, never really disappeared. While Federal agencies have taken action on 13 of GAO's 24 recommendations, 11 of the recommendations that GAO has made over the past 3 years have not been fully implemented. With the possibility that the H1N1 virus could become more virulent this fall or winter, the administration and Federal agencies should use this time to turn their attention to filling in the planning and preparedness gaps GAO's work has pointed out.

Mr. Chairman and Members of the committee: I am pleased to be here today to discuss key themes from the body of work GAO has developed over the past several years to help the Nation better prepare for, respond to, and recover from a possible influenza pandemic. An influenza pandemic remains a real threat to our Nation and to the world, as we are witnessing during the current H1N1 pandemic. The previous administration took a number of actions to plan for a pandemic, including developing a national strategy and implementation plan. However, much more needs to be done, and many gaps in planning and preparedness still remain. Strengthening preparedness for large-scale public health emergencies, such as an influenza pandemic, is one of 13 urgent issues that we identified earlier this year as among those needing the immediate attention of the new administration and Congress.¹

In the past 3 years, GAO has issued 12 reports and 4 testimonies on influenza pandemic planning.² We synthesized the results of most of our work in a February 2009 report, which I will discuss in more detail today.³ In addition, I will discuss key results from our recent report on protecting the Federal workforce in the event

¹ GAO's 2009 Congressional and Presidential Transition website: http://www.gao.gov/transition_2009.

² We also have two pandemic-related reviews underway on the following topics: (1) The status of implementing the *National Strategy for Pandemic Influenza Implementation Plan* (National Pandemic Implementation Plan); and (2) the effect of a pandemic on the telecommunications capacity needed to sustain critical financial market activities.

³ GAO, *Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts*, GAO-09-334 (Washington, DC: Feb. 26, 2009).

of a pandemic.⁴ We have made 24 recommendations based on the findings from these reports, 13 of which have been acted upon by the responsible Federal agencies. The responsible Federal agencies have generally agreed with our recommendations and some actions are underway to address them. However, 11 recommendations have not yet been fully implemented. While our February 2009 report made no new recommendations, it reflects the status of those recommendations that were made prior to our June 2009 report that had not yet been implemented. Many of the recommendations that remain unimplemented have become even more pressing in light of the very real possibility of the return of a more severe form of the H1N1 virus later this year. Lists of our open recommendations and related GAO products that are referenced throughout this statement are located in attachments I and II.*

In summary, my statement will address the following issues which were drawn from the key themes of GAO's pandemic work:

- Leadership roles and responsibilities for an influenza pandemic need to be clarified, tested, and exercised, and existing coordination mechanisms, such as critical infrastructure coordinating councils, could be better utilized to address challenges in coordination between the Federal, State, and local governments and the private sector in preparing for a pandemic.
- Efforts are underway to improve the surveillance and detection of pandemic-related threats in humans and animals, but targeting assistance to countries at the greatest risk has been based on incomplete information, particularly from developing countries.
- Pandemic planning and exercising have occurred at the Federal, State, and local government levels, but important planning gaps remain at all levels of government. At the Federal level, agency planning to maintain essential operations and services while protecting their employees in the event of a pandemic is uneven.
- Further actions are needed to address the capacity to respond to and recover from an influenza pandemic, which will require additional capacity in patient treatment space, and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines.
- Federal agencies have provided considerable guidance and pandemic-related information to State and local governments, but could augment their efforts with additional information on school closures, State border closures, and other topics.
- Performance monitoring and accountability for pandemic preparedness needs strengthening. For example, the May 2006 *National Strategy for Pandemic Influenza Implementation Plan* (National Pandemic Implementation Plan) does not establish priorities among its 324 action items and does not provide information on the financial resources needed to implement them. Also, greater agency accountability is needed to protect Federal workers in the event of a pandemic because there is no mechanism in place to monitor and report on agencies' progress in developing workforce pandemic plans that provide the operational details of how agencies will protect their employees and maintain essential operations and services.

As noted earlier, this statement is based on our prior work, which was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

BACKGROUND

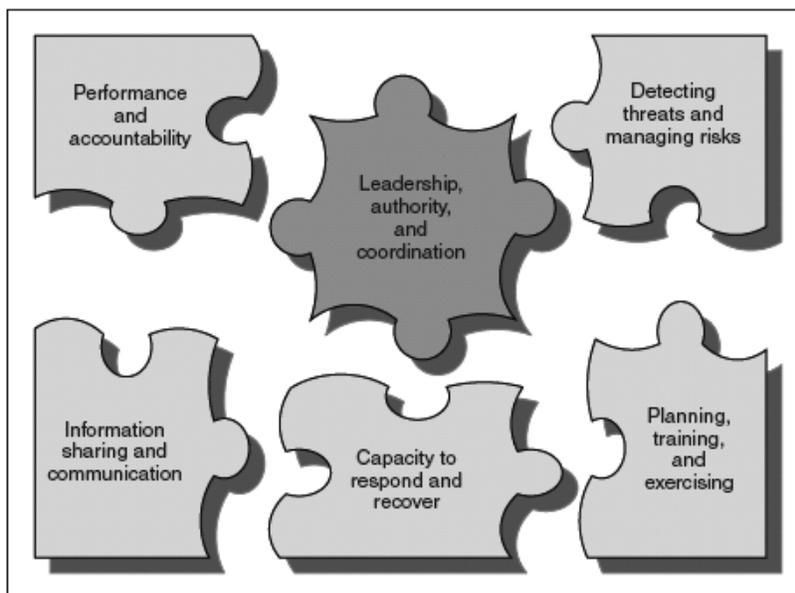
Given the consequences of a severe influenza pandemic, in 2006, GAO developed a strategy for our work that would help support Congress's decision-making and oversight related to pandemic planning. Our strategy was built on a large body of work spanning two decades, including reviews of Government responses to prior disasters such as Hurricanes Andrew and Katrina, the devastation caused by the 9/11 terror attacks, efforts to address the Year 2000 (Y2K) computer challenges, and assessments of public health capacities in the face of bioterrorism and emerging infectious diseases such as Severe Acute Respiratory Syndrome (SARS). The strategy was built around six key themes as shown in figure 1. While all of these themes

⁴GAO, *Influenza Pandemic: Increased Agency Accountability Could Help Protect Federal Employees Serving the Public in the Event of a Pandemic*, GAO-09-404 (Washington, DC: June 12, 2009).

* The information has been retained in committee files.

are interrelated, our earlier work underscored the importance of leadership, authority, and coordination, a theme that touches on all aspects of preparing for, responding to, and recovering from an influenza pandemic.

Figure 1: Key Themes of GAO's Pandemic Strategy



Source: GAO.

Influenza pandemic—caused by a novel strain of influenza virus for which there is little resistance and which therefore is highly transmissible among humans—continues to be a real and significant threat facing the United States and the world. Unlike incidents that are discretely bounded in space or time (e.g., most natural or man-made disasters), an influenza pandemic is not a singular event, but is likely to come in waves, each lasting weeks or months, and pass through communities of all sizes across the Nation and the world simultaneously. However, the current H1N1 pandemic seems to be relatively mild, although widespread. The history of an influenza pandemic suggests it could return in a second wave this fall or winter in a more virulent form.⁵ While a pandemic will not directly damage physical infrastructure such as power lines or computer systems, it threatens the operation of critical systems by potentially removing the essential personnel needed to operate them from the workplace for weeks or months. In a severe pandemic, absences attributable to illnesses, the need to care for ill family members, and fear of infection may, according to the Centers for Disease Control and Prevention (CDC), reach a projected 40 percent during the peak weeks of a community outbreak, with lower rates of absence during the weeks before and after the peak.⁶ In addition, an influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity.

The President's Homeland Security Council (HSC) took an active approach to this potential disaster by, among other things, issuing the *National Strategy for Pandemic Influenza* (National Pandemic Strategy) in November 2005, and the National Pandemic Implementation Plan in May 2006.⁷ The National Pandemic Strategy is

⁵ On June 11, 2009, the World Health Organization (WHO) raised its influenza pandemic alert level from phase 5 to the highest phase, phase 6, signaling the widespread human infection associated with a pandemic for the H1N1 virus.

⁶ GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, GAO-07-781 (Washington, DC: Aug. 14, 2007).

⁷ On May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The Homeland Security Council will be main-

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 provides expectations for non-Federal entities—including State, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities. The National Pandemic Implementation Plan is intended to lay out broad implementation requirements and responsibilities among the appropriate Federal agencies and clearly define expectations for non-Federal entities. The Plan contains 324 action items related to these requirements, responsibilities, and expectations, most of which were to be completed before or by May 2009. HSC publicly reported on the status of the action items that were to be completed by 6 months, 1 year, and 2 years in December 2006, July 2007, and October 2008 respectively. HSC indicated in its October 2008 progress report that 75 percent of the action items have been completed. We have on-going work for this committee assessing the status of implementing this plan which we expect to report on in the fall of 2009.

LEADERSHIP ROLES AND RESPONSIBILITIES NEED TO BE CLARIFIED AND TESTED, AND COORDINATION MECHANISMS COULD BE BETTER UTILIZED

Federal Government leadership roles and responsibilities for pandemic preparedness and response are evolving, and will require further testing before the relationships among the many Federal leadership positions are well understood. Such clarity in leadership is even more crucial now, given the change in administration and the associated transition of senior Federal officials. Most of these Federal leadership roles involve shared responsibilities between the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS), and it is not clear how these would work in practice. According to the National Pandemic Strategy and Plan, the Secretary of Health and Human Services is to lead the Federal medical response to a pandemic, and the Secretary of Homeland Security will lead the overall domestic incident management and Federal coordination. In addition, under the Post-Katrina Emergency Management Reform Act of 2006, the Administrator of the Federal Emergency Management Agency (FEMA) was designated as 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.⁸ To assist in planning and coordinating efforts to respond to a pandemic, in December 2006 the Secretary of Homeland Security predesignated a national Principal Federal Official (PFO) for influenza pandemic and established five pandemic regions each with a regional PFO and Federal Coordinating Officers (FCO) for influenza pandemic. 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. Moreover, as we testified in July 2007, State and local first responders were still uncertain about the need for both FCOs and PFOs and how they would work together in disaster response.⁹ Accordingly, we recommended in our August 2007 report on Federal leadership roles and the National Pandemic Strategy that DHS and HHS develop rigorous testing, training, and exercises for influenza pandemic to ensure that Federal leadership roles and responsibilities for a pandemic are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges.¹⁰ In response to our recommendation, HHS and DHS officials stated in January 2009 that several influenza pandemic exercises had been conducted since November 2007 that involved both agencies and other Federal officials, but it is unclear whether these exercises rigorously tested Federal leadership roles in a pandemic.

In addition to concerns about clarifying Federal roles and responsibilities for a pandemic and how shared leadership roles would work in practice, private sector officials told us that they are unclear about the respective roles and responsibilities of the Federal and State governments during a pandemic emergency. The National Pandemic Implementation Plan states that in the event of an influenza pandemic, the distributed nature and sheer burden of the disease across the Nation would mean that the Federal Government's support to any particular community is likely

tained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as influenza pandemic.

⁸Pub. L. No. 109-295, Title VI.

⁹GAO, *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-07-1142T (Washington, DC: July 31, 2007).

¹⁰GAO-07-781.

to be limited, with the primary response to a pandemic coming from States and local communities. Further, Federal and private sector representatives we interviewed at the time of our October 2007 report identified several key challenges they face in coordinating Federal and private sector efforts to protect the Nation's critical infrastructure in the event of an influenza pandemic.¹¹ One of these was a lack of clarity regarding the roles and responsibilities of Federal and State governments on issues such as State border closures and influenza pandemic vaccine distribution.

Coordination Mechanisms

Mechanisms and networks for collaboration and coordination on pandemic preparedness between Federal and State governments and the private sector exist, but they could be better utilized. In some instances, the Federal and private sectors are working together through a set of coordinating councils, including sector-specific and cross-sector councils. To help protect the Nation's critical infrastructure, DHS created these coordinating councils as the primary means of coordinating Government and private sector efforts for industry sectors such as energy, food, and agriculture, telecommunications, transportation, and water.¹² Our October 2007 report found that DHS has used these critical infrastructure coordinating councils primarily to share pandemic information across sectors and government levels rather than to address many of the challenges identified by sector representatives, such as clarifying the roles and responsibilities between Federal and State governments.¹³ We recommended in the October 2007 report that DHS encourage the councils to consider and address the range of coordination challenges in a potential influenza pandemic between the public and private sectors for critical infrastructure. DHS concurred with our recommendation and DHS officials informed us at the time of our February 2009 report that the department was working on initiatives to address it, such as developing pandemic contingency plan guidance tailored to each of the critical infrastructure sectors, and holding a series of "webinars" with a number of the sectors.

Federal executive boards (FEB) bring together Federal agency and community leaders in major metropolitan areas outside of Washington, DC, to discuss issues of common interest, including an influenza pandemic. The Office of Personnel Management (OPM), which provides direction to the FEBs, and the FEBs have designated emergency preparedness, security, and safety as an FEB core function. The FEB's emergency support role with its regional focus may make the boards a valuable asset in pandemic preparedness and response. As a natural outgrowth of their general civic activities and through activities such as hosting emergency preparedness training, some of the boards have established relationships with, for example, Federal, State, and local governments; emergency management officials; first responders; and health officials in their communities. In a May 2007 report on the FEBs' ability to contribute to emergency operations, we found that many of the selected FEBs included in our review were building capacity for influenza pandemic response within their member agencies and community organizations by hosting influenza pandemic training and exercises.¹⁴ We recommended that, since FEBs are well-positioned within local communities to bring together Federal agency and community leaders, the Director of OPM work with FEMA to formally define the FEBs' role in emergency planning and response. As a result of our recommendation, FEBs were included in the National Response Framework (NRF)¹⁵ in January 2008 as one of

¹¹ GAO, *Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination*, GAO-08-36 (Washington, DC: Oct. 31, 2007).

¹² The 18 critical infrastructure and key resource sectors are: Food and agriculture; banking and finance; chemical; commercial facilities; commercial nuclear reactors, materials, and water; dams; defense industrial base; drinking water and water treatment systems; emergency services; energy; governmental facilities; information technology; national monuments and icons; postal and shipping; public health and health care; telecommunications; transportation systems; and critical manufacturing. Critical infrastructure are systems and assets, whether physical or virtual, so vital to the United States that their incapacity or destruction would have a debilitating effect on national security, national economic security, and national public health or safety, or any combination of those matters. Key resources are publicly or privately controlled resources essential to minimal operations of the economy or government, including individual targets whose destruction would not endanger vital systems but could create a local disaster or profoundly damage the Nation's morale or confidence.

¹³ GAO-08-36.

¹⁴ GAO, *The Federal Workforce: Additional Steps Needed to Take Advantage of Federal Executive Boards' Ability to Contribute to Emergency Operations*, GAO-07-515 (Washington, DC: May 4, 2007).

¹⁵ Issued in January 2008 by DHS and effective in March 2008, the NRF is a guide to how the Nation conducts all-hazards incident response and replaces the National Response Plan. It focuses on how the Federal Government is organized to support communities and states in cata-

the regional support structures that have the potential to contribute to development of situational awareness during an emergency. OPM and FEMA also signed a memorandum of understanding in August 2008 in which FEBS and FEMA agreed to work collaboratively in carrying out their respective roles in the promotion of the national emergency response system.

EFFORTS ARE UNDERWAY TO IMPROVE THE SURVEILLANCE AND DETECTION OF PANDEMIC-RELATED THREATS, BUT TARGETING ASSISTANCE TO COUNTRIES AT THE GREATEST RISK HAS BEEN BASED ON INCOMPLETE INFORMATION

International disease surveillance and detection efforts serve as an early warning system that could prevent the spread of an influenza pandemic outbreak. The United States and its international partners are involved in efforts to improve pandemic surveillance, including diagnostic capabilities, so that outbreaks can be quickly detected. Yet, as reported in 2007, international capacity for surveillance has many weaknesses, particularly in developing countries.¹⁶ As a result, assessments of the risks of the emergence of influenza pandemic by U.S. agencies and international organizations, which were used to target assistance to countries at risk, were based on insufficiently detailed or incomplete information, limiting their value for comprehensive comparisons of risk levels by country.

PANDEMIC PLANNING AND EXERCISING HAS OCCURRED, BUT PLANNING GAPS REMAIN

The National Pandemic Strategy and National Pandemic Implementation Plan are important first steps in guiding national preparedness. However, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. In our August 2007 report on the National Pandemic Strategy and Implementation Plan, we found that while these documents are an important first step in guiding national preparedness, they do not fully address all six characteristics of an effective national strategy, as identified in our work.¹⁷ The documents fully address only one of the six characteristics, by reflecting a clear description and understanding of problems to be addressed. Further, the National Pandemic Strategy and Implementation Plan do not address one characteristic at all, containing no discussion of what it will cost, where resources will be targeted to achieve the maximum benefits, and how it will balance benefits, risks, and costs. Moreover, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints. Although the remaining four characteristics are partially addressed, important gaps exist that could hinder the ability of key stakeholders to effectively execute their responsibilities. For example, State and local jurisdictions that will play crucial roles in preparing for and responding to a pandemic were not directly involved in developing the National Pandemic Implementation Plan, even though it relies on these stakeholders' efforts. Stakeholder involvement during the planning process is important to ensure that the Federal Government's and non-Federal entities' responsibilities are clearly understood and agreed upon. Further, relationships and priorities among actions were not clearly described, performance measures were not always linked to results, and insufficient information was provided about how the documents are integrated with other response-related plans, such as the NRF. We recommended that the HSC establish a process for updating the National Pandemic Implementation Plan and that the updated plan should address these and other gaps. HSC did not comment on our recommendation and has not indicated if it plans to implement it.

Federal Workforce Pandemic Planning

The National Pandemic Implementation Plan required Federal agencies to develop operational plans for protecting their employees and maintaining essential operations and services in the event of a pandemic. In our June 2009 report, we found that Federal agency progress in pandemic planning is uneven.¹⁸ We surveyed the

strophic incidents. The NRF builds upon the National Incident Management System, which provides a national template for managing incidents.

¹⁶GAO, *Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic*, GAO-08-92 (Washington, DC: Dec. 21, 2007).

¹⁷The six characteristics of an effective national strategy include: (1) Purpose, scope, and methodology; (2) problem definition and risk assessment; (3) goals, subordinate objectives, activities, and performance measures; (4) resources, investments, and risk management; (5) organizational roles, responsibilities, and coordination; and (6) integration and implementation. GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, DC: Feb. 3, 2004).

¹⁸GAO-09-404.

pandemic coordinators from the 24 agencies covered by the Chief Financial Officers Act of 1990, which we supplemented with a case study approach of 3 agencies.¹⁹ We used the survey to get an overview of Government-wide pandemic influenza preparedness efforts. The survey questions asked about pandemic plans; essential functions other than first response that employees cannot perform remotely; protective measures, such as procuring pharmaceutical interventions; social distancing strategies;²⁰ information technology testing; and communication of human capital pandemic policies. Although all of the surveyed agencies reported being engaged in planning for pandemic influenza to some degree, several agencies reported that they were still in the early stages of developing their pandemic plans and their measures to protect their workforce. For example, several agencies responded that they had yet to identify essential functions during a pandemic that cannot be performed remotely. And, although many of the agencies' pandemic plans rely on telework to carry out their functions, 5 agencies reported testing their information technology capability to little or no extent.

The three case study agencies also showed differences in the degree to which their individual facilities had operational pandemic plans. The Bureau of Prisons' correctional workers had only recently been required to develop pandemic plans for their correctional facilities. The Department of Treasury's Financial Management Service, which has production staff involved in disbursing Federal payments such as Social Security checks, had pandemic plans for its four regional centers and had stockpiled personal protective equipment. By contrast, the Federal Aviation Administration's air traffic control management facilities, where air traffic controllers work, had not yet developed facility pandemic plans or incorporated pandemic plans into their all-hazards contingency plans.

State and Local Pandemic Planning

We reported in June 2008 that, according to CDC, all 50 States and the 3 localities that received Federal pandemic funds have developed influenza pandemic plans and conducted pandemic exercises in accordance with Federal funding guidance.²¹ A portion of the \$5.62 billion that Congress appropriated in supplemental funding to HHS for pandemic preparedness in 2006—\$600 million—was specifically provided for State and local planning and exercising. All 10 localities that we reviewed in depth had also developed plans and conducted exercises, and had incorporated lessons learned from pandemic exercises into their planning.²² However, an HHS-led interagency assessment of States' plans found on average that States had “many major gaps” in their influenza pandemic plans in 16 of 22 priority areas, such as school closure policies and community containment, which are community-level interventions designed to reduce the transmission of a pandemic virus. The remaining 6 priority areas were rated as having “a few major gaps.” Subsequently, HHS led another interagency assessment of State influenza pandemic plans and reported in January 2009 that although they had made important progress, most States still had major gaps in their pandemic plans.²³

As we had reported in June 2008, HHS, in coordination with DHS and other Federal agencies, had convened a series of regional workshops for States in five influenza pandemic regions across the country.²⁴ Because these workshops could be a useful model for sharing information and building relationships, we recommended that HHS and DHS, in coordination with other Federal agencies, convene additional meetings with States to address the gaps in the States' pandemic plans. As reported in February 2009, HHS and DHS generally concurred with our recommendation, but have not yet held these additional meetings.²⁵ HHS and DHS indicated at the time of our February 2009 report that while no additional meetings had been planned,

¹⁹The survey was conducted from May through July 2008, and the results were confirmed or updated in early 2009.

²⁰Social distancing is a technique used to minimize close contact among persons in public places, such as work sites and public areas.

²¹GAO, *Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning*, GAO-08-539, (Washington, DC: June 19, 2008).

²²We conducted site visits to the five most populous States including California, Florida, Illinois, New York, and Texas for a number of reasons, including that these States constituted over one-third of the U.S. population, received over one-third of the total funding from HHS and DHS that could be used for planning and exercising efforts, and were likely entry points for individuals coming from another country given that the States either bordered Mexico or Canada or contained major ports, or both. Within each State, we also interviewed officials at 10 localities, which consisted of 5 urban areas and 5 rural counties.

²³DHS and HHS and other agencies, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council* (Washington, DC: January 2009).

²⁴GAO-08-539.

²⁵GAO-09-334.

States will have to continuously update their pandemic plans and submit them for review.

We have also reported on the need for more guidance from the Federal Government to help States and localities in their planning. In June 2008, we reported that although the Federal Government has provided a variety of guidance, officials of the States and localities we reviewed told us that they would welcome additional guidance from the Federal Government in a number of areas, such as community containment, to help them to better plan and exercise for an influenza pandemic.²⁶ Other State and local officials have identified similar concerns. According to the National Governors Association's (NGA) September 2008 issue brief on States' pandemic preparedness, States are concerned about a wide range of school-related issues, including when to close schools or dismiss students, how to maintain curriculum continuity during closures, and how to identify the appropriate time at which classes could resume.²⁷ NGA also reported that States generally have very little awareness of the status of disease outbreaks, either in real time or in near real time, to allow them to know precisely when to recommend a school closure or reopening in a particular area. NGA reported that States wanted more guidance in the following areas: (1) Workforce policies for the health care, public safety, and private sectors; (2) schools; (3) situational awareness such as information on the arrival or departure of a disease in a particular State, county, or community; (4) public involvement; and (5) public-private sector engagement.

Private Sector Pandemic Planning

The private sector has also been planning for an influenza pandemic, but many challenges remain. To better protect critical infrastructure, Federal agencies and the private sector have worked together across a number of sectors to plan for a pandemic, including developing general pandemic preparedness guidance, such as checklists for continuity of business operations during a pandemic. However, Federal and private sector representatives have acknowledged that sustaining preparedness and readiness efforts for an influenza pandemic is a major challenge, primarily because of the uncertainty associated with a pandemic, limited financial and human resources, and the need to balance pandemic preparedness with other, more immediate, priorities, such as responding to outbreaks of foodborne illnesses in the food sector and, now, the effects of the financial crisis.

In our March 2007 report on preparedness for an influenza pandemic in one of these critical infrastructure sectors—financial markets—we found that despite significant progress in preparing markets to withstand potential disease pandemics, securities and banking regulators could take additional steps to improve the readiness of the securities markets.²⁸ The seven organizations that we reviewed—which included exchanges, clearing organizations, and payment-system processors—were working on planning and preparation efforts to reduce the likelihood that a worldwide influenza pandemic would disrupt their critical operations. However, only one of the seven had completed a formal plan. To increase the likelihood that the securities markets will be able to function during a pandemic, we recommended that the Chairman, Federal Reserve; the Comptroller of the Currency; and the Chairman, Securities and Exchange Commission (SEC), consider taking additional actions to ensure that market participants adequately prepare for a pandemic outbreak. In response to our recommendation, the Federal Reserve and the Office of the Comptroller of the Currency, in conjunction with the Federal Financial Institutions Examination Council and the SEC directed all banking organizations under their supervision to ensure that the pandemic plans the financial institutions have in place are adequate to maintain critical operations during a severe outbreak. SEC issued similar requirements to the major securities industry market organizations.

FURTHER ACTIONS ARE NEEDED TO ADDRESS THE CAPACITY TO RESPOND TO AND RECOVER FROM AN INFLUENZA PANDEMIC

Improving the Nation's response capability to catastrophic disasters, such as an influenza pandemic, is essential. Following a mass casualty event, health care systems would need the ability to adequately care for a large number of patients or patients with unusual or highly specialized medical needs. The ability of local or regional health care systems to deliver services could be compromised, at least in the short term, because the volume of patients would far exceed the available hospital

²⁶ GAO-08-539.

²⁷ National Governors Association Center for Best Practices, *Issue Brief: Pandemic Preparedness in the States—An Assessment of Progress and Opportunity* (September 2008).

²⁸ GAO, *Financial Market Preparedness: Significant Progress Has Been Made, but Pandemic Planning and Other Challenges Remain*, GAO-07-399 (Washington, DC: Mar. 29, 2007).

beds, medical personnel, pharmaceuticals, equipment, and supplies. Further, in natural and man-made disasters, assistance from other States may be used to increase capacity, but in a pandemic, States would likely be reluctant to provide assistance to each other due to scarce resources and fears of infection.

Over the last few years, Congress has provided over \$13 billion in supplemental funding for pandemic preparedness. The \$5.62 billion that Congress provided in supplemental funding to HHS in 2006 was for, among other things: (1) Monitoring disease spread to support rapid response, (2) developing vaccines and vaccine production capacity, (3) stockpiling antivirals and other countermeasures, (4) upgrading State and local capacity, and (5) upgrading laboratories and research at CDC.²⁹ The majority of this supplemental funding—about 77 percent—was allocated for developing antivirals and vaccines for a pandemic, and purchasing medical supplies. Also, a portion of the funding that went to States and localities for preparedness activities—\$170 million—was allocated for State antiviral purchases for their State stockpiles. In June 2009, Congress approved and the President signed a supplemental appropriations act that included \$7.7 billion for pandemic flu preparedness, including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools and to assist international efforts and respond to international needs relating to the 2009–H1N1 influenza outbreak.³⁰ This amount included \$1.85 billion to be available immediately and \$5.8 billion to be available subsequently in the amounts designated by the President as emergency funding requirements. On July 10, 2009, HHS announced its plans to use the \$350 million designated for upgrading State and local capacity for additional grants to States and territories to prepare for the H1N1 pandemic and seasonal influenza. State public health departments will receive \$260 million, and hospitals will receive \$90 million of these grant funds.

An outbreak will require additional capacity in many areas, including the procurement of additional patient treatment space and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines for an influenza pandemic.³¹ In a severe pandemic, the demand would exceed the available hospital bed capacity, which would be further challenged by the existing shortages of health care providers and their potential high rates of absenteeism. In addition, the availability of antivirals and vaccines could be inadequate to meet demand due to limited production, distribution, and administration capacity.

The Federal Government has provided some guidance in addition to funding to help States plan for additional capacity. For example, the Federal Government provided guidance for States to use when preparing for medical surge and on prioritizing target groups for an influenza pandemic vaccine. Some State officials reported, however, that they had not begun work on altered standards of care guidelines, that is, for providing care while allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in mass casualty event, or had not completed drafting guidelines, because of the difficulty of addressing the medical, ethical, and legal issues involved. We recommended that HHS serve as a clearinghouse for sharing among the States altered standards of care guidelines developed by individual States or medical experts. HHS did not comment on the recommendation, and it has not indicated if it plans to implement it.³² Further, in our June 2008 report on State and local planning and exercising efforts for an influenza pandemic, we found that State and local officials reported that they wanted Federal influenza pandemic guidance on facilitating medical surge, which was also one of the areas that the HHS-led assessment rated as having “many major gaps” nationally among States’ influenza pandemic plans.³³

FEDERAL AGENCIES HAVE PROVIDED CONSIDERABLE GUIDANCE AND PANDEMIC-RELATED INFORMATION, BUT COULD AUGMENT THEIR EFFORTS

The National Pandemic Implementation Plan emphasizes that Government and public health officials must communicate clearly and continuously with the public throughout a pandemic. Accordingly, HHS, DHS, and other Federal agencies have shared pandemic-related information in a number of ways, such as through

²⁹ Pub. L. No. 109–148 and Pub. L. No. 109–234.

³⁰ Pub. L. No. 111–32.

³¹ Antivirals can prevent or reduce the severity of a viral infection, such as influenza. Vaccines are used to stimulate the production of an immune system response to protect the body from disease.

³² GAO, *Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit From Shared Guidance for Allocating Scarce Medical Resources*, GAO–08–668, (Washington, DC: June 13, 2008).

³³ GAO–08–539.

websites, guidance, and State summits and meetings, and are using established networks, including coordinating councils for critical infrastructure protection, to share information about pandemic preparedness, response, and recovery. Federal agencies have established an influenza pandemic website (www.pandemicflu.gov) and disseminated pandemic preparedness checklists for workplaces, individuals and families, schools, health care, community organizations, and State and local governments.

However, State and local officials from all of the States and localities we interviewed for our June 2008 report on State and local pandemic planning and exercising, wanted additional influenza pandemic guidance from the Federal Government on specific topics, on how to implement community interventions such as closing schools, fatality management, and facilitating medical surge. Although the Federal Government had issued some guidance at the time of our review, it may not have reached State and local officials or may not have addressed the particular concerns or circumstances of the State and local officials we interviewed. More recently, CDC has issued additional guidance on a number of topics related to responding to the H1N1 outbreak. CDC issued interim guidance on school closures which originally recommended that schools with confirmed H1N1 influenza close. Once it became more clear that the disease severity of H1N1 was similar to that of seasonal influenza and that the virus had already spread within communities, CDC determined that school closure would be less effective as a measure of control and issued updated guidance recommending that schools not close for suspected or confirmed cases of influenza.³⁴ However, the change in guidance caused confusion, underscoring the importance of clear and continuous communication with the public throughout a pandemic. In addition, private sector officials have told us that they would like clarification about the respective roles and responsibilities of the Federal and State governments during an influenza pandemic emergency, such as in State border closures and influenza pandemic vaccine distribution.

PERFORMANCE MONITORING AND ACCOUNTABILITY FOR PANDEMIC PREPAREDNESS
NEEDS STRENGTHENING

While the National Pandemic Strategy and Implementation Plan identify overarching goals and objectives for pandemic planning, the documents are not altogether clear on the roles, responsibilities, and requirements to carry out the plan. Some of the action items in the National Pandemic Implementation Plan, particularly those that are to be completed by State, local, and Tribal governments or the private sector, do not identify an entity responsible for carrying out the action. Most of the implementation plan's performance measures consist of actions to be completed, such as disseminating guidance, but the measures are not always clearly linked with intended results.

For example, one action item asked that all HHS-, Department of Defense-, and Veterans Administration-funded hospitals and health facilities develop, test, and be prepared to implement infection control campaigns for pandemic influenza within 3 months. However, the associated performance measure is not clearly linked to the intended result. This performance measure states that infection control guidance should be developed and disseminated on www.pandemicflu.gov and other channels.³⁵ This action would not directly result in developing, testing, and preparing to implement infection control campaigns. This lack of clear linkage makes it difficult to ascertain whether progress has in fact been made toward achieving the national goals and objectives described in the National Pandemic Strategy and Implementation Plan. Without a clear linkage to anticipated results, these measures of activities do not give an indication of whether the purpose of the activity is achieved. In addition, as discussed earlier, the National Pandemic Implementation 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. Moreover, the National Pandemic Strategy and its Implementation Plan do not provide information on the financial resources needed to implement them, which is one of six characteristics of an effective national strategy that we have identified. As a result, the documents do not provide a picture of priorities or how adjustments might be made in view of resource constraints.

³⁴ Centers for Disease Control and Prevention, *Update on School (K-12) and Child Care Programs: Interim CDC Guidance in Response to Human Infections with the Novel Influenza A (H1N1) Virus* (Updated May 22, 2009).

³⁵ Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* (Washington, DC: May 2006).

As discussed earlier, the National Pandemic Implementation Plan also required Federal agencies to develop operational pandemic plans to describe, among other requirements, how each agency will protect its workforce and maintain essential operations and services in the event of a pandemic.³⁶ We recently reported, however, that there is no mechanism in place to monitor and report on agencies' progress in developing these plans. Under the Implementation Plan, DHS was charged with this responsibility, but instead the HSC simply requested that agencies certify to the council that they were addressing in their plans the applicable elements of a pandemic checklist. The certification process did not provide for monitoring and reporting on agencies' abilities to continue operations in the event of a pandemic while protecting their employees. Moreover, even as envisioned under the Implementation Plan, the report was to be directed to the Executive Office of the President with no provision for the report to be made available to Congress.

As noted earlier, given agencies' uneven progress in developing their pandemic plans, monitoring, and reporting would enhance agencies' accountability to protect their employees during a pandemic. We therefore recommended that the HSC request that the Secretary of Homeland Security monitor and report to the Executive Office of the President on the readiness of agencies to continue their operations while protecting their employees in the event of a pandemic. We also suggested that to help support its oversight responsibilities, Congress may want to consider requiring DHS to report to it on agencies' progress in developing and implementing their plans, including any key challenges and gaps in the plans. The HSC noted that it will give serious consideration to the report findings and recommendations, and DHS said the report findings and recommendations will contribute to its efforts to ensure that Government entities are well-prepared for what may come next.

CONCLUDING OBSERVATIONS

The current H1N1 influenza pandemic should serve as a powerful reminder that the threat of a more virulent pandemic, which seemed to fade from public awareness in recent years, never really disappeared. While Federal agencies have taken action on many of our recommendations, about half the recommendations that we have made over the past 3 years are still not fully implemented. It is essential, given the change in administration and the associated transition of senior Federal officials, that the shared leadership roles that have been established between HHS and DHS, along with other responsible Federal officials, are tested in rigorous tests and exercises. Likewise, DHS should continue to work with other Federal agencies and private sector members of the critical infrastructure coordinating councils to help address the challenges of coordination and clarify roles and responsibilities of Federal and State governments. DHS and HHS should also, in coordination with other Federal agencies, continue to work with States and local governments to help them address identified gaps in their pandemic planning. Moreover, the 3-year period covered by the National Pandemic Implementation Plan is now over and it will be important for HSC to establish a process for updating the National Pandemic Implementation Plan so that the updated plan can address the gaps we have identified, as well as lessons learned from the current H1N1 outbreak. Finally, greater monitoring and reporting of agencies' progress in plans to protect their workers during a pandemic are needed to insure the readiness of agencies to continue operations while protecting their employees in the event of a pandemic.

Pandemic influenzas, as I noted earlier, differ from other types of disasters in that they are not necessarily discrete events. While the current H1N1 pandemic seems to be relatively mild, the virus could become more virulent this fall or winter. Given this risk, the administration and Federal agencies should use this opportunity to turn their attention to filling in some of the planning and preparedness gaps our work has pointed out, while time is still on our side.

Chairman Thompson and Members of the committee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

Chairman THOMPSON. Thank you very much for your testimony. I now recognize myself for 5 minutes of questioning.

Mr. CORR, if we had an outbreak of H1N1 tomorrow, do we have enough vaccine on hand now to address it or are we still short?

Mr. CORR. Mr. Chairman, we are taking all of the necessary steps to develop the vaccine, but it will not be available for use for several more months. Clinical trials at the National Institutes of

³⁶ GAO-09-404.

Health and among the vaccine manufacturers are now underway. We need the results of those trials to understand the level of dosing and the immune response, whether we are getting sufficient immune response. We also need further information about the virus itself which we are collecting in the southern hemisphere as well as in the States.

So we expect that we will be in a position to do a vaccination campaign if the decision is made to proceed with one in the September/October time frame.

Chairman THOMPSON. Thank you.

Dr. Lute, given the fact that we don't at this point have enough of the vaccine on hand, what plans has DHS put into place in the interim to address any potential outbreak?

Ms. LUTE. Mr. Chairman, as I mentioned in my opening remarks, there is a Federal plan for 2009 H1N1 that is in final stages of completion, as well as a Departmental plan within DHS. As was noted, all of the Federal agencies are themselves responsible for developing plans to continue to execute their mission responsibilities in the event of an outbreak.

Equally, State and local authorities, municipalities, have been engaged in planning and we have been providing them through FEMA planning templates and planning training and assistance to prepare for the coming fall.

Chairman THOMPSON. Thank you.

Now Ms. Steinhardt, in your review, you indicated that some of these National plans probably needed updating or, in some instances, were outdated. Did you make some suggestions to either DHS or HHS that they do this? If so, do you have any knowledge as to whether or not they have updated those plans?

Ms. STEINHARDT. Thank you, Mr. Chairman for your question. To our knowledge, they have not updated the plans. I am interested in Secretary Lute's comments about a Federal implementation plan that is in draft stage. We haven't seen that yet and so can't comment on it.

But I would say in the past when we have looked at the current version of the implementation plan and National strategy, we noted a number of gaps in what is included there.

But I would say that the most significant one was the fact that many of the action items in the plan were assigned to State and local governments, but there had been no consultation with State and local governments in the drafting of that plan. When we talked to some of them, some of the State and local governments, particularly at the local level, they weren't even aware that they had responsibility for any of the action items.

Chairman THOMPSON. Dr. Lute, could you provide the committee with a copy of this draft plan you talked about?

Ms. LUTE. Mr. Chairman, we will certainly share with this committee all of the preparations that we are undertaking. Let me just use this opportunity, if I might, to reflect on Ranking Member King's questions on lessons learned from the spring.

What we learned over the past several months is that several principles are operating here:

No. 1, rest on the science.

No. 2, planning is key.

No. 3, consistent communication across the Federal Government and between the Federal Government and State and local municipal authorities across public health sectors, public policy sectors, governmental sectors as well is also key. While we are not satisfied with progress to date, we can say with great conviction that a good deal of progress has occurred and we now have an elaborated matrix of action requirements across the Federal Government and between us and the State and locals to ensure that we are prepared for the fall.

Chairman THOMPSON. Thank you.

Mr. CORR, I am not certain, are you aware of some information that we have that some pages might have come down with H1N1-like symptoms?

Mr. CORR. I read that in the paper this morning, yes.

Chairman THOMPSON. But you don't have any knowledge beyond what you read in the paper?

Mr. CORR. I do not.

Chairman THOMPSON. Dr. Lute.

Ms. LUTE. Equally.

Chairman THOMPSON. Well, part of our dilemma as Members of Congress is we have been involved and potentially in contact with some of the people, and we have no knowledge of it other than reading it in the paper. I think part of the issue that Ms. Steinhardt's report goes to is we don't have a plan of informing people when potential situations like this exist.

Ms. Steinhardt, do you have any comments on what you think people in a situation like this at a minimum should be informed of?

Ms. STEINHARDT. Well, I can't speak, Mr. Chairman, to the specifics of this situation. But I do think it underscores the importance of having operational plans, plans at a sufficient level of detail so that when these kinds of situations arise, organizations, people within the organization know exactly what they need to do to follow up on that situation. It is not enough to just have something that is very high level.

Chairman THOMPSON. Again, this was brought to my attention in the newspaper, too. I thought it was kind of interesting that Members of Congress didn't have any way of being told of the situation or the Senate or what have you. The gentleman from New York for 5 minutes.

Mr. KING. Thank you, Mr. Chairman.

Secretary Corr, you said right now you are evaluating the virus. Is it too early to say how virulent it might be, to make estimates if it is going to be more severe than last spring?

Mr. CORR. Congressman, the experts at CDC are continuing to watch what happens in this country with regard to the spread and the virulence of the virus. We are watching very closely in the southern hemisphere, and so far it appears to have a similar pattern. In some places the disease has had a serious effect on individuals. In other places it has been mild, as it has been in the United States. The virus itself does not appear to be mutating which is important information.

But again, we are collecting information. We are just reaching the height of the southern hemisphere's flu season. So the short an-

swer is that there is a great deal of information that we will continue to collect that will inform the decision about whether to do a vaccination campaign here in the United States.

In the mean time, there is a great deal that every individual can do. One of the most important messages that I think we need to get out to the American people is that every individual, every family, every business, every school, has a responsibility to understand what they can do to mitigate the spread of the disease. It certainly is an issue for Members. As many people as you shake hands with and see every day, there is some very basic information that we need in everyone's knowledge base, which is wash your hands frequently, cover your nose and mouth with your arm and not with your hand when you sneeze or cough. If you have a fever or flu-like symptoms, stay home.

We need to get this message out. We are working daily with State and local health departments. We are developing communication plans that will continue to spread this word. There is a great deal of public information.

Mr. KING. Secretary Corr, along those lines, if and when a vaccine is being used, are you going to have rapid response teams ready to answer the questions that the public will have because I am sure we can expect rumors, some true, some false, conspiracy theories, and everything else. Are you going to be able to go after them right away and have answers for the public?

Mr. CORR. As best we can. We understand that it is critical for the public to trust the vaccines and the public health experts who are recommending them. We will do everything that we can to make sure that we have accurate information available for everyone.

Mr. KING. As far as lessons learned, as far as your two departments are concerned, do you feel that the level of coordination was sufficient? Can that be improved on? After, Ms. Steinhardt, I would ask if you would comment on what you think of the level of coordination during the last crisis, if you will?

Ms. LUTE. Thank you. From our point of view, the spring was an excellent example of very tight and close coordination from the leading public health agency in the Federal Government and the leading National incident management agency. From the very outset of the outbreak of H1N1 in the spring, we closely liaised with HHS to establish what the science was. Our aim jointly that we pursued at every level from the Secretaries on down to the working level was designed to create empowered individuals, capable communities, and a responsive Federal system to identify where the gaps were in our knowledge, to understand what were the responsible messages to be sending out, and to engage State and local tribal authorities at times on multiple times a day during the spring. So from our point of view, this coordination was important. It was emblematic. We have built on it over the intervening weeks to prepare ourselves for the fall.

Mr. CORR. I certainly agree with that. Given the speed with which the virus came upon us, we felt like at HHS, that there was outstanding leadership from DHS in coordinating all of our activities and integrating our science and public health experts into the decision-making process. Our two Secretaries were leaders in terms

of talking to the American people about what to expect. We felt like it was an excellent working relationship. We need to always build on it and we need to incorporate, as GAO has pointed out, our State and local and territorial and tribal partners. We need to incorporate the business communities in all of our plans going forward, and are attempting to do that.

I urge you to take a look at the CDC website at Flu.gov. There are extensive guidelines that are for different provider groups, businesses, individuals. We are trying to provide as much information as rapidly as we can. It is evolving as we learn more. But we are trying to provide guidance to the Department of Education. Our Departments are working very closely with the Department of Education so we give good guidance for schools for the fall.

Ms. STEINHARDT. I would say certainly looking at it from the outside, the coordination seemed to work very well at the beginning of the H1N1 outbreak. But I would point out that at the time, Secretary Sebelius hadn't been confirmed yet in her position so we just had at the beginning Secretary Napolitano leading the effort, as it were, along with obviously others in the two departments.

The pandemic itself, it hadn't reached pandemic proportions yet. It was not yet a severe outbreak, and so it didn't call on all of the resources that might be called on in a more severe pandemic situation. We still haven't tested that kind of scenario, and that still remains to be done.

Mr. KING. Thank you very much. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

Mr. Corr, for the sake of the information, once the vaccine is available, do you plan to make it available to the public free of charge?

Mr. CORR. The short answer is, yes; but let me just back up, Mr. Chairman, to say one of the big differences in this effort with this virus is that the decision to make a vaccine and the decision to use it have been separated. We are doing everything in our power to get a vaccine ready; and in the coming months, we will make the decision whether we should have a vaccination campaign. We expect there will be one, but that decision hasn't been made. It would be distributed free of charge. We hope in the distribution system, if there is insurance coverage—Mr. Chairman, let me back up and correct myself just a little bit.

There are still some key decisions like the feasibility of having private insurance that already covers vaccines to cover it. We are moving very quickly on trying to develop a distribution system since we will need a mixed distribution system, some through the private system and some publicly if we have to vaccinate a large number of Americans. So the feasibility of some aspects of the distribution system still have to be determined.

Chairman THOMPSON. Thank you very much.

The gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman. I thank the witnesses. I especially thank the staff members for the excellent material that has been accorded us. I have found it to be fascinating. I am moved by an indication and perhaps I should ask a question rather than make a statement.

Is it true that the United States of America has more cases recorded than any other country? Is this true?

According to what I am looking at, we have 40,556, and that makes us about 40 percent of all of the known cases on record.

Mr. CORR. Congressman Green, between the United States and Mexico, you have the vast majority of confirmed cases. But let me point out that the CDC estimates that there may have been a million Americans exposed to H1N1. So the number of confirmed cases is a fraction of what we actually expect has happened.

Mr. GREEN. With 40,000, that gives us about 40 percent of the known cases, and it appears, and I would be tempted to ask a question, is it true that we have the most deaths reported? My intelligence indicates that we have 263 which appears to be half of all of the known deaths; is this true?

Mr. CORR. The latest CDC numbers are 302 deaths in the United States as of July 24. Let me just ask. This is Dr. Nicole Lurie, who is the Assistant Secretary for Preparedness and Response and has some of the individual numbers. We will get that for you.

Mr. GREEN. Listen, let me just say this to you, I have been where you are, and I have had to look back too, and I appreciate that.

Mr. CORR. Thank you. I want to get you accurate information.

Mr. GREEN. I am asking because while we have more population, we don't have more than China or India. We don't have more than a lot of other places in the world, and when we are 40 percent of all of the known cases in the world and half of all of the known deaths in the world, that causes me to pause and ask what is happening here in the United States?

Mr. CORR. Congressman Green, we also have the finest surveillance system in the world, and I think we have a great deal more knowledge about what is happening among our citizens.

Let me point out to you that in a normal flu season, 36,000 Americans die from seasonal flu, including 500 to 1,000 children. So the regular seasonal flu takes a huge impact on our population. That is why we are so concerned about H1N1, because it is a novel virus and could potentially do greater harm.

Mr. GREEN. I would assume that we are concerned because of the possibility of simultaneous infections that will lead to mutations?

Mr. CORR. That is the reason we are doing enhanced surveillance in the southern hemisphere. What can happen with a virus, as it moves to the southern hemisphere during their flu season is it can mutate and come back to the United States in a more virulent form. We are tracking it as carefully as we can to understand whether that is happening. So far it doesn't appear that it is, but we won't have final conclusion until we get further into the southern hemisphere's flu season.

Mr. GREEN. Just one final question. The magnitude of this, we don't want to overexaggerate. We want to make sure that we maintain a level of understanding such that the public won't panic. It is important not to panic. But by the same token, it is important to understand the magnitude of what we may be confronting. I have a little bit of concern when I read the report that I have about the possibility of mutation and the impact of a mutated virus and also when I look at how we have handled this thus far. Just do this for me, when do you think we will know, have some idea as to

whether the current vaccines that we have will be efficacious as opposed to having to deal with a mutation that may create another dynamic that we need not discuss?

Mr. CORR. I will correct this for the record if I need to, but I think the clinical trials will occur over the next 2 months. But I think in the next month, we will have additional information about the type of vaccine that we would use. Within the next 2 months, we will have a great deal more information about the actual virus itself and whether it has mutated as it had moved from the southern hemisphere back to the United States.

Mr. GREEN. Thank you. I yield back the balance of my time.

Chairman THOMPSON. I recognize Mr. McCaul from Texas for 5 minutes.

Mr. MCCAUL. Thank you, Mr. Chairman.

So the strain we see today when seasonal flu season hits, it more likely than not will be a different type of influenza; is that correct?

Mr. CORR. That is correct.

Mr. MCCAUL. So the challenge will be to predict what the mutations will be, like you do with the influenza vaccines every year; is that correct?

Mr. CORR. That is precisely the case.

Mr. MCCAUL. I am concerned about this going into even a more deadly strain and what DHS and HHS has planned to deal with that. One is obviously the vaccine, trying to predict that, and the other issue would be the antivirals. Would the antivirals we have today be effective on a mutated strain?

Mr. CORR. Well, we know that the antivirals we have today are effective against H1N1. I am not probably in the best position to answer the question about if there are mutations, but we can certainly get that information for you.

Mr. MCCAUL. Just hypothetically, if it mutates into a strain that the vaccine cannot deal with or cover, we obviously would be looking at another vaccine and then the reliance on these antivirals would increase; is that fair?

Mr. CORR. Yes. We would have to rely also upon community mitigation practices. It would involve encouraging people not to form in large groups. It may involve closing schools. The guidance as to when to consider closing schools is being written and will be available. Individual practices are so important under those circumstances. Businesses will have to plan. All of these things need to happen if we go forward with H1N1; and certainly if there is a variation on H1N1 as it comes back, it would be even more important for those practices to be followed.

Mr. MCCAUL. Where are we right now with the stockpiling of these antivirals? I know that the National strategy relies on the States to purchase these, and maybe 31 million courses of treatment. The States have not purchased that amount yet; have they?

Mr. CORR. My understanding is that we have roughly 35 million courses of treatment which is a full course among the States now. An additional—the total is somewhere between 75 and 100 million total courses available through the Federal Government and the State governments.

Mr. MCCAUL. Do you feel that we have an adequate supply stockpiled to deal with this if the vaccine is not successful?

Mr. CORR. Our public health experts believe that for the virus as we now project it, that we have sufficient antivirals. We have the manufacturers working full speed on antivirals, and we have purchased the capacity to develop the vaccine so we have moved ahead to make contracts to be sure that we have the manufacturing capacity committed to us to make the necessary medicines and vaccines.

Mr. MCCAUL. When you look at mutations, and I am not an expert in this area but you are, but as we look at mutations, is it typical to look at, say, Latin America as they are dealing with their different change of seasons from ours and then it moves up north?

Mr. CORR. It is across the entire southern hemisphere, in South America. We are looking in South Africa and Australia. Basically it is the flu season in the southern part of the world where we are looking because the virus moves to the colder climate, and then as it turns colder here, it is back in the United States.

Mr. MCCAUL. So it is safe to say that when we hit the fall, we will have an increase in cases of H1N1?

Mr. CORR. We expect we will; and we expect we will also have seasonal flu circulating at the same time.

Mr. MCCAUL. What we have seen happen in terms of the colder climates, this influence of virus has not mutated in any significant way?

Mr. CORR. So far.

Mr. MCCAUL. That is the good news.

Mr. CORR. It certainly is.

Chairman THOMPSON. The gentleman from Pennsylvania for 5 minutes.

Mr. CARNEY. Thank you, Mr. Chairman.

My question goes back to the planning aspect also. How are you employing the universities for the regional bio labs that exist, or are you for this?

Mr. CORR. There is a network of universities that work with the NIH in our clinical studies, and the NIH has extensive experience in vaccine research and they are employing all of the resources that we have across the country to conduct the necessary trials and to collect as much information as we can as we go forward to make the decision about a vaccination program.

Mr. CARNEY. Are those research labs, biocontainment labs part of a surge capacity? Ms. Lute.

Ms. LUTE. We are relying on the National labs for modeling information, and I think it is fair to say that we are jointly with HHS and with the other parts of the Federal family working very hard to mobilize the very best resources this country has to offer in order to fully anticipate how this virus will reoccur in the United States and be attentive and responsive if it does mutate. We are anticipating a number of scenarios. Again, we are in constant touch across the Federal agencies with State and local authorities with these sources of expertise to be sure that the very best knowledge is deployed to keep Americans safe.

Mr. CARNEY. Respectfully, we spent \$250 million on these regional biocontainment labs, and the upkeep hasn't been there. Are they going to be ready to go if we need them? Is there a way to make sure that we can continue to fund them because the upkeep

hasn't been there? Are you planning on doing an investigation into their levels of readiness should they have to surge? Are you talking about perhaps a competitive grant program for them to ensure that they can meet the standards that we expect, that were intended?

Ms. LUTE. A process of readiness and preparedness for the fall, it ranges across all of the capabilities that will be required. We know that facilities are important, a important component of that.

Mr. CARNEY. That is not the question.

Ms. LUTE. We are doing everything that we can to ensure that we will be ready for the fall.

Mr. CARNEY. Okay. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

The gentleman from Louisiana, Mr. Cao for 5 minutes.

Mr. CAO. Thank you, Mr. Chairman.

This is a question to the panel. Besides incapacitating the work force, what other Homeland Security issues do you anticipate from the H1N1 virus?

Ms. LUTE. Among the issues that we are looking at is how State and local authorities, municipal authorities, are able to respond to the challenges that they face across public health, emergency response. Are there medical centers that they have and the critical infrastructure that sustains those medical centers? Have they done adequate planning? Are they doing adequate cross communication and talk? Are we aware of what weaknesses and gaps may exist? Are we taking appropriate action to fill them?

Secretary Corr mentioned the importance of schools. Schools are a particular source of incubation and transmission for H1N1. We know that. We are working very closely with the Department of Education and CDC to ensure that responsible guidance is formulated and disseminated in a timely way.

So in every dimension of public health, Secretary Corr can speak to, but emergency management and public policy response, we are paying attention.

Mr. CAO. Is there a possibility that the H1N1 virus can be turned into a weapon?

Ms. LUTE. There are scenarios under which biological agents naturally occurring or occurring through man-made processes can be weaponized; but we have no indication in the current circumstance that anything regarding the H1N1 outbreak in the United States, or as it has unfolded in the hemisphere is, in any way, associated with that.

Mr. CAO. Are the amounts of funding that you have received, are they sufficient to help your agencies coordinate with the State and local governments in connection with the H1N1 virus?

Mr. CORR. Congressman, the supplemental funds that we have received, as I mentioned in my opening statement, a portion of those, \$350 million have been granted to State and local government as well as to hospitals for preparedness planning. So that is the initial sources of funding that are going out. CDC is providing extensive guidance to State and local and territorial health departments, as well as Tribal governments, and we are working closely with them.

Mr. CAO. A district like mine, 80 percent of the city post-Katrina lacks a health care system and possibly medical providers to ad-

dress a pandemic. How would Homeland Security and the different agencies address areas that are in tremendous need like New Orleans?

Mr. CORR. May I just say initially in terms of the distribution of a vaccine if we were to conduct a vaccination campaign, one of the reasons for a mixed distribution system is to provide public health department sites so that individuals who don't have a regular provider, or if there is an inadequate number of medical providers, there is a place where all individuals would be able to go to get vaccinated.

Mr. CAO. Thank you very much.

Chairman THOMPSON. Thank you very much.

The gentleman from New Mexico, Mr. Luján, for 5 minutes.

Mr. LUJÁN. Thank you, Mr. Chairman.

Mr. Chairman, before I begin with my questions, in regards to the committee markup of H.R. 1881, the Transportation Security Workforce Enhancement Act of 2009, I ask unanimous consent that the record for the markup reflect that I would have voted "yea" on the question of adoption had I been present.

Chairman THOMPSON. Hearing no objection, so ordered.

Mr. LUJÁN. Mr. Chairman, thank you very much for this very important hearing.

Mr. Corr, did I hear correctly that as we are preparing for this, that one of the things that has been looked at on how we will deliver some of the antiviral medication necessary to be distributed to people will be if their health insurance allows for it to be paid for?

Mr. CORR. The question involved the vaccine distribution system. If we were to do a vaccination campaign that covers hundreds of millions of Americans, which is one possibility, the question is how we do that in a timely fashion? The expectation is that we would want to distribute it to providers, but also through public sites so that we can be sure that the priority groups that need the vaccine first receive it; and, secondly, so we actually reach the Americans that we need to.

One of the issues we will have to deal with is we have the funds to pay for that vaccine, but to the extent that private insurance covers it, the decision would have to be made about whether to have the insurance companies cover that particular shot. The first and most important aspect of this is to get people vaccinated. If people go without vaccination, they may be exposed to H1N1 and become sick and expose others. So it is first and most important that we have a vaccination campaign, and those decisions will be made in that context.

Mr. LUJÁN. So in that situation, Mr. Corr, it sounds like the more people we have covered, the better off we will be?

Mr. CORR. I think that is always the case when it comes to health care.

Mr. LUJÁN. Interesting.

My next question is for Dr. Lute. In regards to H1N1, earlier in the year there was attention brought to the fact that Los Alamos National Laboratory and Sandia National Laboratory have in place a National Infrastructure Simulation and Analysis Center. I know some work was done in order to collaborate with them from a mod-

eling perspective and preparation for what we could anticipate with this pandemic. What is the Department doing to work with our laboratories in utilizing NISAC and other resources to allow us to get out in front of this and continue to see what we can do from a preparedness perspective?

Ms. LUTE. Preparedness, as I mentioned, is a key concern of ours. To the extent planning and good modeling can inform planning, not only for how the virus will unfold and potentially spread in a community, there is a certain degree of unpredictability to this. This virus has a degree of virulence which is uneven, as we have come to understand it. So working very closely with the labs on the modeling and the entire environment of biosurveillance is key. As I mentioned earlier, we will rest on the science in making policy recommendations to State and locals.

Mr. LUJÁN. In regards to preparation, getting the word out, coming from a border State, I hope that we are preparing in multiple languages, including Spanish. The district I represent represents many native nations, and so I hope that is being considered as we prepare in that regard.

Speaking to that specifically with our tribal nations, what is being done to specifically coordinate with them and how can that be improved?

Ms. LUTE. From the perspective of the Department of Homeland Security, we have engaged in extensive coordination. We have had weekly conference calls continuing from the spring experience that we have had. We send out e-mail updates. The flu summit, as I mentioned earlier, involved State and local authorities, and urging them to put the word out. There will be webcasts in August. FEMA is engaging at a regional level to provide additional information and guidance for State and local plans. In addition, we are putting out teams specifically focused on pandemic preparedness to ensure that we are aware of gaps or problems that exist at the earliest opportunity.

Mr. LUJÁN. Mr. Chairman, I would just close bringing our attention to one of the points that staff put in our report, which is that we need to drive to make every effort to do what we can now to save as many lives as possible in the future, and I think that should include now and in the future, Mr. Chairman. I think that it is important that we keep our eye on that ball.

Chairman THOMPSON. I agree with you. The gentleman from New Jersey for 5 minutes.

Mr. PASCRELL. Mr. Chairman, may I simply start by saying that I think our committee should ask, and I am asking and if you think it is not in order—

Chairman THOMPSON. Excuse me, Mr. Pascrell. Mr. Olson is next for 5 minutes. I hope the gentleman from New Jersey forgives me for that.

Mr. OLSON. Thank you all for coming today. I have a question for both Secretary Lute and Secretary Corr. About this time last year in September, my region was hit by Hurricane Ike which devastated much of the region and had a particular impact on some of the health care aspects, particularly the University of Texas, Galveston's medical branch. It basically was lost. They opened up their level 3 trauma center just this past week. They had been a

level 1 before. We are under siege again. August and September are historically the big months when the strong hurricanes come through.

If we had the misfortune of having a category 3, 4, or 5 hurricane come hit the Texas Gulf Coast while we are in the middle of some sort of pandemic, H1N1, have you done the planning and do you have the resources to make sure that you can respond to both of those so that the pandemic doesn't run out of control?

Mr. CORR. Congressman, you raise a very, very important question which we have asked ourselves. What the Department has done is go through our hurricane preparedness planning in every aspect and ask ourselves the question if we are in the middle of an H1N1 outbreak, how does it change what we need to do? How do we move patients? Where do we put individuals?

The one thing you don't want to do in an H1N1 outbreak is collect lots of people in a small room, but that may be all we can do to move people out of the way of a hurricane. All aspects are being gone through thoroughly. We meet regularly with our State preparedness and emergency manager coordinators. So we will be working closely with them. We will be discussing this very situation, and we will provide extensive guidance before we get to flu season here again so we are in a comfortable position that we know how to act in the case we have an outbreak at the same time.

Mr. OLSON. Secretary Lute.

Ms. LUTE. What I would say is that the health and safety of citizens in a circumstance where we would have multiple issues to deal with of a significant traumatic nature for a community are very much on both of our minds. This is part of the contingency planning that we are doing. FEMA, at the outset of the hurricane season, convened a meeting of governors of States where hurricanes routinely hit during the hurricane season to advise them of preparedness measures, changes from procedures and issues to make them more aware of the hurricane dimension of that. In the context of that meeting, which I attended, and the Secretary did as well, the H1N1 virus and its reappearance was raised as well. As I mentioned, we have been in weekly contact, sometimes daily contact on these issues, to ensure preparedness, and we are thinking about the contingencies that you have raised.

Mr. OLSON. Thank you very much for that answer.

One question about the liability, and that is for you, Secretary Corr: Can HHS ensure us that the liability issues are being addressed concerning the administration of a new vaccine so the health care workers are provided the coverage and will participate in the vaccination programs and won't be worried about the liability?

Mr. CORR. My understanding is that current law protects them.

Mr. OLSON. Thank you very much, Mr. Chairman. I yield back the balance of my time.

Chairman THOMPSON. Now the gentleman from New Jersey, Mr. Pascrell. We have about 4 minutes left on the vote.

Mr. PASCRELL. No problem, Mr. Chairman.

Mr. Chairman, I am going to be asking for unanimous consent from both sides. We have heard some very startling testimony today from GAO. Every time you come here it is startling.

I think that we should ask both Departments, who I have a great deal of respect for, that they respond to all of the concerns and recommendations laid before us today within the next 3 months. I ask unanimous consent for that request, Mr. Chairman?

Chairman THOMPSON. Without objection.

Mr. PASCARELL. Thank you.

Mr. Chairman, there are some concerns about whether Stafford Act disaster assistance is applicable here. Will the Department retain the FEMA disaster assistance policy on influenza pandemic which was issued in 2007?

Ms. LUTE. Congressman, what I can say is that the Stafford Act may be invoked under certain contingencies, and as may arise in the fall with the pandemic, and we plan for those contingencies and are prepared to respond appropriately.

Mr. PASCARELL. I just wanted to get you on the record for that. I think that is very critical to what we are talking about today.

My next question is to both you, Dr. Lute, and Mr. Corr. Can you tell me, the replenishing of the 11 million antivirals in the Strategic National Stockpile, was that a one-time act or do you view it as the standard operating procedure as the Federal Government moves forward in facing the threat of H1N1 in the coming months?

Chairman THOMPSON. We have 2 minutes left in the vote.

Ms. LUTE. Certainly from the perspective of the Department of Homeland Security, maintaining a current and effective stockpile is essential. That is an on-going process.

Mr. PASCARELL. So this is going to be a regular practice?

Mr. CORR. Certainly the purpose of the stockpile is to have it ready and available in the event it is needed.

Mr. PASCARELL. That may be the purpose. But I want to hear from you that this is going to be regular procedure and that this is not simply a one-shot deal. That is my concern.

Mr. CORR. The Department of Health and Human Services certainly values the Strategic National Stockpile and hopes that it will stay full.

Mr. PASCARELL. My final question is what do you tell mothers and fathers about what they should be telling their kids about this particular virus we are talking about today?

Mr. CORR. They should make getting the vaccination, if it happens, something that children view as, and I have got children and I am not sure how you make it fun to do, but you have to impress upon them the importance of it. Because I think they are going to hear about it in school. They are going to hear about the things they need to do depending upon their age, so I think we need to have a broad public discussion about this if we are going to succeed in our efforts.

Chairman THOMPSON. Thank you very much. The committee will recess to take three votes. It should be about 20 minutes.

[Recess.]

Chairman THOMPSON. We would like to reconvene our recessed meeting. We have been told that we have about an hour before the next series of votes.

At this point, our gentlelady from New York, if she has any questions, while she is getting ready, a comment came to mind for the panel relative to the vaccine that we talked about a little earlier

and the question continues to be, when we have reached the critical number that the Department is comfortable with, will the Department look at some distribution process that would allow the immunization to occur; or is your testimony, Mr. Corr, that that is still being looked at?

Mr. CORR. Mr. Chairman, one of the important lessons learned in 1976 with the previous swine flu vaccination program is that it is important to separate the decision to make a vaccine from the decision to use it. We have made the decision because we have to in order to have the vaccine manufactured as quickly as possible, to go forward with the manufacturing.

But the decision to start the vaccination campaign will benefit from the additional information we can collect. If you ask us—Do we expect there will be a vaccination campaign?—I think the answer is yes. But the decision needs to await additional information that we will collect in the Southern Hemisphere and in the United States. That decision will be made soon.

Chairman THOMPSON. Thank you very much.

I hope the point Mr. Pascrell made was not overlooked. It is the committee's intention, based on GAO recommendations, for some 3-month period of time, if at all possible, for you to fully implement the recommendation. If not, the expectation is you would indicate back to the committee which ones you are unable to accomplish.

The gentlelady from New York for 5 minutes.

Ms. CLARKE. Thank you very much, Mr. Chairman.

Thank you, Ranking Member.

This examination of the current status of H1N1 is so very important right now. We are still hearing of occurrences not only in our Nation, but around the world; and so it is very timely that we address this now, particularly before we go into our recess and come back towards the fall.

My question to both you, Mr. Corr, and to you, Dr. Lute, has to do with the sale and movement actually of counterfeit pharmaceuticals across our borders.

As you know, the sale and movement of counterfeit pharmaceuticals across our borders into the United States is a growing problem, and both of your agencies have been involved in investigating cases involving these counterfeits, the FDA under HHS and ICE of the DHS.

Can you talk about what the FDA and ICE, as well as CBP, are doing to address counterfeit vaccine for H1N1 as well as counterfeit antivirals and other medications that make unsubstantiated claims to treat H1N1 influenza illness?

Ms. LUTE. I might just begin by underscoring what you know already to be true about the role of ICE in investigating any suspected cross-border engagement of counterfeit pharmaceuticals. This is very much a contingency that we are aware of.

We recognize that there are certain incentives for groups to profit from what we expect to be a major national incident, come the fall; and we are very vigilant on that and working together with our colleagues throughout the system to be sure that we have complete—as complete as possible surveillance and detection and interdiction and disruption and proper law enforcement accountability, should that circumstance arise.

Mr. CORR. Congresswoman, I think that is a complete answer certainly as far as the Food and Drug Administration and HHS are concerned.

Ms. CLARKE. I think that our vigilance is really going to be important here, and unfortunately, there are those out there who would exploit a situation like this. We already know that in many instances, there is a big profit to be gained from counterfeiting, and we just want to make sure that our population is well-protected.

So we look forward to any finding that you may have about any developments, any cooperation that you would be getting from any of our partners across the border about any instances that they may have encountered as they are beginning to deal with the flu season in their respective areas.

My next question is about science and technology challenges.

The committee is always on the lookout for new technologies that will help us address the threats facing this Nation. But I am kind of disappointed to see that we have not made further progress in getting beyond the use of egg-based technologies for vaccine production, still depending on that technology for the H1N1 vaccine this time around. However, I am heartened that the administration is supporting the development of new technologies to create new vaccines, diagnostic tests, et cetera.

Mr. CORR, could you tell us about the contract that HHS has with Protein Sciences Corporation to develop its technique for making influenza vaccines by growing flu virus proteins in insect cells?

Dr. Lute, please discuss what DHS is doing to support information via its Science and Technology Directorate.

Ms. CLARKE. Congresswoman, as you point out, the resources of the Department, our advanced research resources, have focused on developing new methods of making vaccines and other products. I can't speak to you off the top of my head about that particular methodology. We will get that information for you.

But rest assured that we recognize that using egg-based technology is not as efficient and as productive as we need. As we move forward with this, it is a very important aspect of our advanced development program to find other development technologies that will produce more vaccine and at lower prices.

Ms. CLARKE. Thank you.

Ms. LUTE. I would only add, Congresswoman, that we work very closely with HHS and Science and Technology, along with personnel and partnerships, forms the backbone of the Department of Homeland Security's response to all risks and hazards that the country faces.

While HHS has the lead on the medical side and the scientific side, we are certainly attentive and alert to technologies that enhance our ability to understand how risks are approaching our shores, how we can more effectively communicate the necessary actions people need to take. We will stay in close coordination with our other colleagues, especially HHS, as this season unfolds.

Ms. CLARKE. Thank you very much.

Thank you, Mr. Chairman. I yield back.

Chairman THOMPSON. Thank you very much.

The Chair now recognizes the gentleman from Florida, Mr. Bili-rakis, for 5 minutes.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman. This question is to for Deputy Secretary Lute, Deputy Secretary Corr.

In his written testimony, Mr. Farley, New York City's Health Commissioner, stated the majority of individuals who die each year in New York City from influenza are over the age of 65. As you may know, my district in Florida is home to a significant elderly population, and the H1N1 strain of influenza is particularly virulent.

How are you, how are your Departments working with the State and local governments to provide outreach and information to elderly and other special needs populations? What recommendations are you making to State and local governments as they work to prepare these populations? Who should be vaccinated?

That is the question for the two of you. Thank you.

Ms. LUTE. Mr. Chairman, with your permission, perhaps I will begin as reaching out to State and local authorities and municipalities.

From the very beginning, in the spring when this virus presented itself, this was recognized by the Department, by the Federal Government, as an important aspect of mobilizing any national response to this virus; in other words, that we needed to have the Federal Government tightly connected to State and local authorities to ensure that the best information based on the best science was put out in as timely a way as possible, and that we had plain language guidelines that people could follow. CDC and HHS have worked tirelessly to improve the websites and to improve the content of the information and the substance that is being put out to the public.

As I mentioned earlier, we have been giving daily e-mail updates, twice weekly conference calls to the private sector, which represents an important component of community life, we recognize; weekly conference calls, e-mails, updates to State and local authorities, a flu summit that was conducted so that people were aware of the best knowledge that we had at the time. A webcast is planned for August, and FEMA has been making available planning templates and planning training as well.

Mr. CORR. Congressman, I would just add that one of the challenges this flu season is going to be that we expect seasonal flu to be circulating at the same time that H1N1 is. From an elderly person's or a senior citizen's perspective, H1N1, at least so far, appears to be more severe among younger people, among children and younger people that have other underlying conditions. It doesn't seem to be as severe in senior citizens. It may be because of some partial immunity developed from the swine flu in 1976 or earlier flus that they were exposed to.

This just points up, though, the incredible importance of communicating clearly to the public through our work with the State and local and Tribal and territorial health departments, as Secretary Lute was saying, so that people understand how important it is to get their seasonal flu shot and to get their H1N1 shot.

So we will be endeavoring to make sure the public understands what they need to do.

Mr. BILIRAKIS. With regard to the younger people, my State's acting epidemiologist has said that as many as 5 million Floridians

could contract the H1N1 virus within the year if the virus follows the pattern of previous pandemics. There have been at least 22 deaths in my State of individuals who had the H1N1 virus. I am especially concerned that the number of cases in Florida will skyrocket when schools begin in the fall.

Since this virus has disproportionately, as you said, affected school-age children, would each of you please comment on the following questions:

What recommendations should we provide parents of school-age children in my district about how to protect their children from this virus;

Should children with this virus stay home from school;

Should school administrators close schools;

Which schools have become infected with this virus; and,

Are there uniform recommendations about how long schools should remain closed under such circumstances?

If you could address those—one more—what Federal Department or Agency is the lead authority when it comes to such guidance?

Thank you very much.

Ms. LUTE. Again, Mr. Chairman, with your permission, I might just begin in response.

The issue of schools and school closures was one of the things that we learned during the spring. This is, as you rightly point out, a source of quickly spreading the disease among—the virus among young people. So we are very aware of the importance of getting good guidance out, again, based on the principle of the best scientific knowledge and evidence.

We are in the process of formulating, with the Department of Education and our colleagues from CDC and Health and Human Services, that guidance, so that it can be promulgated and that school administrators can have a plain-language—access to plain-language instructions for making those decisions on a school-by-school and municipality basis.

Mr. CORR. Congressman, I would just add that it is very important for parents to explain to their children some basic steps they can take that will protect them. It is the same instructions, really, for all of us, which is that if you are coughing or sneezing, you cough into your arm; that if you are sick, you stay home, that you wash your hands frequently; do not touch your eyes, nose or mouth. Those basic steps can make a huge difference in the transmission of the virus.

Having said that, the guidance that Secretary Lute talked about and worked with the school systems are very important for them to understand what steps they should take as the exposure to the virus spreads.

Chairman THOMPSON. The gentleman's time has expired.

The gentleman from Texas, Mr. Cuellar, for 5 minutes.

Mr. CUELLAR. Thank you, Mr. Chairman. This question is to Dr. Lute and Mr. Corr.

How has the pandemic influenza National planning scenario informed you of your plans and response efforts, question No. 1? The second part is, have your agencies considered how a pandemic could be taken advantage of by terrorists and how do you respond under that particular scenario?

Ms. LUTE. With your permission, Mr. Chairman, I will begin.

The National scenarios provide a basis and a foundation for understanding how to approach with best planning needs and understanding the gaps that exist in the state of our National preparedness to deal with this.

We have learned a lot, I would like to underscore, Mr. Chairman, about this pandemic and how we could—we should respond to it, the state of readiness that exists in the Federal Government, at the State and local level, what knowledge gaps exist and what tools are necessary so that individuals can be empowered, communities can be capable of dealing with the scenarios that may unfold, and the Federal Government is responsive to meet their needs.

We have also—in the Department of Homeland Security we remain vigilant every single day about the potential for terrorists to exploit any set of circumstances which they may perceive as a vulnerability. This virus will not represent a vulnerability for terrorists to exploit. This is a circumstance, it is a public health circumstance; it is Nation-wide.

It is unique; we are taking, in some cases, unique measures. For example. We are deploying regional coordination teams which will focus on pandemic preparedness and response to allow the other elements of the Homeland Security family to be able to focus on their responsibilities in maintaining vigilance and leading the American effort to protect ourselves.

Mr. CORR. Congressman, I would just add that looking back at the preparedness planning that has gone on, as the GAO did, is very helpful in recognizing where we still have gaps. But we are learning first-hand a great deal about how to prepare for and implement our plans. I think that as we work our way through this, we are going to be able to substantially enhance and improve our long-term planning for pandemics of other types.

Mr. CUELLAR. Thank you.

Dr. Lute, let me focus on Customs Border Protection folks, which are the men and women in blue, as you know, on the border area. If they don't have a sufficient—well, let me ask you, let me put it this way.

Are they sufficiently qualified to determine who might display symptoms of a particular illness, No. 1?

No. 2 is, what protection are we giving to those men and women at the border?

Ms. LUTE. Congressman, these extraordinary men and women who police our borders and provide the protection and the secure borders that the American people have a right to expect conduct screening of individuals every day as they cross. They are not medical doctors, equipped with the expertise that doctors do have to be able to specifically identify symptoms and the underlying condition which may give rise to those symptoms. But we have a very close working relationship with CDC, as you know, so that when individuals are identified that may present particular symptoms and conditions, they can be referred for additional screening and appropriate action as necessary.

Mr. CUELLAR. I do understand that they are not M.D.s. I do understand that you have got resources. But I guess my question is, what sort of training have they gotten to identify those symptoms?

Ms. LUTE. We have conducted training of the Customs Border as well as our Transportation Security officers on H1N1, the symptoms that present themselves. It is important to recognize that the virus can be present and a person can be asymptomatic for a period of time. Again, we rely on medical advice and assistance for this purpose.

But we screen every day, and we are adding this information to their skill set as they perform their duty.

Mr. CUELLAR. Thank you, Dr. Lute.

Mr. Corr and Ms. Steinhardt, I appreciate what you do at the GAO with the strategic work. Thank you.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

I would like to thank our first panel of witnesses for their valuable testimony and Members for their questions. Before being dismissed, I would remind our first panel of witnesses that the Members of the committee may have additional questions for you, and we ask that you respond expeditiously in writing to those questions.

I would like to ask the clerk to prepare the witness table for our second panel of witnesses; and again, thank our first panel of witnesses for their very valuable testimony.

We have been told that we have another series of votes, and I am going to try to get through the witness statements first, and then we will come back to questions and we will go right into the questions.

I would like to welcome our second panel of witnesses. Our first witness, Ms. Colleen Kelley, is president of the National Treasury Employees Union.

Our second witness is Mr. Richard Muth. Mr. Muth is director of the Maryland Emergency Management Agency.

Our third witness is Dr. Mark Horton. He serves as the California State health officer and as the director of the California Department of Health.

The fourth witness is Dr. Thomas Farley. Dr. Farley is health commissioner for New York City.

We thank our witnesses for their service to their States and to the Nation and for being here today. As previously stated, each witness's full statement will be inserted in the record. I now ask each witness to summarize his or her statement for 5 minutes, beginning with Ms. Kelley.

STATEMENT OF COLLEEN M. KELLEY, PRESIDENT, NATIONAL TREASURY EMPLOYEES UNION

Ms. KELLEY. Thank you very much, Chairman Thompson and Ranking Member King and committee Members. I appreciate the opportunity to testify on behalf of thousands of employees represented by NTEU, who work every day to protect our country from threats and who have continued to do their critical work diligently during the on-going H1N1 flu outbreak.

This outbreak has raised serious concerns about how the Federal Government creates and communicates policies to protect the health of front-line Federal personnel. Most troubling to NTEU is that key stakeholders, including Federal employees and their em-

ployee representatives, are not consulted in the development of pandemic response strategies. We have not had the opportunity to participate in the development of or comment on the November, 2005 National Strategy for Pandemic Influenza and the May 2006 Implementation Plan.

NTEU commends you, Mr. Chairman, for recognizing this glaring weakness in the committee's January 2009 report *Getting Beyond Getting Ready for Pandemic Influenza* and for calling on the new administration to address this shortcoming.

The NTEU members at the Department of Homeland Security most affected by the outbreak of the H1N1 influenza are Customs and Border Protection officers and agriculture specialists who work at the land, sea, and air ports of entry and Transportation Security officers who work at the airports. Both groups of employees interact with thousands of travelers in a single shift. Their work includes reviewing immigration documents, wanding passengers, questioning them and sometimes patting them down or detaining them. It requires them to be within 6 feet of the travelers that they process.

The CDC's general guidelines of avoiding crowds and maintaining a distance of 6 feet from those exhibiting illness is clearly not possible for these DHS employees who are at increased risk of exposure. Specific guidance must be developed and communicated clearly and in writing to them.

For the past 3 months, NTEU has repeatedly requested clear, written guidance from DHS with respect to the voluntary use of personal protection equipment, including N95 masks for these front-line employees at CDC and TSA. Because of the Agency's reluctance to issue clear and written voluntary use guidance, NTEU worked with Congress on this critical subject. On June 4, the full House approved an NTEU-supported amendment to the TSA Authorization Act that requires TSA to allow personnel to voluntarily wear PPE during an emergency.

House appropriators also added NTEU-supported language to the fiscal year 2010 DHS appropriations bill, which ensures that DHS personnel may voluntarily use PPE, including masks, without being subject to discipline. We appreciate this committee's support on these efforts and its continued focus on pandemic preparedness, particularly with regard to the impact on the Federal workforce.

NTEU believes that congressional involvement has helped to move Homeland Security to begin to clarify and communicate its guidance. On May 29, TSA issued policy guidance on PPE that is clear and allows TSA's discretionary use of the N95 masks; but the May 29 TSA guidance was not initially shared with TSA employees, and according to our Members, was only recently distributed to TSA personnel, just 10 days ago. This delay in publicizing the TSA PPE voluntary use guidance is very troubling.

With respect to PPE guidance at CBP, after initially prohibiting voluntary use, I am pleased to report that just a few hours ago, NTEU signed an agreement with CBP to permit employees the option, at their discretion, of donning protective masks including the N95 respirators. NTEU's experience with Homeland Security during the initial and continuing outbreak of H1N1 influenza high-

lights the need for open and frank communication between all Federal agencies, their employees and their employee representatives.

A resurgence of the H1N1 flu is expected in the fall, as we know, and important issues must be addressed now that will impact all Federal workers, but especially those on the front line who, by the very nature of their jobs, work in close contact with huge numbers of travelers who may be infected. Therefore, NTEU makes the following recommendations:

No. 1, that a determination must be made as to whether some Federal workers should receive priority in a vaccination distribution;

No. 2, that Federal leave policies must be clear, especially in the case of working parents who may have a sick or quarantined child or a child whose school or day care is closed;

No. 3, social distancing is a key factor in preventing the spread of the flu, and for this reason Federal telework programs must be up and running to facilitate continuity of operations;

No. 4, in the case of substantial reduction of personnel due to illness, shifting of job location and duties of Federal personnel may be necessary to maintain operational control; shift extensions, overtime, cancellation of leave and travel requirements will be critical in order to address a pandemic-induced reduction in the Federal workforce; and

No. 5, clear written personnel policies must be in place to address these contingencies, and frequent, updated communication with the Federal workforce and Federal employee representatives is absolutely essential.

Thank you again for the opportunity to testify, and I look forward to any questions.

[The statement of Ms. Kelley follows:]

PREPARED STATEMENT OF COLLEEN M. KELLEY

JULY 29, 2009

Chairman Thompson, Ranking Member King, distinguished members of the Committee: I would like to thank the committee for the opportunity to provide this testimony. As President of the National Treasury Employees Union (NTEU), I have the honor of leading a union that represents hundreds of thousands of Federal worker including thousands of Transportation Security Officers (TSOs) at the Department of Homeland Security's (DHS) Transportation Security Administration (TSA) and 22,000 Customs and Border Protection (CBP) Officers, Agriculture Specialists (CBP AS) and trade enforcement specialists who are stationed at 327 land, sea, and air ports of entry (POEs) across the United States. TSOs, CBP Officers and CBP AS make up our Nation's first line of defense in the wars on terrorism, drugs, contraband smuggling, human trafficking, agricultural pests, and animal disease while at the same time facilitating legitimate trade and travel.

Employees on the frontlines of our Nation's borders and airports are exposed to many threats, the newest being exposure to the H1N1 influenza. On Wednesday, April 22, 2009, the first reports of H1N1 flu exposure in the United States became public and the press began reporting on a swine flu outbreak originating in Mexico. To date, it is suspected that there have been as many as 2 million H1N1 flu cases in the United States. H1N1 flu outbreaks are documented daily. Currently, at the U.S. Coast Guard Academy in New London, Connecticut, over 10 percent of the freshman class has H1N1 flu.

This outbreak has raised serious concerns about how the Federal Government creates and communicates policies to protect the health of key frontline Federal personnel. Most troubling to NTEU, is that key stakeholders, including Federal employees and their employee representatives, are not being consulted in the development of pandemic response strategies and had not been afforded the opportunity to participate in the development of or comment on the November 2005 National Strategy

for Pandemic Influenza and the May 2006 Implementation Plan. NTEU commends the Chairman for recognizing this glaring weakness in the committee's January 2009 report entitled, "Getting Beyond Getting Ready for Pandemic Influenza" and for calling the new administration to address this shortcoming. I applaud the Homeland Security Committee for holding this timely hearing.

Policies to mitigate health risks for Federal employees should vary according to the type of work being done and the potential for exposure. The general guidelines, which include staying out of crowds, do not adequately address situations where an employee's entire work shift requires him or her to be in close contact (within 6 feet) of literally thousands of travelers, which is the case for Transportation Security Officers, Customs and Border Protection Officers, and Agriculture Specialists.

Specific guidance must be developed and communicated clearly and in writing to these employees who are at increased risk of exposure. It is unacceptable and shocking that more than 3 months after the initial onset of H1N1 flu in the United States and despite repeated urging from NTEU and others, there is still no comprehensive guidance in place to protect the health of these frontline employees.

The September 2007 CBP Operations Plan for Pandemic Response states that "CBP is the first line of our Nation's defense against a pandemic, both overseas and along our border." This plan was formulated in response to the possible outbreak H5N1 avian flu pandemic. According to this plan, "CBP could experience a substantial reduction of personnel due to illness (approximately 30% to 50%), potentially having a substantial impact on sustaining continuity of CBP operations Once a pandemic begins to spread, significant numbers of infected travelers at and between the POEs may be searched, detained, transported, and housed by CBP pending removal or transfer into the custody of medical authorities, impacting CBP's ability to perform its mission In spite of this, CBP must continue to carry out its priority mission to prevent the entry of terrorists and their weapons, regardless of the circumstances. To accomplish this, CBP will need to protect its workforce"

It was therefore extremely troubling to NTEU that DHS issued conflicting and confusing guidance to frontline CBP Officers and TSOs during the initial H1N1 spring outbreak. Shortly after the swine flu outbreak became public in late April 2009, NTEU started receiving questions from our members at ports of entry around the country. In numerous locations, personal protection equipment (PPE), including gloves and N-95 respirators, was distributed to employees. At JFK Airport in New York, for example, distribution to CBP employees began on April 25 and continued through April 26 with little guidance. In the afternoon of the 26th employees were initially told they were only to wear the respirators if in contact with an ill individual. Later they were told they were not to wear the respirators at all, so as not to alarm the public or offend passengers.

On April 26 Homeland Security Secretary Napolitano sent a message to DHS employees working near the Southwest border. That message stated: "CDC recommends that a distance of 6 feet should be maintained between all employees and someone who appears ill. The use of N95 masks is suggested if an employee must maintain closer contact than the 6 feet of distance."

On April 28, a CBP spokesperson was quoted in CNSNews.com saying, "CBP officers and Border Patrol agents are provided personal protection gear which they may utilize at their discretion."

On April 30 a DHS spokesperson was quoted in a media report saying, "the Department of Homeland Security has not issued an order saying our employees cannot wear masks."

Transportation Security Officers at Dallas/Fort Worth Airport were issued masks on April 26 and on the 28th told they could not wear them unless they were dealing with a traveler exhibiting swine flu symptoms.

According to a press report in the Washington Times on May 2, a TSA PowerPoint presentation was distributed to TSA employees on April 29 that stated: ". . . . the routine wearing of protective masks by TSA personnel in the workplace is not authorized In addition to not being medically necessary, the masks interfere with normal [transportation security operation] duties and hold the potential for unnecessarily alarming the public"

NTEU requested a copy of the PowerPoint presentation, but was told it was not available for public distribution.

As soon as questions began coming in to NTEU from our members around the country as to whether they could wear respirators or masks, NTEU began trying to find out what the current policy was and urged that these employees be allowed to wear the masks if they felt their health was at risk. We contacted CBP, TSA, and DHS. DHS was saying it had not issued a Department-wide order prohibiting

the voluntary wearing of masks, but CBP and TSA were clearly enforcing such a prohibition.

Some statements from DHS that appeared in the press indicated that managers who were preventing the wearing of masks were misinformed about the actual policy. The idea that a few managers were misinformed is clearly not accurate. NTEU heard from many, many employees from around the country and attached to this testimony are affidavits from some of them relating instances of supervisors demanding that they remove respirator masks.* Many of them are disturbingly threatening and many include comments indicating the reason was fear of alarming the public. I trust this committee will ensure that the employees providing these affidavits will be free from any negative impact.

On April 30, DHS issued Interim Guidance stating that: "Employees who work closely with (either in contact with or within 6 feet of) people specifically known or suspected to be infected with the H1N1 virus must wear respiratory protection." The guidance did not address the question of the voluntary donning of masks. In addition, the Interim Guidance noted it was being released "as an interim measure until the Office of Personnel Management provides comprehensive guidance for all Federal employees." OPM has since indicated it does not intend to provide such Government-wide guidance, stating that on questions such as this, affecting narrow segments of the workforce, decisions are up to the individual agency.

On May 1, I wrote to DHS Secretary Napolitano and OPM Director Berry urging that written guidance be issued immediately clarifying that these frontline employees would be allowed to wear masks at their discretion. On May 5, CBP Acting Commissioner Ahern sent out an employee message reiterating the mandatory use of respirators when employees were in close contact with people known or suspected to be infected with the H1N1 virus. The message included no reference to the voluntary wearing of respirators despite NTEU's repeated requests to CBP for such guidance.

On May 8, I sent a second letter to Acting TSA Administrator Rossides and a letter to Acting CBP Commissioner Jayson Ahern asking again for written guidance that these employees be allowed to wear respirators/masks at their discretion.

On May 14, 2009, I testified before the House Committee on Oversight and Government Reform Subcommittee on the Federal Workforce, Postal Service and District of Columbia about the Department of Homeland Security's (DHS) refusal to allow Customs and Border Protection (CBP) and Transportation Security Administration (TSA) employees to wear a respiratory mask, if they so choose, to help protect them from infection from the swine flu virus.

At the hearing, Subcommittee Chairman Stephen Lynch (D-MA) offered to work with NTEU on legislation if this situation was not quickly corrected by the Department. On Friday, May 29, the Department of Homeland Security Under Secretary for Management, Elaine Duke, issued an updated guidance regarding the use of Personal Protective Equipment (PPE), as it applies to working in close proximity to persons exhibiting symptoms of the H1N1 virus. But again, the guidance failed to provide a clear and reasonable policy allowing for the donning of a mask at your discretion in situations not involving close contact with an apparently infected person. On June 1, I sent a letter to DHS Under Secretary Duke seeking clarification of the May 29 guidance.

On June 4, the House of Representatives passed H.R. 2200, the TSA Authorization Act. On the House floor, Representative Lynch offered an amendment to provide that any TSA personnel may voluntarily wear personal protective equipment (including surgical and N95 masks, gloves, and hand sanitizer) during any emergency. NTEU worked closely with Representative Lynch and strongly supported this amendment. The Lynch amendment was passed by voice vote and became part of the bill. The bill now goes to the Senate for consideration.

Unfortunately, H.R. 2200 was limited to TSA-related provisions; therefore, the amendment does not address the discretionary use of PPE by CBP Officers and CBP Agriculture Specialists at the ports of entry that also daily come into close contact with thousands of travelers transiting into the United States.

On June 16, NTEU testified before the Senate Homeland Security and Governmental Affairs Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia on this issue. NTEU asked the committee to include similar language to the Lynch amendment in any upcoming legislation that includes CBP jurisdiction.

Working with House Appropriators and Representative Lynch, NTEU got language in H.R. 2892, the fiscal year 2010 DHS House appropriations bill that would

*The information has been retained in committee files.

allow DHS personnel the discretionary use of masks without being subject to discipline.

Also, NTEU serves on the Federal Advisory Committee on Occupational Safety and Health (FACOSH). NTEU believes that the Occupational Safety and Health Administration has the expertise to formulate the pandemic flu workplace health and safety response and submitted a resolution to that effect at their scheduled meeting in June. As a result, a FACOSH work group was established to address emerging worker health and safety issues, including the voluntary use of PPE by Federal workers, surrounding the H1N1 flu.

Despite these continued efforts, CBP issued a new guidance on June 17, 2009 that stated that "employees may use the personal protective equipment (PPE) in situations where they believe it is needed to safely carry out their duties." This guidance, however, was followed by management guidance on June 19 that stated "Any employee who feels it is necessary to don PPE to perform their normal duties, must first contact their immediate supervisor . . . If after consultation with their supervisor the employee still has concerns, the employee will be allowed to wear PPE . . . Each request to don PPE must be considered on a case by case basis by CBP management."

NTEU met with DHS and CBP officials on July 14 and raised this contradictory language and asked them to agree to a Memorandum of Understanding (MOU) with us that is clear and unambiguous. On July 23, NTEU received a proposal that we believe will be acceptable to our members. As of the submission of this testimony, NTEU and CBP appear close to an agreement.

Unlike the June 19 CBP guidance, on May 29, 2009, TSA issued Policy Guidance on Personnel Protective Equipment that is clear and allows TSOs discretionary use of N95 masks. But the May 29 TSA guidance was not shared with TSA employees and, according to TSOs, was only just distributed to TSA personnel after the reported H1N1 flu-related death of a TSO at the San Juan Airport on July 19.

These experiences with DHS during the initial and continuing outbreak of H1N1 influenza highlights the need for open and frank communication between Federal agencies, their employees, and their employee representatives. The U.S. Government expects a resurgence of the H1N1 flu strain in the fall and continues to prepare for the upcoming 2009–2010 winter flu season. The timing, severity, and the geographic location of the resurgent H1N1 influenza remains unknown, but important issues must be addressed now for all Federal workers, especially those on the frontline who are responsible for keeping our air, sea, and land ports open to trade and travel. Those issues include:

- (1) Clear guidance is needed as to whether some Federal workers should receive priority when a vaccination is approved and distributed to the public.
- (2) Federal leave policy must be clear, especially in the case of working parents who may have a sick or quarantined child or a child whose school or daycare is closed.
- (3) Social distancing is a key factor in preventing the spread of flu. For this reason, Federal telework programs must be up and running to facilitate continuity of operations.
- (4) In the case of substantial reduction of personnel due to illness, shifting of job location and duties of Federal personnel may be necessary to maintain operational control. Shift extensions, overtime, cancellation of leave, and travel requirements will be critical in order to address a pandemic-induced reduction in the Federal workforce.
- (5) Clear written personnel policies must be in place to address these contingencies and frequent, updated communication with the Federal workforce and Federal employees' representatives is absolutely essential.

NTEU appreciates the committee's continued focus on pandemic preparedness and its insistence on common-sense guidance with respect to protecting frontline DHS personnel and the entire Federal workforce. NTEU pledges to work with Congress and our agency partners to address the personnel challenges of a potentially severe pandemic and help to ensure the continuity of Federal services.

Thank you again for holding this important hearing.

Chairman THOMPSON. Thank you very much for your testimony. We now recognize Mr. Muth for 5 minutes.

**STATEMENT OF RICHARD G. MUTH, EXECUTIVE DIRECTOR,
MARYLAND EMERGENCY MANAGEMENT AGENCY**

Mr. MUTH. Good afternoon, Chairman Thompson, Ranking Member King and Members of this committee. Before being appointed

to my current position, I served in the Baltimore County Fire Department for over 30 years, including 15 years as the county's Emergency Manager. I thought that was important to say, because I come here today representing both the State government but also with much experience at the local level.

It is an honor to be invited here today to discuss Maryland's current preparedness and response activities for the H1N1 and the critical issues that remain a challenge for the future.

A pandemic flu response presents a set of challenges are that different from other emergencies. Since the last severe pandemic in the United States happened about 90 years ago, we don't have any hands-on experience dealing with one; and unlike most emergencies, especially declared disasters, it does not have a well-defined beginning and ending. It does not have geographic limitations and potentially lasts much longer.

We have experienced a relatively mild spring outbreak, but experts tell us the fall flu season will be much worse. Maryland is committed to using all available resources and personnel to address the situation.

This committee's majority staff report identified four major categories of action items to strengthen: Establish effective management, address and meet key medical requirements, evaluate update plans, and improve early warning and detection. Here are some of Maryland's accomplishments in these areas, or plans in our areas that we are still working on:

First, Governor Martin O'Malley instructed the Maryland Department of Health and Mental Hygiene in my agency to lead an H1N1 leadership task force to address some of these issues, determine who is in charge, integrate the response in the incident command system and improve communications among various State and local agencies and with the public.

Next, the Governor mandated State agencies' Continuity of Operations Plans to be updated and completed by October 1, along with updated pandemic flu operational plans and our Strategic National Stockpile plan. Just 2 days ago, we hosted the H1N1 summit to ensure open dialogue between public health and school officials, emergency medical providers, and local emergency managers.

While we are working diligently to prepare for a possible pandemic as schools return to session next month and as the traditional flu season hits later in the fall, we have identified several issues that must be addressed at the Federal level either by Congress or the administration.

First, leadership and coordination issues must be resolved at the Federal level, which will give the States more confidence in the guidance we receive from the Department of Health and Human Services and the Department of Homeland Security and other Federal partners. There may have been legitimate political and logistical reasons for having HHS and DHS as the Federal voices of H1N1, but that may have confused the public, and while the leadership issue may have been resolved at the Federal level, that resolution need to be communicated to the States.

I had the opportunity to speak to some of my peers across the country, and they all had the same concerns that we had; so this communication certainly needs to be worked on.

It is vital that all agencies use the incident command system. Failure to use this consistent common language in commands can delay the coordination of resources and may endanger both responders and the general public.

It is important that the public receive timely, credible, and definitive guidance from the Centers for Disease Control. For example, the radical change in school closing guidance several days into the spring pandemic clearly colored the public's perception of Government decisions.

Second, as was shown with both the inaugural activities last January and the spring H1N1 outbreak, it may be time for legislative review of the Stafford Act to help make sure it is appropriate to deal with today's events and their potential enormous cost. The Stafford Act was designed to deal with disasters like tornadoes and hurricanes, but it does not work so well with emergencies that don't have a definitive ending date or may have a lull of several months between activities, such as we are seeing now with the pandemic.

We need Federal guidance about what types of disaster assistance might be available for responding to a pandemic and what thresholds are required for a disaster declaration. In this economic climate, States cannot afford to guess at what may or may not qualify for assistance.

Third, State and local governments need greater flexibility to use various Federal grants to help with H1N1 prevention and response. Protection for first responders and workers in the medical field needs to be one of the top priorities. I am asking that Congress and the administration develop a new funding source so that these front-line workers can be supplied with appropriate personal protective equipment.

It is also vital that these grants allow States the flexibilities to manage their own need. One-size-fits-all does not always fit all.

Finally, we must have consistency between public health and emergency management planning guidance so that the various agencies can work together seamlessly. Not only is the current guidance inconsistent with established emergency management guidance, it does not allow for the needed flexibility or scalability for each State or situation. The spring outbreak, for example, while it was a fast-spreading, novel virus, it did not seem to have the high mortality of previous pandemics. However, much of the planning guidance was based on the high mortality pandemics in 1918 and 1919.

In addition, I would like to mention one other area of concern. I sit on a subcommittee of National Children and Disasters, and one area they have is that the children not be forgotten in all areas, including planning and any type of inoculation.

So I thank you for giving me the opportunity to discuss these important issues today.

[The statement of Mr. Muth follows:]

PREPARED STATEMENT OF RICHARD G. MUTH

JULY 29, 2009

INTRODUCTION

Chairman Thompson, Ranking Member King, and Members of the committee, my name is Richard Muth and I am the Executive Director of the Maryland Emergency Management Agency. It is an honor to be invited here today to discuss Maryland's current preparedness and response activities for the H1N1 pandemic influenza and the critical issues that remain a challenge for the future.

What is the Maryland Emergency Management Agency?

The Maryland Emergency Management Agency (MEMA) is mandated under State law to ensure that the State is prepared to deal with all emergencies, especially those that exceed the capabilities of the local jurisdictions, and to coordinate the overall State's response in a declared emergency or major disaster. In addition to supporting the local governments, MEMA coordinates assistance with the Federal Emergency Management Agency (FEMA) and other Federal partners when the Governor declares a state of emergency and receives a Presidential disaster declaration. While MEMA is part of the Maryland Military Department and under the authority of the Adjutant General, during emergencies the Governor assumes direct authority over the Agency and the Executive Director of MEMA reports directly to the Governor.

A key element within MEMA is the Maryland Joint Operations Center (MJOC). Operated round-the-clock by National Guard and MEMA employees, it is a joint civilian-military watch center. In addition to serving as a communications hub for emergency responders State-wide and supporting local emergency management, the MJOC monitors local, State, national, and international events, including weather, and advises decision-makers in Maryland when a situation warrants.

MEMA coordinates the States' response to an emergency at the State Emergency Operations Center (SEOC) in Reisterstown, Maryland. When the SEOC is fully activated, each State agency, as well as some Federal agencies, private sector, and volunteer organizations sends a representative to the SEOC with authority to make decisions and allocate needed resources and funds to response efforts on behalf of their agency.

MEMA also serves as the State administrative agent for all homeland security grants received from the Federal Government.

Pandemic flu response presents challenges distinguishable from most emergencies.—There are a few aspects of pandemic flu that distinguish it from other emergencies that States and localities are accustomed to handling. The nature of this type of event is new and unfamiliar to almost all Americans because the United States has not experienced nor witnessed a severe flu pandemic since 1918–1919. With little to no past experience to guide us outside of history books, aspects of our response efforts have to be revised and reconsidered. The unknown duration and potentially long-term nature of this novel event also creates enormous resource strains, especially in an environment of budget deficits.

As we approach the fall, States and localities will have to balance competing priorities: Meeting the demands of a flu of unknown duration and severity, ensuring the ability to manage the needs of other emergencies (such as a possible hurricane), and continuing to provide basic and essential Government services to the public. The response and implications of pandemic influenza are not simply a public health or individual medical issue. The health response will require an increase in resources, coordination, and support from all levels and sectors of government while at the same time will create a severe reduction in the available government and private workforce. Pandemic influenza has the potential to severely impact every aspect of our economy.

The Committee on Homeland Security Majority Staff Report, "Getting Beyond Getting Ready for Pandemic Influenza" identified four major categories of action items to strengthen response: (1) Establishing effective management and coordination; (2) addressing and meeting key medical requirements; (3) evaluating and updating plans; and (4) improving early warning and detection. Maryland strongly agrees with these recommendations and is currently taking steps to complete these actions. I will highlight some of our accomplishments, future intentions, and remaining gaps in these four areas.

1. ESTABLISHING EFFECTIVE MANAGEMENT AND COORDINATION

On June 24, 2009, Maryland Governor Martin O'Malley hosted a State after-action meeting to discuss and evaluate Maryland's initial response to the H1N1 outbreak. As a result of the information gleaned from this meeting, Governor O'Malley immediately established an H1N1 Leadership Task Force. This Task Force is co-chaired by the Secretary of the Department of Health and Mental Hygiene (DHMH) and me and includes executive level personnel from all relevant State agencies. To ensure that Maryland is prepared to respond effectively to H1N1 this fall, the Task Force has been assigned specific action items and a 45-day timeline to report back to the Governor on the ways in which it has corrected gaps and resolved issues. This Task Force has been charged with the following deliverables:

1. Resolve any issues involving implementation of the unified command/incident command system during public health emergencies; the number, location, and staffing of operations centers; and the use and implementation of a Joint Information Center.
2. Ensuring that the States' Pandemic Flu, Strategic National Stockpile (SNS), and Mass Vaccination plans are completed and have been reviewed and signed by all agencies to ensure they understand and can execute their roles during an emergency.
3. Identifying a date within 60 days to convene meetings among State and local leadership such as local public health officials and emergency managers, school officials, emergency medical service providers, and/or hospital leadership and local elected officials to ensure a two-way dialogue and discussion regarding communications and response to fall H1N1 operations.
4. Determine whether reconsideration of State-wide human resource and personnel policies (leave, tele-work, and on-call situations) for public health emergencies is needed, and as appropriate, develop and implement these policies.
5. Pre-identify trigger points and guidance for State agencies to activate their pandemic influenza Continuity of Operations Plans (COOP).
6. Pre-identify optimal procedures, combinations, and sequences for requesting a Stafford Act emergency, public health emergency, and authoring emergency powers in conjunction with H1N1.
7. Develop a streamlined system to ensure comprehensive and consistent internal communications across State agencies and externally with local partners which can be applied to all-hazard situations.
8. Conduct an exercise of the State's plan for mass distribution of an H1N1 vaccine, as well as any other aspects of the State's pandemic influenza plan deemed in need of exercise by the taskforce.
9. Provide an assessment of local jurisdictions and private sector partners' readiness.

By identifying and demanding timely action on these issues, Maryland will increase its ability to respond to a potentially more severe wave of H1N1 this fall. Many of these action items will address critical components of effective management and coordination for future response. However, there is additional assistance and clarity that could be provided by the Federal Government to assist us with our efforts.

All Federal Government Agencies must use the Incident Command System (ICS) and provide a consistent message to the States regarding who is in charge during a public health emergency:

It is the State's policy to coordinate, to the extent possible, all emergency management functions of the State with the comparable functions of the Federal Government. Despite State mandates to use the incident command system (ICS), it does not appear to the States that all Federal agencies have fully adopted or institutionalized its use, particularly within the Department of Health and Human Services (HHS). Traditionally, first responders, fire, police, Emergency Medical Services, etc. understand and use ICS every day. There appears to be confusion with other agencies as to the use of and fully understanding of this system. One of our first lessons learned from the event last spring was that, in the future, we must use the ICS standard as soon as practical because failure to use it can cause inconsistent commands across government, can delay the coordination of resources and information, and may endanger responders and the safety of the public.

We know that moving forward, it must be clear to all stakeholders that DHMH is the lead response agency in a public health emergency and MEMA is the lead coordinating agency. The roles are analogous to that of an airline pilot and air traffic control tower. An airplane pilot is responsible for the safe takeoff, flight, and landing of an aircraft. To successfully accomplish these tasks, an airplane pilot needs to receive a steady stream of information on weather conditions and other

traffic in the area to make appropriate decisions on how to fly the plane. The air traffic control tower is responsible for maintaining situational awareness, coordinating any needed resources, and providing the pilot with the information required to fly the plane in a skillful manner. These roles are similar to that of DHMH and MEMA in a public health emergency. MEMA will maintain situational awareness of the conditions of the emergency throughout the State and coordinate this information with DHMH so it can use its subject matter expertise to make effective decisions on responding to the emergency. This division of roles must be the same at the Federal level between HHS and DHS.

There continue to remain questions and inconsistent messages about whether HHS or DHS is in charge of the response to a public health emergency at the Federal level. In July, the DHS Secretary Napolitano and HHS Secretary Sebelius held a H1N1 Summit with the States. Even at this event, it was not clear to participants about the differences in roles and responsibilities between HHS and DHS in pandemic influenza. For example, DHS has a new initiative of H1N1 Field Response Teams and the States would like to know how these will be used in the most effective manner.

During the spring incident, guidance and information from the Centers for Disease Control (CDC) was disparate, sometimes confusing, and constantly changing, especially as it applied to recommendations on school closings. When guidance from the Federal Government changes frequently, it affects the public's perception of the Government's control of the event and impacts the likelihood that the public will comply with Government's decisions and recommended advice. While the constantly changing decisions were only somewhat understood this past spring due to the new and unknown nature of H1N1, it is critical this fall that States receive timely, definitive guidance from the Federal Government, especially on recommendations for school closings. The authority to close schools within Maryland depends on the nature of the emergency. To avoid delay and confusion during times of emergency, the Maryland State Department of Education (MSDE) and DHMH recently signed a Memorandum of Understanding to clarify their respective roles when an emergency requires the closing of public and non-public schools.

It is extremely important that the public perceive that governments are relying on the same credible information before making decisions. This is of particular importance in Maryland, due to its proximity to the District of Columbia and the Commonwealth of Virginia. It would be very difficult for a parent who lives in the District of Columbia, works in Virginia, and possibly has a child attending school in Maryland to understand why each jurisdiction has different policies on social distancing measures such as school closings or tele-work policies. The local governments in the National Capital Region are meeting to find ways to coordinate school closing decisions so that each government is informed of the decisions and justifications before they are announced to the public.

2. ADDRESSING AND MEETING KEY MEDICAL REQUIREMENTS AND RESOURCES

States and Localities Need Flexibility with the Use of Grant Funding for H1N1.—As noted in the February 2009 GAO report on pandemic influenza, the usual emergency management approaches to increasing resource capacity during disasters, such as requesting assistance from other States through the Emergency Management Assistance Compact (EMAC), may not be viable options during a pandemic because other States may want to hold onto resources in order to meet their own needs or may not wish to expose their staff to the disease. EMAC still will play a role in flu response but the amount of resources available from other States will depend on the extent of cases and the severity of illness in other States.

Workforce protection is an issue of key concern for States and localities. While some funding for EMS protection is included in the recent supplemental HHS Healthcare Preparedness Program grant, the level is not sufficient to cover Personal Protective Equipment for all EMS responders and does not offer any protection for law enforcement and other public safety responders who may be at risk during a pandemic in the line of duty. Public safety agencies have not been included in these grants but will need to provide support to the health and medical response. They will need the resources to protect their workforce and also to ensure the ability to continue providing services with a reduced workforce. Recent Congressional appropriations for pandemic influenza only appear to provide funds to States and localities through grant awards to public health departments and hospitals.

I ask that Congress and the administration introduce new funding for PPE. In the absence of new funding, flexibility in the usage of current grants would address these issues. Each State and locality will have different needs that will not fit into "a one size fits all" box.

As for medical resources, Maryland knows it has gaps in surge capacity that will require tough policy decisions this fall. The State has insufficient knowledge of private antiviral inventories and needs to encourage partnerships and communications with the private medical sector. CDC has indicated it will assist States with a better understanding of the commercial pipeline for critical pharmaceuticals and medical supplies by developing a “supply chain dashboard” using aggregated proprietary data from the manufacturers and distributors. States look forward to access to such a dashboard to support resource allocation and SNS decisions. While we cannot address everything this fall, Maryland is in the process of developing forward-thinking approaches to potential resource shortages through the use of volunteers and by using health care workers in non-traditional roles to assist with response. These efforts are described in detail below:

The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP).—ESAR-VHP is a Federal program that establishes and implements guidelines and standards for registering, credentialing, and deploying medical professionals in the event of a large-scale national emergency. Maryland purchased a web-based, fully compliant ESAR-VHP system in June 2009 from Collaborative Fusion, Inc., called CORES. After multiple phases of testing, it is anticipated that the system will go “live” August 24, 2009 and will be available for volunteers to register the following month. This system will allow Maryland to register volunteers through a website, with volunteers able to log into the system with a password at any time to update their information. The CORES system will directly access State licensing and National credentialing agencies to ensure volunteers are practicing professionals in good standing. The system has a messaging and notification component that will send messages through a variety of methods (e-mail, pager, cell phone, etc). It also has a mission manager component that will allow volunteers to view a detailed description of missions as they arise.

Maryland Civic Guard.—Maryland’s Civic Guard, launched July 16, 2009 by Governor O’Malley, is a coordinated effort between MEMA and the University of Maryland’s Center for Health and Homeland Security (CHHS) that will engage local governments, private groups, businesses, corporations, and nonprofit organizations to enhance the system of cooperative volunteering during emergencies. The Civic Guard seeks to build on the strength of current partnerships between local governments, volunteer organizations, private businesses, and Maryland State government. Under the first phase of the initiative, supported in part by a FEMA Regional Catastrophic Preparedness Grant, MEMA and CHHS will work with local government, the private sector, and non-profit entities to identify resource needs and potential opportunities for private sector and non-profit entities to create or expand partnerships. The Civic Guard initiative will seek to share information on needs and resources and, where possible, create agreements and memoranda of understanding—before disaster strikes—with business and non-profit partners.

Broadening scope of practice and use of non-traditional professionals to assist with mass vaccination.—The State is developing procedures that would have the Governor modify State regulations on a temporary basis under a declared state of emergency to broaden scope of practice standards among various trained health care providers and also use trained health care providers in non-traditional roles to assist with a mass vaccination this fall. Under this plan, the State would consider using veterinarians, pharmacists, dentists, emergency medical technicians, and other auxiliary providers to meet the personnel requirements associated with a State-wide vaccination campaign.

3. EVALUATING AND UPDATING PLANS

Continuity of Operations Plans (COOP).—The recent H1N1 influenza situation highlighted the need for up-to-date and comprehensive COOP plans within State government to ensure the ability to maintain vital operations and services for our citizens, especially in the face of possible reduced workforce availability due to illness.

By request of the Governor, MEMA and DHMH are leading an initiative to ensure that all executive agencies have viable, operational, and up-to-date Pandemic COOP plans by September 1, 2009 and full COOP plans by October 1, 2009. As part of this initiative, MEMA, in coordination with DHMH, provided a series of free training sessions on developing a COOP plan to State employees, locals, and non-profit agencies in July. In addition, the Governor is requiring executive level personnel from all State agencies and departments to participate in a 1-day COOP tabletop exercise and is scheduling a State-wide COOP drill for late summer/early fall. MEMA will begin a peer review process of all COOP plans submitted October 1, 2009 or before.

Even with free training for local governments, it will be difficult for some local agencies to complete or update their COOP plans because of budget and staff shortages. The State is aware, but cannot currently assist, in addressing known gaps in COOP planning within many private businesses.

Coordinating Emergency Management and Public Health Planning.—On July 27, Maryland initiated a meeting among each locality’s public health officers and emergency managers to share their experiences from H1N1 and address communication gaps. This was an important first step in bringing together two disciplines that, in the past, have not had a great deal of experience working together and not always understood the others roles and responsibilities. In the future, it will be critical to have these disciplines integrate and coordinate their planning efforts, especially for the myriad of issues in an influenza pandemic that implicate both disciplines, such as mass fatality and special needs populations planning. One way to assist with this task is to ensure that public health and emergency management planning guidance at all levels of government must be consistent. Unfortunately, the Federal Government has created barriers to accomplishing this task because public health planning guidance released by HHS is often inconsistent with established emergency management planning guidance that is released by FEMA. The States would like to see emergency planning guidance come from DHS in coordination and conjunction with appropriate subject matter experts, to ensure that all planning guidance provided to the States is consistent.

CDC Pandemic Influenza Planning Guidance.—One area of public health planning guidance in need of serious revision is the Centers for Disease Control’s (CDC) guidance to States on pandemic influenza planning. In addition to being inconsistent with established emergency management planning guidance, it does not sufficiently allow for necessary flexibility or scalability to the specific needs of a State. Maryland’s pandemic influenza plan closely corresponds to the template provided by the CDC, which ended up not being easily understood in an operational context this past spring. DHMH is currently reviewing and revising the State plan to address these issues in time for fall.

State Strategic National Stockpile Plan.—Maryland’s SNS plan was developed and exercised with the assumption that all of the available resources would be deployed to the State, rather than the 25% that was distributed in May. This demonstrates a flaw in the CDC’s planning requirements established for State plans. State SNS plans are rigidly reviewed annually using a tool developed by the CDC. Under Federal requirements, a State SNS plan is required to be written under the assumption of receiving a 100% deployment of SNS assets. The CDC has already recognized this gap and is actively working to develop the scalable concept at the Federal level to provide to the States.

The Federal planning assumption was that a State’s SNS shipment would follow a request from the Governor, an assumption which proved to be inaccurate in May 2009. Upon announcement that the State was to receive 25% of its antiviral allocation, DHMH made arrangements for receipt at the designated RSS site, and upon arrival, the shipment was immediately inventoried by type, lot number, and expiration dates. A long-term lease for secure, temperature-controlled storage was obtained through an emergency procurement and the assets transported and secured. Since then, the CDC and FDA have successfully worked out a protocol for the extension of the shelf life of those antiviral medications and soon-to-expire dates.

This effort to safely maximize the shelf life and therefore the economic utility of these anti-virals should be replicated for the FDA for other medication caches purchased by the States with Federal funding.

4. IMPROVING EARLY WARNING AND DETECTION OF INFLUENZA

Maryland uses the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE). This is a web-based syndromic surveillance system designed for the early detection of disease outbreaks, suspicious patterns of illness, and public health emergencies. It automatically categorizes data such as chief complaints from 46 acute care hospitals, over the counter medication sales from two large pharmacy chains (approximately 300 total stores), and call data from two State poison control centers into syndromes to detect aberrations in the expected level of disease. ESSENCE runs automated statistical algorithms on each syndrome and generates alerts when the observed counts are higher than expected. To our knowledge, Maryland is the only State with 100% connectivity to all acute hospitals, reflecting achievement of a priority goal of Governor O’Malley.

DHMH epidemiologists review ESSENCE alerts daily and determine if follow-up is necessary. Follow-up investigation of alerts includes contacting local health departments and the hospital infection control staff to obtain more information. In ad-

dition, DHMH epidemiologists notify the DHMH Physician On-Call and State Epidemiologist for alerts determined to have public health significance and initiate an active investigation.

ESSENCE provides situational awareness on the health of Maryland residents, detects disease clusters and exposures to allow for a more rapid response to disease prevention and mitigation, and provides early indication of increased influenza activity before cases are confirmed. This analysis provides a critical tool for planning and resource allocation. Maryland will continue sustained year-round flu surveillance and is currently working with the State Superintendent of Schools to assess what is needed to add school absenteeism data to the system.

CHALLENGES IN APPLYING THE STAFFORD ACT TO PANDEMIC FLU

Recent events, such as the 2009 Presidential Inauguration, have demonstrated the need for Congress to review the Stafford Act declaration process and regulations, particularly to ensure relevancy to post-9/11 threats and emergencies. The Stafford Act was designed to deal with disasters like tornados and hurricanes. The time has come for Congress and the administration to revisit the Stafford Act, particularly as it might apply to pandemic influenza and other public health threats.

Under 42 U.S.C. § 5121(b), the purpose of the Stafford Act is to provide an orderly and continuing means of assistance by the Federal Government to States and localities in carrying out their responsibilities to alleviate the suffering and damage from disasters.

There are two major types of declarations:

1. *Emergencies*.—Any assistance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of catastrophe in any part of the United States. 42 U.S.C. § 5122(1)
2. *Major Disasters*.—Include any natural catastrophe, which in the determination of the President cause damage of sufficient severity and magnitude to warrant major disaster assistance under the Act to supplement the efforts and available resources of States, local governments, and disaster relief organizations. 42 U.S.C. § 5122(2)

There are two main types of assistance that correspond with these declarations: Major disaster assistance and emergency declaration assistance. Significantly less assistance is available under an emergency declaration than under a major disaster declaration. Expenditures made under an emergency declaration, unlike under a major disaster declaration, are limited to \$5 million per declaration, unless the President determines that there is a continuing need for immediate emergency assistance.

To qualify for Federal assistance, the Governor must:

- (1) Certify that the situation or disaster is of such severity and magnitude that effective response is beyond the capabilities of the State and local governments;
- (2) Direct execution of the State's emergency plan;
- (3) Describe the State and local efforts and resources which have been or will be used to alleviate the emergency;
- (4) For emergencies, define the type and extent of Federal aid required; and
- (5) For major disasters, certify that State and local government obligations and expenditures will comply with all applicable cost-sharing requirements of the Act. See 42 U.S.C. § 5170, § 5191.

There are at least two challenges with applying the Stafford Act to pandemic influenza. First, the Stafford Act requires that a State describe the nature of the emergency or disaster and certify that it is beyond the capacity of the State to respond. While this process is relatively straightforward in the context of a storm or flood, it is more difficult in a lengthy event of unknown duration without a well-defined start and end date/time attached it, such as pandemic influenza. FEMA has noted that a pandemic influenza will last longer than other public health emergencies and may include waves of activity separated by months. See FEMA Disaster Assistance Policy, DAP9523.17 (March 17, 2007). Unlike a request to rebuild a bridge, human service needs are more difficult to quantify, especially with regard to a State's capacity to handle the issue.

Given the unique characteristics of pandemic influenza, States need specific guidance from the Federal Government on when this event would be considered of such severity and magnitude that effective response is beyond the capabilities of the State and local governments. In addition, States need guidance on the level of specificity that would be required in the declaration request with regard to available State and local resources and the type and extent of Federal aid required.

Second, there is ambiguity in the law concerning whether the Stafford Act would cover an influenza pandemic under a major disaster declaration or just under a declaration of emergency. This legal uncertainty has been noted in several recent congressional reports. See e.g., CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster under the Stafford Act?*, by Edward C. Liu, at 6–10 (Oct. 20, 2008.)

This ambiguity is significant for a number of reasons. Assistance for declared emergencies is generally capped at \$5 million while major disaster assistance does not have this cap. A declaration of a major disaster also expands the types of aid that are available to States, localities, and individuals. For example, a major disaster declaration permits the distribution of aid directly to individuals and households to meet disaster-related medical and other expenses. 42 U.S.C. § 5174.

States need guidance from the Federal Government on whether and what type of major disaster assistance is potentially available for responding to pandemic flu outbreaks and what thresholds would have to be met for pandemic flu to be considered a major disaster, as opposed to an emergency. Maryland is not the only State looking for this advice. We are aware of the States of California and Oregon also raising this issue.

Effective response to a pandemic flu requires a closely coordinated effort among Federal, State, and local partners. Disaster assistance should be clearly defined. States should not be left to guess and debate what might or might not qualify for assistance. In light of recent and emerging threats, it is time not only to provide guidance on these issues, but to revisit the Stafford Act to make sure it is relevant to 21st century threats and disasters.

CONCLUSION

The State requests the following actions by the Federal Government to help close gaps in preparedness and response for pandemic influenza:

1. We request guidance from FEMA on whether and what type of major disaster assistance will potentially be available for responding to pandemic influenza and what thresholds would have to be met for pandemic influenza to be considered a major disaster, as opposed to an emergency. We also ask that the Stafford Act be revisited for its relevance and applicability to post-9/11 threats and incidents like pandemic influenza.
2. We are concerned about leadership, coordination, and communication at the Federal level. States need to understand who is in charge at the Federal level and the difference in roles and responsibilities between DHS/HHS. We need assurance that all Federal agencies are using the incident command system. We need to ensure we have timely, credible, definitive guidance from HHS on issues such as school closings.
3. We ask for expansion and or flexibility on use of grant funds for H1N1 and also ask that you consider providing funds to other public safety disciplines outside of public health and hospitals.
4. We ask that the Federal Government revise pandemic flu planning guidance for the States and ensure that all public health planning guidance is consistent with established emergency management planning guidance.

Chairman THOMPSON. Thank you very much. We will have some time for the explanation on the question.

We have 10 minutes left on this vote, and we have two 5-minute witnesses.

Dr. Horton.

STATEMENT OF MARK B. HORTON, M.D., M.S.P.H., DIRECTOR, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, AND STATE HEALTH OFFICER

Dr. HORTON. Thank you, Honorable Chairman Thompson and Ranking Member King and other Members. It is a pleasure to be here to speak and give a State health officer's perspective on what has worked to date, what we have learned to date going forward, and what are our major challenges.

As I begin, though, I wanted to reiterate points that have been made about this virus. First of all, it is a novel virus, and we don't have a vaccine. This means that there are huge numbers of suscep-

tible individuals still in our population. We can fully expect a lot of sick people through the summer and into the fall, a lot of hospitalizations and, yes, a lot of deaths. We can, I think, fully expect that.

Second, this virus is acting very differently than seasonal flu. The fact that we are seeing still growing activity in many States right now today—we talk about a resurgence, but the fact of the matter is, it with us right now and it is affecting different populations; and it is mutable, which means we have to maintain full capacity in our epidemiology in laboratories in order to adequately monitor this and give us the information to make the correct public health decisions.

What worked well: I want to congratulate the Centers for Disease Control in taking the lead and ensuring that there was good vertical collaboration and communication connecting the State health officers with the local health officers throughout the first wave of this pandemic. Some of the manifestations of that were, for example, within days of the first identification of the first cases in southern California, there were teams of epidemiologists on the ground that included CDC epidemiologists, State epidemiologists, and local epidemiologists to ask the right questions to help us better characterize the seriousness of the illness it was causing and the transmissibility.

Second, laboratory capacity: Certainly, in California, the coordination between the 24 local laboratories, the State laboratory, and the California laboratories allowed us to test fully 14,000 specimens within a period of 6 to 8 weeks—unprecedented capacity—so it was good working together.

Similarly, with the Strategic National Stockpile, each State received 25 percent of its allotment of antiviral medications and masks. We were able to receive those and redistribute those to 51 local jurisdictions in California within a matter of days. We think this is a huge success and speaks to the excellent planning and resources that have been provided to us for putting things together.

What are the lessons that we have learned? First of all, as I can congratulate the epidemiological and laboratory capacity, I should also state that they were stretched to the limit. We—no way could we have sustained the effort that we put forward in the first weeks of this campaign. I am very concerned about our ability to continue to monitor this pandemic adequately as we move through the summer into the fall, into the regular season.

Second, I think previous mention was made about the supply chain for critical materials. We detected some serious vulnerabilities there. Laboratories in the State of California were telling me that we were within hours of having to stop testing for influenza because we didn't have the proper laboratory reagents. Similar problems were occurring about the availability of antiviral medications and masks.

We need to rethink and reconfirm the consistency of the manufacturers, the distributing systems to ensure that we can continue to supply those materials to local and State health departments that need them.

Third, we have inadequate data systems. Now, in the epidemiology area, I think we have good systems in place to gather epi-

miological information at the local, State, and Federal level, to be able to collate that data and tell us what is going on.

We don't have similar effective data systems in the health care system. At the local level, local health officers, and emergency medical technicians can tell you what is available, what is happening in their emergency rooms and in their hospitals, but we have no way consistently to collate that information regionally and at the State level so that I, as State Health Officer, have a heck of a time telling my Governor what is happening broadly in the health care system throughout California.

What are our challenges moving forward? I think there are three big ones, I think. The ones I will reiterate:

Maintaining epidemiological and laboratory capacity at the State, local, and Federal level to be able to give us the information we need on an on-going basis to make the right public health decisions is of vital importance and is a major challenge for us.

Mass vaccination, it has been mentioned before, but what I want to emphasize in my comments is that I think we have the capacity, if we decide to do this, to get the vaccine delivered from the Federal Government to the State to the locals. The real challenge is administering that vaccine to individuals. That is going to be left up to the locals. The State and the Federal Government and agencies need to be prepared to support local agencies that are going to be responsible for actually administering that vaccine.

Then one final comment is on surge capacity. There is no question in my mind that our health care system is going to be stretched to the limit if not overwhelmed. We need to take major steps forward to assist the health care system in preparing for this overwhelming increase in sick people that we are likely to see later on this year, and I have further details on how we can do that.

Thank you for the opportunity to testify.

Chairman THOMPSON. Thank you very much.

[The statement of Dr. Horton follows:]

PREPARED STATEMENT OF MARK B. HORTON

JULY 29, 2009

Good afternoon Chairman Thompson, Ranking Member King and distinguished Members of the committee. I am Dr. Mark Horton, Director of the California Department of Public Health (CDPH) and California's State Health Officer. CDPH, in partnership with the Centers for Disease Control (CDC), local health departments (LHDs), the California Emergency Medical Services Authority (EMSA)¹ and the California Emergency Management Agency (CalEMA),² responded to the recent outbreak of a novel influenza virus (H1N1) which has resulted in over 3,200 reported cases of illness, 537 hospitalizations and 60 deaths in California.

Thank you for asking me here today to discuss our response to this outbreak, activities underway to address on-going illness, and our continued preparations to respond to future pandemic influenza, most urgently for the upcoming the influenza season. In my testimony I will briefly outline our experience with the H1N1 outbreak this spring, including lessons learned, but will focus on our activities to confront the next pandemic influenza outbreak by highlighting:

- Disease surveillance;
- Public health interventions, including mass vaccination campaigns;

¹The California Emergency Medical Services Authority is responsible to ensure quality patient care by administering an effective, State-wide system of coordinated emergency medical care, injury prevention, and disaster medical response.

²In 2009 the California Office of Emergency Services and the California Department of Homeland Security were combined in the California Emergency Management Agency, CalEMA.

- Health care surge capacity;
- Social disruption; and
- Communications.

The California Department of Public Health operates more than 150 discrete programs³ ranging from communicable disease control, to food, drug and radiation safety; drinking water management; hospital and clinic inspections; chronic disease and injury control; maternal, child and adolescent health; and, most pertinent to today's hearing, public health emergency response. We employ more than 3,500 staff and our current budget is approximately \$3.7 billion to serve California's 38 million residents.

INTRODUCTION

California was the first State to identify the H1N1 virus. On April 17, 2009, the CDC, through laboratory data supplied by the Federal Border Infectious Disease Surveillance (BIDs) program office located in San Diego, determined that two California influenza cases had a unique combination of gene segments not previously reported among swine or human influenza viruses in the United States or elsewhere. Within days CDC epidemiologists were on the ground in these counties to augment local and State investigative resources.

By June 11, 2009, the World Health Organization categorized H1N1 as Phase 6, indicating a global pandemic was underway. At that time, 74 countries on five continents reported more than 28,000 illnesses and 144 deaths due to H1N1. We continue to experience significant H1N1 activity worldwide and there is much that remains unknown about this virus. Therefore, although our comprehensive public health surveillance allowed California to be the first to recognize the circulation of pandemic H1N1 and mount an aggressive response, we cannot relax our vigilance.

BACKGROUND

The delivery of public health services in California, including public health emergency response, is accomplished through a partnership of Federal, State, and local agencies. In California local public health departments have primary responsibility for responding to outbreaks in their jurisdiction. In outbreaks involving multiple jurisdictions, the State public health department, in conjunction with CDC, and our State and local emergency management and homeland security agencies, takes the lead to provide additional laboratory capacity, confirmatory testing, coordinate distribution of stockpiled equipment and supplies, develop State-wide policy guidance for public and private agencies and assist with development and dissemination of public information campaigns and provide resources when local needs exceed available capacity. In California, public health follows incident command system principles and county and State emergency management agencies coordinate closely with public health during all responses. In H1N1, CalEMA, in recognition that this is a public health emergency, designated CDPH as the lead agency while serving as a close and supportive partner.

Since 2002, the State of California has provided \$470 million in Federal grant funds to local health departments to build local health department preparedness capacity for all-hazard and specific public health emergencies. This funding included the fiscal year 2006 Congressional investment in State and local pandemic influenza preparedness activities (\$600 million allocated nationally).

Additionally, since 2004, California has invested more than \$170 million in State funds to support activities to increase medical surge capacity. These funds were used to purchase all available antivirals to supplement the Federal investment in the Strategic National Stockpile. California purchased three mobile field hospitals, alternate care site caches, ventilators, respirators, and funded preparation of Standards and Guidelines for clinics, long-term care facilities, and health professionals.

Those resources were put to use when on April 21, in response to growing numbers of cases of this pandemic H1N1, CDPH, and EMSA activated the Joint Emergency Operations Center (JEOC), the State's health operational center that coordinates and provides multijurisdictional response support for our Federal, State, and local partners. In addition, our 500,000-square-foot laboratory complex in Richmond, California activated its emergency response function, the Richmond Campus Coordinating Center (RCCC) to assist with identification of cases which could be "probable" H1N1, which were then sent to CDC for verification. Shortly thereafter, our Richmond laboratories received equipment, training, and CDC certification to conduct the confirmatory tests leading to a more rapid collection of surveillance data. California was the first State in the Nation to receive this certification for H1N1.

³<http://www.cdph.ca.gov>.

The JECC and RCCC conducted numerous daily policy and operational meetings/briefings that included congressional staff, our State legislature, local health departments, sister agencies and departments, and media (daily briefings for up to 200 media outlets). We established a multi-lingual hotline available 7 days per week, and developed public information materials (flyers, public service announcements, blogs, Facebook, and Twitter outreach).

CDPH, through a State General Fund allocation, had already purchased 3.7 million treatment courses of antivirals and CDC shipped an additional 1.325 million courses of antivirals to California from the Strategic National Stockpile for distribution to local communities. During the course of this outbreak, CDPH received requests for antivirals from 51 local health departments, 100 percent of which were shipped within 24 hours. The California Highway Patrol provided 24-hour security for the stored materials and escorts for all antiviral shipments.

Governor Arnold Schwarzenegger declared a state of public health emergency clearing the way for redirection of resources from other departments, relief from administrative procedures, and pursuit of Federal resources.

As we continue to monitor H1N1 activity our JECC and RCCC remain at a moderate level of activation. The State laboratory and the California network of 26 local public health laboratories continue to test hundreds of hospitalized and fatal cases each week; since the start of the pandemic 4 months ago these labs have collectively tested over 14,500 specimens, compared to a typical volume of 2,000 in a regular influenza season.

The data provided by this testing has enabled CDPH to have continuous, timely, and reliable data on the pandemic and who is being affected, allowing CDPH to better prepare for the 2009–10 respiratory season and planning for antiviral and vaccination priority needs. Data from the CDPH influenza surveillance has had a major impact Nation-wide, including providing the first description of the clinical and epidemiologic profile of hospitalized cases, identifying obesity as a possible risk factor for death, and actively monitoring and providing important data on the rare occurrence of antiviral resistant viruses following the identification of the first U.S. case in San Francisco.

California led the way with the identification of this new virus and with an aggressive multiagency response. We appreciate the Federal investment which has taken place up to this point. Without it, our capacity would have been significantly diminished.

LESSONS LEARNED

Planning Assumptions.—As we prepare to respond to future outbreaks, mindful not only of the experiences of the past few months, but of more than 100 years of public health science and service to inform us, we must stress that planning for pandemic illness, or any emergency, requires certain assumptions which during an actual event may be realized, or not. The test of those assumptions through the course of an actual event becomes the basis for adjustments in the next phase of planning. For example, as you may know, the planning models assumed the initial outbreak of pandemic influenza would occur somewhere within the Asian countries and would then take approximately 6 weeks to arrive in North America. H1N1 did not follow that model. With the information available to us now, we believe it started in North America, dramatically reducing the amount of time to organize the response.

Decision-making Process.—Certain technical and operational questions can be resolved relatively quickly and do not need to be revisited, allowing attention and resources to be directed to emerging or more complex issues. CalEMA and our California Department of Forestry and Fire (CalFire) embedded incident response experts in our State health operations center and laboratory operations center to assist with application of incident command strategies. More extensive use of the incident command structure will benefit future responses and the CDPH is using experts from CalEMA to conduct incident command structure training to strengthen the depth of that expertise within CDPH.

Communications.—Because public health emergency response involves a system of Federal, State, and local partners it is critical to ensure that information flows efficiently among all parties. CDC and the Federal Department of Homeland Security laid the groundwork for robust and integrated interagency communications.

Yet it is critical to coordinate timing and frequency of information exchange among relevant parties. The numerous daily conference calls hosted by various Federal and State actors often conflicted, forcing officials to choose between calls or redirect other staff to participate in order to stay informed of new information. Often the same officials who conduct the briefings are also the officials who must be engaged in urgent policy decisions. Using incident command strategies, California re-

vised its briefing strategies to avoid duplication and scheduling conflicts and smooth the timely flow of relevant information to affected Federal, State, and local officials.

Supply Chain.—We experienced an early and inexplicable collapse of the private industry pipeline for antivirals and masks which, if not resolved, would have rapidly depleted our stockpiles. The resolution required Federal intervention as the suppliers were national companies. Because the public sector relies so heavily on the private sector for a range of goods and services, including the emergency response supplies, Government will need to work more closely with the private sector to ensure supply chain reliability.

Public Health Continuity of Operations.—Despite a compressed timeline for response, the system responded appropriately and effectively to the H1N1 outbreak. However, had the event been more prolonged or more severe in its intensity, the public health systems, most likely, and the health care delivery system, certainly, would have been stretched to the limit. Our workforce of epidemiologists and microbiologists were redirected from other disease investigations to support the emergency response. If pandemic H1N1 becomes more severe or if there is another pandemic outbreak, we could not sustain core public health service levels, the continuity of our business operations would be affected. As we look ahead to the start of seasonal influenza activities we recognize the most optimistic scenario will find us confronted with the demands of the seasonal influenza, with H1N1 response as an additional pressure on our public health and health care delivery systems.

In order to support the State health and laboratory operations centers' response to a more sustained or severe epidemic, California has organized three additional response teams composed of staffs from within and outside of the Department who are already receiving training in the public health emergency response functions—everything from epidemiologic emergency response to support functions such as accounting and administrative support.

The new strategies must also take into account that the public health workforce will also be stricken with influenza, resulting in a high degree of absenteeism. In addition, we must commit to close collaboration with the private sector to enhance their planning for continuity of operations to ensure continued availability of essential goods and services.

LOOKING FORWARD

CDPH and CalEMA have been working together to plan for further escalation of the disease and the rollout of a vaccination campaign this coming fall and winter. While CDPH focuses on some of the core public health functions that must be in place, CalEMA is working with CDPH on triggers for activation of the overall emergency response structure, use of its business operations center to address resource shortages in the supply chain and other issues.

H1N1 Surveillance/Monitoring and Laboratory.—Preparation for surveillance to monitor for increasing pandemic activity, and possibly increased morbidity and mortality, is under way. These active surveillance activities include:

- Continuing and expanding current surveillance components to measure severity of the pandemic in different populations at risk;
- Laboratory testing to perform numerous activities including detecting the emergence of new strains that may cause more severe disease, identifying new strains that may be poorly matched to the vaccine, and developing antiviral resistance; and
- Continuing to monitor for morbidity and mortality associated with seasonal influenza.

Further, the emphasis on laboratory diagnosis is the key to strong surveillance. Because H1N1 is a laboratory-based diagnosis, without laboratory testing and results, there can be no H1N1 diagnosis. The laboratory is the cornerstone of influenza diagnosis. As such, laboratory monitoring of the pandemic and seasonal viruses in the following populations will be the cornerstone of the surveillance activities for the upcoming respiratory season:

- Severely ill cases hospitalized in intensive care;
- Fatal cases;
- Sampling of hospitalized cases from Kaiser Permanente and other academic and community hospitals State-wide;
- Outbreaks in institutions, including hospitals, prisons, schools, long-term care facilities; and
- Outpatient specimens from over 150 volunteer sentinel providers State-wide.

The CDPH Viral and Rickettsial Disease Laboratory (VRDL) is prepared to test over 16,000 specimens in the upcoming respiratory season to accomplish the above goals (the normal volume in a typical season is ~1,000 specimens). Approximately

15–20% of specimens will be tested for antiviral resistance to continue to monitor for the emergence of antiviral resistance. A subset of fatal and severely ill cases will undergo genetic analysis to monitor for the emergence of new strains that may not respond to a pandemic vaccine. Surveillance will also monitor changes in the circulating seasonal influenza virus in order to determine the formulation for the season influenza vaccine in the subsequent 2010–11 season.

In addition, the laboratory surveillance data will be used so that CDPH can monitor clinical and epidemiologic data associated with severely ill and fatal cases and from outbreak settings for populations at increased risk for morbidity and mortality. CDPH receives surveillance data from many different sources, including electronic hospitalization and outpatient data (Kaiser Permanente), influenza-like illness (ILI) data from a group of sentinel providers who voluntarily report ILI data to CDPH and from hospitals about severely ill cases hospitalized in ICUs. The data will allow CDPH to provide guidance on outbreak management, including in schools, and recommendations on antiviral prophylaxis and treatment for hospitalized patients and patients at high-risk, and vaccine prioritization strategies.

Public Health Interventions/Medical Countermeasures.—In planning for the large task of providing pandemic influenza vaccine, it is helpful to review the capacity to produce and deliver the seasonal influenza vaccine. Influenza vaccine production has increased dramatically over recent years, resulting in over 100 million doses of licensed vaccine available in the United States every autumn. Meanwhile, the public health system's capacity for vaccine administration has diminished since 1976, when it delivered 40 million doses of swine flu vaccine. As a result of increased vaccine and decreased public infrastructure, public health departments provide less than 10% of flu shots each year in California.

Just as in 1976, public health is needed in 2009–10 to coordinate the delivery of pandemic influenza vaccine. However, instead of 40 million doses, the public health system is being asked to oversee the administration of many times this amount, up to hundreds of millions of doses of vaccine, with approximately one-eighth of this total going to California.

While we are awaiting final information about the decision to vaccinate and the amount and timing of vaccine production, California is working quickly to:

- Identify as many current private and public vaccinators who can also administer pandemic vaccine;
- Identify additional vaccinators who can fill in gaps in services and map vaccinators to the prioritized populations they serve;
- Identify or build systems to distribute vaccine to potentially thousands of vaccinators;
- Establish or strengthen systems to share information with vaccinators and receive and validate vaccine orders;
- Track administration of vaccine; and
- Monitor the safety of pandemic vaccines.

These vaccination program activities will require substantial resources beyond what is already available. Public health will have to allocate, distribute, and administer a two-dose vaccine for the entire population in addition to the separate administration of the seasonal influenza vaccine.

CDPH continues to work closely with LHDs, health care providers and other State organizations such as the Board of Pharmacy to ensure that mass vaccination campaigns and antiviral dispensing plans are able to meet the needs of providing such medical countermeasures to all affected persons in California. CDPH has developed an allocation and distribution plan for shipping State and Federal stockpiles of antivirals to local jurisdictions utilizing the Standardized Emergency Management System. In addition, State-wide distribution plans for vaccines is currently under development and we continually communicate with local pandemic planning partners.

*Surge Capacity*⁴.—CDPH will continue to work with LHDs and health care providers to ensure that California can respond to a surge in the need for patient care.

At the local level, LHDs, and health care facilities are building partnerships and planning for patient distribution across the continuum of care from home health to expansion of existing health care facilities to Government-authorized alternate care sites to respond to an otherwise overloaded health care system. LHDs have purchased supplies to implement their plans and CDPH has stockpiled supplies and equipment for 21,000 alternate care site beds.

⁴Surge capacity is defined as a "health care systems' ability to rapidly expand beyond normal services to meet the increased demand for qualified personnel, medical care, and public health in the event of bioterrorism or other large-scale public health emergencies or disasters". (Addressing Surge Capacity in a Mass Casualty Event, AHRQ, 2004)

CDPH has stockpiled 50.9 million N95 respirators and 2,400 ventilators (estimated to supply hospital works for 6 months) to ensure the protection of health care workers. CDPH has allocated these on a population based share and is packaging county allocations to enable quick distribution.

CDPH has provided LHDs, hospitals, and other health care facilities with standards and guidelines for emergency planning and operation of alternate care sites, expansion of existing facilities, and tools to move from individual to population-based care.

Social Disruption.—As Secretary Napolitano expressed many times during the initial stages of the H1N1 outbreak, the potential for social disruption during a pandemic is one of the most compelling arguments for interagency communication and collaboration. As the Director of Public Health and the State Health Officer one of my major concerns is the lack of widespread emergency planning for continuity of operations in the private sector and the potential for a disruption of public and private sector goods and services. During the H1N1 response we experienced a breakdown in the supply chain for antivirals. Without adequate planning we can also experience collapse of the supply chains for gasoline, food, and water. There must be a concerted and coordinated effort between and among all levels of Government to engender and support the necessary planning.

Communications.—As previously mentioned, under the leadership of CDC and Homeland Security, the flow of information from the local to the State to the Federal level and back again was nearly constant, even at the initial stages of the outbreak. But we need to recognize that it is communication with the public that will play a critical role in our efforts to reduce the illnesses and deaths from pandemic influenza. As history demonstrated during the 1918 influenza pandemic, communities in which public officials made a commitment to sharing timely information about self-protective measures reported a lower level of social disruption from the flu. The public must be involved in our preparedness efforts. They will need advice on non-pharmaceutical interventions, such as staying home when sick. They will need advice on the appropriate use of available health services otherwise the health care delivery system will be quickly overwhelmed. These messages will need to be repeated often and shared widely.

Public communication must be coordinated and emphasize the actions that families, schools, and businesses must take to reduce the toll of influenza. New tools, such as Web-based videos, text messaging, Facebook, Twitter, and other social media will be employed. Community-based organizations, faith-based organizations, and neighborhood groups will be messengers, too, disseminating life-saving information. We must motivate people to action without causing them alarm.

CLOSING REMARKS

A mantra of emergency preparedness is that we are most ready for a disaster right after we have experienced the last one and that is true of our experience with the H1N1 outbreak this spring. But this type of readiness can deteriorate quickly unless adequate resources are provided to build and maintain the public health infrastructure.

There have been enormous efforts in California, the United States, and globally to prepare for pandemic influenza. Congress has provided significant support for these efforts, as have State and local governments. Our detection of H1N1 came as a result of the investments made in enhanced surveillance and laboratory capacity. Our ability to maintain an effective response to this relatively mild pandemic also came as a result of previous investments. A severe epidemic would require mobilization of the public health work force for a period of many months and has the potential to cause serious social disruption of both public and private sector services.

I will return to my initial outline to suggest specific actions which could strengthen our efforts to achieve readiness for pandemic influenza:

Surveillance

- Additional investment in the public health workforce including epidemiologists, microbiologists, and laboratorians to ensure enough scientists are on the ground to identify and monitor the spread of disease;
- Continued investment in epidemiologic and laboratory physical capacity including expanding the network of sentinel physicians;
- Providing investment to enhance surveillance systems within emergency rooms and hospitals to build capacity to monitor prevalence of disease in real time; and
- Investment in standardized electronic reporting systems and centralized databases (such as automated laboratory information management systems to con-

nect hospital and private laboratory data systems to local and State health departments).

Public Health Interventions

- Investment in resources to ensure rapid development, re-evaluation, and distribution of clear guidelines related to social distancing strategies for schools and workplace;
- Investment in supplies and guidelines for use of personal protective equipment such as masks and the prophylactic use of antivirals; and
- Investment in supplies and distribution for mass vaccinations.

Health Care Surge Capacity

- Continue investment in the Strategic National Stockpile to ensure adequate supplies antivirals, vaccines, and medical supplies as well as the resources to distribute them;
- Restore investment in medical surge capacity to prevent the overload of the health care delivery system including guidelines for patient triage, infection control in health facilities, and vaccination of health care workers; and
- Provide resources for an aggressive public information campaign on the appropriate use of health care services.

Social Disruption

- Dedicate Government resources to lead a multiagency initiative to increase public and private sector development of plans for continuity of operations and continuity of Government. This is a critical undertaking in part because it is the least developed segment of emergency preparedness and the potential consequences could exacerbate any emergency beyond all of our ability to respond.

Communications

- Maintain the resources needed to support the flow of information through the levels of Government and provide resources for sharing among States. The excellent communication spearheaded by CDC and the Department of Homeland Security was well executed and adding the ability for communications across State governments will further enhance information exchange; and
- Invest in development of traditional and new media materials and messages for vaccinators, other medical providers, local, State, and Federal health agencies and the public.

The H1N1 outbreak has demonstrated the unique and essential public health skills and services that are provided for less than 1 percent of health care expenditures. Let me repeat, less than 1 percent of each dollar spent on health care goes to support the public health services which would be required in an emergency response. Core public health functions and the public health emergency response system deserve and require our Nation's support.

The stronger the foundation of the public health system, the better the system is able to respond. Continued Federal support of public health infrastructure and emergency preparedness and response will be vital to our ability to protect public health and safety when the next pandemic influenza strikes.

Thank you for this opportunity to appear before you today. I am pleased to answer any questions you may have.

Chairman THOMPSON. Dr. Farley, I think we are running out of time. We have to go vote. We have about 20 minutes of votes and we will come back to hear your presentation and Members will ask questions.

The committee stands in recess.

[Recess.]

Ms. CLARKE. [Presiding.] I now recognize Dr. Farley to summarize his statement for 5 minutes.

**STATEMENT OF THOMAS A. FARLEY, M.D., NEW YORK CITY
DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

Dr. FARLEY. I would like to thank the Chair, Congressman Thompson, Ranking Member King and the committee for convening this hearing.

Large, densely populated urban areas like New York City face unique challenges when combating highly contagious viruses such as influenza. The city has a population of over 8 million, and the population grows to nearly 12 million on weekdays. More than 1 million students attend about 1,500 public schools in the city. These are ideal conditions for easy transmission of influenza.

We know that we will not be able to prevent pandemic influenza from entering New York City once it emerges anywhere in the world; and that once it arrives, we can try to slow its transmission, but will not be able to halt it. When H1N1 arrived in New York City in late April, we knew little about how easily the virus might be transmitted, the severity of the illness it might cause and who in New York City was at risk for infection or severe illness. Through CDC we quickly acquired the technology necessary to begin performing confirmatory tests for the new H1N1 in our own laboratory, vastly improving our ability to obtain timely information about the virus. The development and distribution of such a test in such a short period of time is a remarkable feat, and we appreciate the support we received from our partners at the CDC.

From reports of severe illness, it appears that H1N1 community transmission in New York City was more widespread than elsewhere in the United States. We estimate that at least several hundred thousand and perhaps at many as 1 million people in the city became ill with H1N1. With 47 recorded deaths from H1N1, the case fatality ratio was approximately 1 per 10,000 cases, roughly the same as or lower than the case fatality ratio for seasonal influenza.

During the outbreak, the Health Department recommended closing 57 schools for 5 days to protect those at highest risk of complications. School closures were not expected to interrupt the spread of influenza in the city as a whole.

Our plans for the expected return of H1N1 in the fall or winter are focused on assessment of current resources, addressing gaps, and implementing enhancements. This process will be greatly aided by the supplemental funding that Congress recently approved, and we would like to express our thanks for that support.

The best tool we have to prevent influenza infection and severe disease is vaccination. We are hopeful that a vaccine against H1N1 will be available before the virus returns. If ample supplies are available, we will provide it to people in ways that will protect those most at risk for severe infection.

However, because we do not yet know how much vaccine will be available, we must prepare for a range of options. These include vaccination by private medical providers, vaccination in public clinics, mass vaccination in schools, and vaccination using point-of-distribution, or POD, sites. If an H1N1 vaccine is not available in ample supply before the virus returns, we will have to rely more on antiviral medications to protect persons at risk for severe disease. We are developing contingency plans for use of antivirals that will rely on distribution to hospitals and community health centers.

A significant challenge for public health departments will be responding to an H1N1 outbreak while we are also promoting vaccination against seasonal influenza. The overlap of these activities

will further strain private providers, health care facilities, long-term care facilities and the health department.

During the peak of the pandemic this past spring, some hospital emergency departments were severely strained. Some hospitals created additional space by setting up tents outside of their emergency departments or used outpatient clinic space to quickly separate influenza patients from others. To avoid this overcrowding this coming season, we are working to develop better ways to guide people's decision-making about when it is necessary to seek medical assistance. We plan to publicize up-to-date guidance on our website and disseminate it through community and faith-based organizations, as well as schools.

To provide alternatives to hospital emergency departments, the health department is working with community health centers to expand their operations. We will also encourage hospitals to develop specialized influenza clinics or alternate emergency departments so they can handle patient load and reduce exposure of influenza to other emergency room patients.

Our current thinking regarding school closure policy is that if the virus does not increase in severity, we are unlikely to recommend widespread or prolonged school closures. Because the disease has been mild in nearly all children, such closures would not stop the spread of the virus, and the economic and social disruption caused by school closures is substantial.

We will recommend that children and staff with symptoms stay home and that children or staff at risk of severe disease who come in contact with ill persons consult with their medical provider about taking antiviral medications. On the other hand, if there is evidence to suggest that the virus is more severe or the disease incidence increases significantly, school closures and other measures to reduce contact among large numbers of persons may be considered.

To date, the cost of the H1N1 response for the health department activities alone has been approximately \$4 million. City-wide costs are estimated to exceed \$12 million. While the funding has been very much appreciated, the funding that will be needed to respond to a more severe return of this virus would be substantially more.

I would like to thank, again, the committee for our opportunity to testify; and I will be happy to answer any questions you have.

[The statement of Dr. Farley follows:]

PREPARED STATEMENT OF THOMAS A. FARLEY

JULY 29, 2009

I want to thank Chairman Thompson, Ranking Member King, and the other distinguished Members of the committee for convening this hearing about the current status and future outlook of the national response to pandemic influenza.

As you know, influenza is a serious viral disease. In New York City, on average 1,000 people die of seasonal influenza each year, the vast majority of whom are over the age of 65. Large densely-populated urban areas like New York City face unique challenges when combating highly contagious viruses such as influenza. The vast majority of New York City commuters travel by public transportation—each day there are between 7 and 8 million trips on the subway, and the population of the city grows to nearly 12 million during the weekday. There are 1.2 million public school students attending about 1,500 public schools in the city. These are ideal conditions for easy transmission of a virus such as influenza.

The new strain of the influenza virus, H1N1, arrived in New York City in late April, when a large number of students from a high school became ill over a few days. At that time we knew little about how easily the virus would be transmitted, the severity of the illness it might cause, and who among the New York City population was most at risk for infection or for severe illness.

Under the Citywide Incident Management System, the New York City Department of Health and Mental Hygiene (DOHMH) is a lead agency in responding to public health emergencies, including pandemics, along with the Police and Fire Departments. In preparation for such an event, the Department had developed a *Pandemic Influenza Preparedness and Response Plan*. The plan is grounded in the reality that we will not be able to prevent pandemic influenza from entering New York City once it emerges anywhere in the world, and that once it arrives we can try to slow its transmission, but will not be able to halt it. A key priority in our plan, which is very relevant in our current response, is minimizing severe illness and death by identifying and treating those New Yorkers who are most at risk as early as possible in the pandemic.

In response to the initial H1N1 outbreak at the high school, the Department activated its Incident Command System (ICS), drawing on all needed agency resources and providing the highest level of coordinated response during emergencies. Our response utilized the preparedness infrastructure capacity and capabilities that DOHMH has been building and enhancing since 2001, largely with the support of Federal funding. The Department's preparedness infrastructure enabled the agency to sustain an effective response over an 8-week period, with over 200 Health Department staff working on response activities at the height of the outbreak.

The New York City Health Department constantly monitors influenza-like illnesses (ILI) activity in community and health care settings using a variety of surveillance methods. We routinely track hospital emergency department visits, pharmacy sales of antiviral and other medications, and influenza virus specimens taken from a network of sentinel physicians, among other indicators, to monitor trends and identify clusters of influenza-like illness.

Because H1N1 was a new virus and we had little information on its clinical and epidemiologic characteristics, our priority for surveillance was monitoring for more severe illness and death, which required scaling up our efforts. In partnership with the health care community and New York City's Chief Medical Examiner, we established enhanced surveillance to track the number of persons who were hospitalized or had died with influenza-like symptoms. We actively worked with the health care providers reporting these suspect cases to arrange testing for H1N1 in our laboratory.

The Department's Public Health Laboratory provides a wide range of public health laboratory testing services. During the early period of the outbreak, the Laboratory was able to determine that the ILI at this high school was probably H1N1. We quickly acquired the technology necessary from CDC and were able to begin performing confirmatory tests for the new H1N1 by May 11. Our laboratory was one of the first nationally to receive this test. Having this capacity locally improved our ability to obtain timely information about the virus. The development and distribution of such a test in such a short period of time is a remarkable feat, and we appreciate the support we've received from our partners at the CDC.

We observed some important patterns about this new H1N1 influenza virus from our early investigations. First, the virus appeared to spread rapidly among children. In contrast to seasonal influenza, the elderly were generally spared. Second, nearly all of the younger people who did become ill had mild symptoms, with most recovering completely in 5–6 days.

The Health Department continued to survey New Yorkers to determine what proportion of the city's population has experienced influenza-like illness since late April, and what types of symptoms people have experienced. The Health Department conducted two population-based telephone surveys, asking about influenza-like illness from early May through mid-June. These surveys were designed to be representative of all New Yorkers, and from these data we estimate that at least several hundred thousand and perhaps as many as 1 million people in the city became ill from H1N1. With 47 recorded deaths from H1N1, the case-fatality ratio is approximately one per 10,000 cases, which is roughly the same as or lower than the case-fatality ratio for seasonal influenza.

The H1N1 community transmission in New York City appears to have been more widespread than elsewhere in the United States. As of July 1, 909 people diagnosed with H1N1 have been hospitalized in New York City. An analysis of H1N1 hospitalization data found that the most common risk factor for complications due to H1N1 in New York City thus far has been asthma. We also observed that individ-

uals who are younger than 2, pregnant, or have a weakened immune system, diabetes or cardiovascular disease were at elevated risk during the current outbreak

As with seasonal influenza, the H1N1 influenza has claimed lives, 47 so far in New York City since the outbreak began. While most of these deaths have involved people with underlying risk factors for influenza complications, some occurred in otherwise healthy people. These deaths are tragic, but not unexpected. An important part of our response is educating New Yorkers about why it is important for individuals with these risk factors or chronic underlying health problems to consult a health care provider when experiencing influenza-like illness. We also urged all New Yorkers to take measures to protect themselves from influenza, including avoiding close contact with people who have influenza-like illness, and washing hands often with soap and water.

During the outbreak, DOHMH recommended closing 57 schools for 5 days. The main goal of school closures was to protect those at highest risk of complications from influenza by slowing transmission in that particular school community and reducing exposures among those with underlying conditions. School closures were not expected to interrupt the spread of influenza in the city as a whole.

One of the greatest challenges facing the city during a pandemic is to provide quick, clear, consistent, and frequent emergency information to the public. Central to our communications strategy is the use of the news media to keep New Yorkers well-informed about the progress of the outbreak and about what measures they can take to protect themselves.

Information was made widely available through Mayor Bloomberg's almost daily press briefings, and the Mayor's leadership in addressing the issue routinely played a significant role in educating the public about H1N1. The health department issued 25 press releases and held eleven press conferences and briefings, generating thousands of media stories. This method of communication is effective and efficient, and allows us to reach the maximum number of people with the latest and most up-to-date information.

The department also issued a wide variety of fact sheets, brochures, posters, and pamphlets targeting various populations, including the school community, employers, and faith and community leaders. We translated these documents into 12 languages, and developed low literacy materials. All of these materials were made available on a dedicated page on the DOHMH website.

Equally important to our public communications is our ability to distribute important clinical information to health care providers. With approximately 29,000 subscribers, our Health Alert Network provides an opportunity to get clinical recommendations and treatment guidance directly into the hands of providers with the click of a button; we sent out health alerts, as well as multiple clinical guidance documents and treatment recommendations during the course of the outbreak, providing physicians with the latest information on H1N1 activity in New York City. Our Provider Access Line, staffed by Health Department and Medical Reserve Corp personnel, fielded nearly 5,000 requests for assistance. We also conducted numerous conference calls with providers to review our guidance.

Importantly, regular teleconferences and communications with the Centers for Disease Control provided invaluable assistance and guidance to our efforts.

PLANNING FOR RECURRENCE OF H1N1

We are now planning for the expected return of H1N1 in the fall or winter, when influenza virus transmission traditionally peaks. We are focusing on assessment of current resources, addressing gaps, and implementing enhancements. DOHMH has established formal planning workgroups, many of which have interagency participation, tasked with implementing solutions to gaps and weaknesses identified. This process will be greatly enhanced by the additional supplemental funding that Congress recently approved and we would like to express our thanks for that support.

SURVEILLANCE & LABORATORY CAPACITY

Perhaps the greatest challenge we face—one that is common to pandemic planning and response—is the need to respond and make policy decisions in the face of medical and scientific uncertainty. Influenza can evolve in unpredictable ways; because we knew little about this virus when it first emerged, our surveillance system was intensive and relied heavily upon identifying and counting individual cases of persons hospitalized for influenza. With the knowledge we have gained, we expect to modify our surveillance approach in the fall to one that is more sustainable and less resource-intensive. Since case-based hospital surveillance will likely be impractical during the expected upsurge in influenza-like illness, the approach entails an overall assessment of the amount of influenza-like illness activity (for both mild and

severe disease), combined with laboratory testing from a limited number of representative outpatient and hospital sites. Our primary approach to track the overall trajectory of the potential outbreak will be to monitor visits to hospital emergency departments for influenza-like illness, through what is called “syndromic surveillance,” and conduct periodic telephone surveys for symptoms of influenza-like illnesses.

MASS VACCINATION AND ANTIVIRAL DISTRIBUTION

The best tool we have to prevent influenza infection and severe disease is vaccination. We are hopeful that a vaccine against H1N1 will be available before the virus returns. If ample supplies of this vaccine are available, we will provide it to people most likely to develop severe illness from influenza, people who are likely to spread the virus to those persons, and essential personnel who are likely to come in contact with the virus such as health care workers. However, because we do not yet know how much vaccine will be available, we must prepare for a range of options, both regarding who will be vaccinated and how vaccines will be administered. These include vaccination by private medical providers, vaccination in public clinics, mass vaccination clinics in schools, and vaccination using Point-of-Distribution (POD) sites. We have conducted numerous POD trainings and exercises for staff and volunteers over the last several years and have identified 200 POD sites within walking distance of most city residents.

If an H1N1 vaccine is not available in ample supplies before the virus returns, we will have to rely more on antiviral medications to protect persons at risk for severe disease. We are developing contingency plans for use of antivirals that will rely on distribution to hospitals as well as community health centers. We are aware that for some populations, such as homebound and incarcerated persons, accessing these sites will be difficult, so we are working on plans to address the needs of vulnerable populations as well.

As part of on-going planning activities, we intend to define the threshold for releasing stockpiled pandemic influenza response items such as antivirals, personal protective equipment, and ventilators, and develop guidance for organizations that would receive supplies from the Strategic National Stockpile (SNS) and to refine plans for the delivery of supplies to hospitals, long-term facilities, home-based care agencies, and other outpatient providers.

A significant challenge for public health departments will be responding to an H1N1 outbreak while we are also promoting vaccination against seasonal influenza. The overlap of these activities will further strain private providers, health care facilities, long-term care facilities, and the Health Department.

HEALTH CARE SURGE CAPACITY PLANNING

DOHMH works closely with New York City’s hospitals, outpatient centers, congregate care facilities, and emergency medical service agencies to handle a surge in persons seeking care for influenza. We have developed medical surge protocols and built a local medical cache of ventilators and personal protective equipment. DOHMH has also conducted city-wide pandemic influenza exercises and drills with local, State, and Federal partners, and hospitals and community health centers. DOHMH has also engaged congregate care facilities and major health agencies to provide guidance regarding care for patients at home or other residential settings during a pandemic.

During the peak of the pandemic this past spring, some hospital emergency departments were overwhelmed. Many emergency departments saw a 200 percent increase in the number of patient visits. To deal with overcrowding, some hospitals created additional space by setting up a tent outside of their emergency departments or used outpatient clinic space to allow those patients with influenza to be quickly separated from others. In response to the demands placed on hospitals, DOHMH provided clinical algorithms, screening, and isolation guidelines. We also delivered personal protective equipment and pediatric Tamiflu suspension to hospitals.

DOHMH recognizes the need to take action to avoid this overcrowding in the future. We are working to develop better ways to guide people’s decision-making about when it is necessary to seek medical assistance. To reduce visits to emergency departments by the “worried well”, we plan to publicize the availability of up-to-date guidance on our website. The website will provide suggestions for people with mild cases of influenza-like symptoms so that they can confidently care for themselves at home. We plan to develop non-hospital sources of medical advice for patients who need it. We are working on ways to disseminate this information through community and faith-based organizations as well as schools. To provide an alternative to

hospital emergency departments, DOHMH is also working with community health centers to assure that they have the resources needed to expand operations during resurgence of H1N1. DOHMH will also encourage hospitals to develop specialized influenza clinics or alternate emergency departments to treat patients with influenza-like illness so that they can handle the patient load and reduce exposure to influenza in patients seen in emergency departments for other reasons.

SCHOOL CLOSURE POLICY

Under what conditions health officials should close schools to limit the spread of H1N1 is a question that will come up again in the fall. Our current thinking is that if the virus does not increase in its severity from the spring, the New York City health department is not likely to recommend widespread or prolonged school closures because the disease has been mild in the nearly all children, because such closures would not stop the spread of the virus, and because the economic and social disruption caused by school closures is substantial. We will recommend that children and staff with symptoms stay home and that children or staff at risk for severe disease who come in contact with ill persons consult with their medical provider about taking antiviral medications. Individual schools may need to be closed by school authorities if too many staff members are ill for the school to administratively function. On the other hand, if there is evidence to suggest that the virus is more severe or the disease incidence is far greater than they were in the spring, school closures and other measures to reduce contact among large numbers of persons may be considered.

INFECTION CONTROL

DOHMH continues to refine its guidance concerning infection control in hospital, community, congregate, and high-risk settings, including day care, universities, home visiting programs, and others. We are also refining worker protection guidance for all public and occupational groups, which will vary depending on the severity of the outbreak. On July 23, 2009, CDC's Healthcare Infection Control Practices Advisory Committee unanimously voted to recommend that surgical masks be worn by health care workers caring for H1N1 patients, except when specific medical procedures are performed, in which case N-95 masks are recommended. DOHMH strongly endorses this infection control recommendation.

INCIDENT RESPONSE

The single most important way to build a strong preparedness foundation is to build a strong workforce. DOHMH, with help from CDC's Public Health Emergency Preparedness grant, supports staff positions with preparedness and response expertise. In addition, DOHMH trains all employees on the agency's Incident Command System. We have also developed automated notification systems so that all agency staff can be quickly mobilized to respond to any public health emergency. DOHMH has also created the largest Medical Reserve Corps in the country, with over 8,300 volunteers to call upon during an emergency response.

DOHMH also provides funding and expertise to key city partners to purchase stockpiles of pandemic countermeasures and facilitate development of pandemic influenza plans for city agencies and the populations they serve, including the Department of Homeless Services, the Human Services Administration, and the Department of Corrections, as well as coordinating plans with the Office of the Chief Medical Examiner.

COMMUNICATIONS AND PUBLIC OUTREACH

To communicate accurately and rapidly to the public about influenza, DOHMH is continuing to develop numerous templates for fact sheets and press releases in many languages. These materials help us provide well-considered information at very short notice to many audiences. DOHMH also continues to focus on the importance of health care provider awareness and education through regular communication and through our Health Alert Network, as providers may be the first to recognize unusual disease patterns that precede an outbreak.

To ensure timely communication with the public and the health care community, DOHMH plans to enhance its existing protocols for rapid development and clearance of public messages. CDC Public Health Emergency Response funds will be used to further develop our ability to communicate to New Yorkers in a variety of ways about H1N1. We will also develop pandemic-specific public information and education initiatives, including a range of community and workplace outreach activities,

especially to high-risk populations, and an advertisement campaign. In addition, funds will be used for health care provider education and training.

FUNDING NEEDS

To date, the cost of the H1N1 response for the city health department activities alone has been approximately \$4 million. City-wide, costs are estimated to exceed \$12.6 million. Core capacity building at DOHMH to prepare for a fall recurrence of H1N1 are expected to cost the Department more than \$70 million, including laboratory equipment, information technology support tools, occupational health supplies and training, vaccine distribution, and procurement, storage, and management of mechanical ventilators, and personal protective equipment for health department and other key city personnel. City-wide, the costs to fully prepare for a pandemic could exceed \$160 million, including costs to the city's school system, the Medical Examiner's Office, the Fire and Police Departments, and the city's public hospital system. The cost of response if the H1N1 recurrence is severe could be almost a half a billion dollars for all city agencies.

We are grateful for the additional funds recently provided by Congress and those being allocated through the Public Health Emergency Response Grants. The additional \$7 million New York City expects to receive for public health preparedness as well as \$2.4 million for hospital preparedness, will provide critical support as we continue to build our core capacity and prepare for the influenza season and the possibility that a more severe H1N1 virus will return. It is, however, only a fraction of the real need.

While there are many factors involved in planning for an influenza outbreak, the single most important resource is personnel. A well-trained workforce is critical to the successful response to any emergency. CDC's Public Health Emergency Preparedness grant, the Hospital Emergency Preparedness Program funding and the Urban Area Security Initiative funding have been extremely important to New York City's preparedness. However, the steady erosion of funding in the last few years hinders our ability to maintain progress and retain the critical workforce needed to respond to the unique risks and public health emergencies in New York City.

The primary source of support for the preparedness infrastructure in New York City, the Public Health Emergency Preparedness Cooperative Agreement through CDC, has steadily decreased since 2002 dropping approximately 26 percent. In 2004, the Cities Readiness Initiative program, initially provided to 21 high-risk cities, was created to prepare major U.S. cities and metropolitan areas to dispense antibiotics to their entire population within 24 hours. Recent formula changes have resulted in a 25 percent reduction in New York City's allocation, and we have been advised that we will receive another 25 percent reduction in the next grant year.

Although we appreciate the gap funding that is being provided through recent supplemental appropriations, this is one-time funding that cannot be used to close our personnel gaps—nor to replenish more than \$12.6 million in tax levy dollars we used for the recent H1N1 outbreak. In authorizing future funding mechanisms, we urge you to consider the need for stable, predictable, and risk-based funding that helps localities maintain their emergency preparedness infrastructure. That is the key to real preparedness.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

Ms. CLARKE. I thank all the witnesses for their testimony. I remind Members that he or she will have 5 minutes to question the panel. I will now recognize myself for questions.

I want to thank all of the witnesses for taking the time to come and share your experiences in managing this outbreak. As the only Member of this committee from New York City, I especially want to welcome Commissioner Farley and thank him for his diligence for managing this crisis in the city.

New York was hit hard with H1N1, with the highest death count—63 total—of any State, and 43 deaths in New York City. Confirmed cases in New York total 2,738 to date, and the fourth-highest case count.

Commissioner Farley also testified that as of July 1, 909 people diagnosed with H1N1 have been hospitalized in New York City alone.

Dr. Farley, tell us about the lessons learned by New York City during the H1N1 outbreaks. Have you been able to rectify the lack of guidance coming out regarding school closures, managing H1N1 in other institutional settings and getting information out to the public?

Dr. FARLEY. H1N1 ended up—while we had a pandemic influenza preparedness plan, H1N1 was a little bit different from what we had expected. It was a very widespread infection, caused many, many cases, but it was milder than what we had prepared for. So we had to adapt our pandemic preparedness plan. That caused changes in policy about issues such as school closures.

One of the lessons, I think, learned from this is that it is important to have the ability to closely track the arrival and the severity of a virus such as this and to be able to change your plan according to the information you get. We were fortunate to have funding for capacity, for surveillance, and for laboratory testing, so we felt we had a very good handle on where the virus was in the city, how severe the cases were.

We had to again adapt our response in light of that. That adaptation at times involved us in giving guidance that was somewhat in conflict with the guidance from the Centers for Disease Control, so one of the lessons learned is that, at the National level, plans need to be flexible for differences in different areas and for differences in how severe the infectious virus may be.

Ms. CLARKE. Let me ask then, your concerns or your challenges around institutional settings, the outbreak, for instance—the Krome DRO facility in Miami, it is a temporary immigration detention center, is just one example, for instance, at the Federal level. We know there has been an outbreak at Rikers Island jail.

Can you tell us about how the city handled the outbreak, as well as the concerns of union and employees there?

Dr. FARLEY. We did have infections occurring in people who were at Rikers Island jail. This is a jail in which many people are arrested frequently, so there is a lot of communication between the general city population and the jail.

We took very aggressive action to try to limit the spread of the infection within the jail and, when necessary, provide prophylactic medication to people who were at risk, who came in contact with those with the infection. We were able to contain the transmission in the jail, but it did point out to us the fact that there are populations who can't follow general guidance. They don't have an opportunity to not come in when they are sick; they are forced to stay in that institution. So we do have to have guidance for congregant settings like that.

But I think we did show that by taking proper precautions, we were able to control the spread of that infection in that institution.

Ms. CLARKE. Aside from the recently issued CDC guidance, what guidance have you given these facilities regarding their operations, protecting both employees and detainees, and their continued operation during a pandemic?

Dr. FARLEY. We provided specialized guidance to a variety of different congregant settings, as well as jails, schools, day care centers, each to a certain extent tailored to their particular operations.

That guidance did, to a certain extent, differ from guidance from the Centers for Disease Control.

There was a period there when the infection was already clearly very widespread in New York City, but the guidance from the Centers for Disease Control was trying to essentially contain it, and it was clearly past the containment stage. So there were settings where, for example, we were not recommending N95 masks because we felt that the virus was similar to seasonal influenza and the droplet precautions were adequate, and the virus was around and that CDC was still recommending N95 masks. So our ability to adapt to the situation, we thought was important, and we still believe it was successful.

Ms. CLARKE. Thank you very much.

I now recognize the Ranking Member of the full committee, the gentleman from New York, Mr. King, for his questions at this time.

Mr. KING. Thank you, Ms. Clarke, and let me thank the witnesses for their patience and forbearance today for putting up with us and our schedule. I can speak for the Chairman; we had no control over it, but I want to thank you for sticking around.

I also want to join with Congresswoman Clarke in welcoming Dr. Farley and thanking you for your service to the city. Let me begin with a question to Dr. Farley, but also open up to Director Muth and Dr. Horton.

I know that Congresswoman Clarke mentioned the fatalities in New York. We had a high number compared to the rest of the country, and I live right outside the city and many of my constituents take the commuter lines into the city. But still, for the most part, this was treated in the papers, after the first few days in the media, as not being a big deal, as being somewhat under control; and yet there was a 200 percent increase in the emergency rooms.

Now, if this were a more severe strain of the virus, and people were more ill than they were this past spring, do you think that you can adapt to that surge both from those who are genuinely sick and those, the "worried well," who are seeing reports in the papers of more fatalities or more serious illnesses who will rush in.

I know when we—I have dealt with a number of New York hospitals as far as if, God forbid, there is ever a dirty bomb attack. Doctors tell me they are more concerned about the people who are not sick, who would rush to the emergency room even, than those who are actually affected by the act itself or the attack itself.

Anyway, I would ask you and also Director Muth and Dr. Horton whether or not you believe the hospitals are prepared for that type of surge capacity.

Dr. FARLEY. As I said, the hospital emergency departments were strained by large numbers of people coming there. Some of those were the "worried well." Some of those were people who had symptoms of disease.

Mr. KING. Those were symptoms that were not that bad? The fact is, you said this was a very mild strain.

Dr. FARLEY. Yes. The vast majority of people got over this fine, so it was not a very severe strain. Nevertheless there were large numbers of people coming to the emergency departments.

Our way of trying to handle that going forward is to, first, communicate to people about the fact that if they are well they do not

need to come to the emergency department. Even if they have mild symptoms, they don't necessarily need to come to any medical provider; they might be able to do it over the telephone. Also to provide alternate sites to get medical care, such as community health centers; and also to work with hospitals to handle people who will nonetheless have to come there, again having potentially separate specialized flu clinics or flu emergency departments.

I think, with that, the hospitals can handle this. I think they will be strained, but I do think they can handle that. But all of these pieces need to be put in place.

As a separate issue, if we have a more severe strain of—a surge of people with very severe disease, the New York City Health Department has done a lot to try to increase the number of ventilators, so that patients who have severe enough disease that they need to be on a ventilator can be handled.

Dr. HORTON. The first point I would like to make is just, I am very reluctant to continue to characterize this as a “mild” virus. We are saying that it is similar to seasonal and—

Mr. KING. As far as results, if there are a high number of deaths there would have been more people rushing to the emergency room. That was the point I was making.

Dr. HORTON. I am making the point, with seasonal flu, even with the fact that a good portion of the population is already partially immune to the new virus and the fact that we have a vaccine in place well before it hits, we still see 35- to 45,000 deaths and hundreds of thousands of hospitalizations.

Now, in this case, where there is a novel virus where virtually nobody is immune to the virus and there was not a vaccine in place early, I think we can anticipate problems.

A couple of other comments; I would just comment on what Dr. Farley said, a couple of other steps.

I think there is some evidence, I could say as a doctor myself, that physicians and nurses working in hospitals are not consistently complying with recommendations about infection control and personal protection. I think we need to get everybody up to snuff and operating to ensure that the hospitals and health facilities themselves not become a nidus of infection in communities and that we are doing everything that we can to protect health care workers so they can stay on board. So I think that is extremely important.

Also individual hospitals, each one of them, should have a surge plan, which means, when they activate it, they can discharge patients that are ready to be sent home early and they can restrict the admission of—new elective admission to the hospital to ensure they maximize hospital capacity. So there are a couple of additional steps I think they can take to help the health system absorb some of this additional activity.

Mr. KING. Director Muth.

Mr. MUTH. Congressman, I spent 30 years at the local level riding medic units and everything, and I would say our system is strained every day, especially the ERs.

So our concern certainly would be that the extra pressure that a pandemic would put onto that system I think would be very

tough to handle, although I do think one of the ways of handling that certainly is through the public education effort.

I think we need to do a push to educate the public at all levels across the country with the same message, which I think is critical. To follow what Dr. Horton said, that if they are not—letting them know if they are not ill, then they don't necessarily need to go to a hospital or to a private physician.

Many in our population depend on a hospital for their primary care. So you are going to have that compounding the situation.

Mr. KING. Just to ask one question on the record; I don't expect an answer, just for the record.

Vice President Biden took a lot of heat when he made the remark about travel on the Metro, but in densely populated areas such as New York, Chicago, Boston, San Francisco, where so many people do go on subways and commuter lines, if this did become a more severe strain, would the city of New York look into whether or not we would cut back or encourage people not to take the subway lines?

Dr. FARLEY. We did look into the issue of mass transit in New York City. The vast majority of people in New York City rely on mass transit, and the feeling was, we could not shut down the mass transit system because then people couldn't go to work including health care workers and other essential personnel.

There are things we can do to reduce the number of people on mass transit and encourage people other ways to get around. But the fact is in a densely populated city like New York, more people are going to come in contact with each other in many locations; and so you will likely have more spread of a virus like this.

Mr. KING. Thank you very much.

Thank you, Madam Chairwoman.

Ms. CLARKE. Ms. Richardson, I understand it is your turn to ask your questions.

Ms. RICHARDSON. Thank you, Madam Chairwoman, and Ranking Member for having this very much-needed hearing.

I would like to speak to the employees, the Federal employees aspect, and I had an opportunity to read your testimony and congratulations to all of you who hung in here through all of these votes we have.

Is anyone still here from DHS? Okay.

HHS? Okay, great.

In your testimony, you said that folks were not receiving consistent and timely information and not adequate resources and differences from a Texas airport and various airports of what the procedure was.

Do you feel better empowered today with the folks to be able to respond? Have you seen any difference since when that occurred to where we are right now?

Ms. KELLEY. I think in TSA, in particular, there is a recognition that they had serious communication issues with not getting the message out to employees.

We had a meeting as recently as yesterday with TSA about communication, and so I think there is a much clearer recognition, hopefully; and we have offered to work with them to help figure it out so it does not happen again.

In CBP, in Customs and Border Protection, this MOU that was just signed this morning was really the issue. In my view, that was much less a communication issue than their not being willing to put out a very clear message that employees had the choice to wear a mask, if they felt that it was important to them and they thought it was important to their families.

Ms. RICHARDSON. So as far as the Customs folks, they are now aware of—as of today, it is their choice to wear a mask?

Ms. KELLEY. As of today, because of the MOU that NTEU negotiated, it will be clear to them and NTEU will communicate that message to every employee we represent there to make sure they have the information, yes.

Ms. RICHARDSON. Has TSA, to this point—the employees—received a blanket communication that that is their option as well?

Ms. KELLEY. My understanding is, the communication we have was issued May 29, but it only got as far as the heads of each of the airports, that it did not seem to get into the hands of the TSOs. I believe—following yesterday's meeting, I know actually, as of about 10 days ago, it started making its way to the front lines; and I believe, following our meeting yesterday, that that will be clarified for all employees.

Ms. RICHARDSON. Could you please advise this committee within the next 2 weeks if for some reason that communication does not get out to all of you?

Ms. KELLEY. I would be glad to do that.

Ms. RICHARDSON. Thank you very much.

I yield back the balance of my time.

Ms. CLARKE. I now recognize the gentlelady from Texas, Ms. Jackson Lee, for 5 minutes.

Ms. JACKSON LEE. Thank you. I appreciate Ms. Richardson and her line of questioning, and I thank you for allowing me to question as well. I am glad that she acknowledged that individuals are here from DHS and from Health and Human Services.

Madam Chairwoman, I was delayed because of the earlier panel because I was in back-to-back meetings on negotiating health care reform in one meeting dealing specifically with the global issue of what we were addressing and a second one that was Texas-based. So I am going to make some comments and ask some questions that sort of generate back to the first panel.

But I do want to place on the record that Texas also had a very high impact; and the number of counties include, for H1N1, Baylor County, Brazoria County, Cameron, Collin, Comal, Dallas, Denton, El Paso, Guadalupe, Hidalgo, Harris, Johnson, Montgomery, Fort Bend, Grimes, Matagorda, Tarrant, Travis, Nueces, Starr, and Upshur Counties. Texas is a huge State with a lot of counties.

I think, Ms. Kelley, you were focusing on the concern that I had, along with the State commissioners, and I am very glad Secretaries Lute and Corr have indicated they will now have regional strategies. I hope they call them regional teams. Obviously, that doesn't go directly to Federal employees.

But, let me ask you, Ms. Kelley, do you think an ounce of prevention is worth a pound of cure?

Ms. KELLEY. I do, and I think especially when it comes to front-line employees who are facing these very real threats of running

into travelers who may be carrying any kind of a virus, that they have the right to make that choice on their own.

Ms. JACKSON LEE. I remember the debate of TSA, in particular, and TSOs asking for masks, and I remember the confusion of not being able to get an answer; is that correct?

Ms. KELLEY. In TSA, that was correct. In Customs and Border Protection, they were told no, they were not allowed to wear the mask.

Ms. JACKSON LEE. So in addition to confusion, it was also an answer that was a rejection. With the MOU, do you feel that there is a greater stakeholder position right now, we don't know how it is going to turn out, but we do know you have a stakeholder position; is that important?

Ms. KELLEY. It is very important, and I believe that the language is very clear that employees now have that right. As you say, implementation will be the real test.

Do you also think, and I really respect scientists because they are dispassionate. They look at things as 1, 2, 3. But isn't it important or do you feel it is important because most of us are laymen and not scientists, that we have the right amount of passion and concern and also quick acting so that there brings a sense of calmness, whether it is a Federal employee or the broader community?

Ms. KELLEY. Absolutely. The more information the better, and in English that employees can understand; not in scientific or medical language which often causes even more confusion. So the clearer, the more direct, the better.

Ms. JACKSON LEE. Thank you very much. Let me ask the two commissioners from California and New York and certainly Maryland, Texas, unique, not represented here on the panel, but a lot of different counties, enormously diverse, as some of your States are as well. My concern is that the CDC and others who were engaged did act dispassionately as scientists. I believe that is very important. But do you believe it is important for there to be quick-acting communication with State agencies, and do you believe that these regional sites which may be over a certain number of States would also be important to come to large cities like New York, large cities like Los Angeles, large cities like Baltimore, and large cities like Houston, that there is an on-site team in these larger cities?

The commissioner from New York.

Dr. FARLEY. Our communication in this outbreak was mainly through Centers for Disease Control on health issues. There are larger issues there, and if this outbreak was more severe and if it impacted on critical infrastructure, we would need to have discussions with agencies outside of health agencies in having a regional coordination, a regional presence, would be valuable.

Ms. JACKSON LEE. You wouldn't object, however, if you had localized coordination, meaning some of these officials on-site in New York City?

Dr. FARLEY. That would be valuable in New York City, yes.

Ms. JACKSON LEE. The gentleman from California.

Mr. HORTON. I certainly agree. I think that representation would be helpful. I think in the case of what we have seen so far, there was very good vertical integration of messaging. But recognizing

the fact that both across the United States and within States there is a lot of regional differences, to the extent that the whole process of communication can be regionalized, that may bring additional helpful information to myself, for example, as a State health officer, to know what is happening and the differences between different regions within the State and perhaps within the country.

Ms. JACKSON LEE. A particular team that might be dispatched to an L.A. or a San Francisco, would also be helpful? A team dispatched to a large city would also be helpful?

Mr. HORTON. An epidemiology team, yes. For example, at the very beginning of the outbreak in southern California, as I mentioned in my comments, the Centers for Disease Control provided epidemiologists on-site that were matched with epidemiologists from the State and that worked locally in southern California to assess. That was a very effective way of getting early information about the outbreak itself, how severe it was, and how transmissible it was. I think that is a very valid approach.

Ms. JACKSON LEE. Thank you. Madam Chairwoman, if I can conclude, I do just want to say this: The most vulnerable were our large school districts, and I would like to place on the record for DHS and HHS that there needs to be some focusing on school districts, and I would ask for a team such as the ones the commissioner has mentioned to not only be on the cities, but that they should be teamed up with school districts because that is where our impact was, that is where parents were panicking, and that is where we had no answers. I know it well, having a number of those schools in my congressional district. I thank this second panel, and I look forward to meeting with HHS and DHS on this issue going forward.

Thank you.

Ms. CLARKE [presiding]. I have a second round of questions. I don't know if the gentlelady from Texas does.

I am very mindful of everyone's time at this stage, but there are a couple of outstanding issues that I want to have on the record, and that has to do with the drug resistance issue. I want to raise this with both Dr. Horton and Dr. Farley.

By January 2009, our committee found that the pharmaceutical interventions for pandemic influenza would be limited. This turned out to be the case with novel H1N1. There was and is no readily available vaccine, and this particular strain of H1N1 was already resistant to two of the four antivirals ordinarily useful in combating influenza. How are you overcoming this problem to deal with the H1N1 now? How do you think this problem needs to be addressed in the future, and what do you need from Congress to make this happen?

Mr. HORTON. I will be the first to speak from California.

First of all, the information I have is that currently the information we have about the H1N1 virus is that it is almost universally sensitive to the two most commonly used and stockpiled antiviral medications that are available to us.

The stockpile that was set up under the direction of the Federal Government, and most States bought their purchases, oseltamivir or Tamiflu, and Relenza. To my knowledge, to date, there have

been only a handful of cases of H1N1 that have been resistant to those drugs.

So I think we are very encouraged at least at this point. To my knowledge, the information we have so far from the southern hemisphere is that the genetic composition and the phenotypic expression of the virus has not changed. So I am feeling that despite the fact that there is some resistance to other organisms, to date anyway, we are feeling good that we have the antivirals on hand to combat the problem.

Dr. FARLEY. I agree that the antivirals we have now are effective against the virus. However, the virus can develop the ability to become resistant to the antivirals we are using now. In which case then, if we didn't have a vaccine, we would have no tools.

So I do think there is value to developing additional antivirals to keep one step ahead of the influenza virus.

Mr. HORTON. I would agree with that.

Ms. CLARKE. I yield 5 minutes to Congresswoman Jackson Lee.

Ms. JACKSON LEE. Thank you very much. I ended on the note dealing with school districts, and I would appreciate it if the three health directors would comment on the uniqueness of schools and school districts as it relates to health intelligence, getting to you as State leaders and then it transmitting to the consumer. I hate to call a student a consumer of H1N1, that is not the interpretation I want given, but the impacted individual. It seems in our State, certainly children were the most vulnerable. Schools were an immediate source, and I would also want to put on the record that we have noted that a few summer camps have also been, in essence, victimized by H1N1. May I start here, please.

Dr. FARLEY. This particular strain of influenza, H1N1, particularly favored younger people. There was transmission among younger people. There may very well have been transmission among schools. That makes them important sites for us to consider how to prevent infection with the next epidemic wave.

I understand today there are recommendations that children are a high priority group for vaccination when the vaccine becomes available. It is important for us to vaccinate children to try to prevent infection in the fall.

Ms. JACKSON LEE. Mr. Horton.

Mr. HORTON. How I would like to address your question and concern is just to point out what really is needed is cross sectorial collaboration on a much stronger level. I think what we experienced early this spring when the CDC came out with recommendations with regard to school closures was a few hiccups, to say the least.

I would like to think vertical integration allowed us to respond to that, and CDC modified it in a very timely fashion. But nonetheless, I think public health needs to be more aware of the implications of public health recommendations, like school closures.

I mean, how is education going to continue? How are nutrition programs going to continue? What is going to be the impact on the parents and their workplaces if we send kids home from schools? All of those factors, we need public health to put the science forward in terms of the effectiveness of closing a school, but we also have to factor in the social impacts of that and make sure that we have everybody on the same page, that we have communicated ef-

fectively with the school authorities to ensure that we all agree that this is the right step, we are aware of the implications, and we have a consistent communication to the parents and the children.

Ms. JACKSON LEE. I think that is what was missing.

Mr. Muth.

Mr. MUTH. Madame, I am from an emergency management field, not the medical field.

I would like to say, getting back to the whole topic of communications, within Maryland, we certainly have the problem with the National Capital Region in that it is very likely that we would have a person living in Maryland, possibly dropping a child off in the District of Columbia for school, and either living or working in VA. Because of that tri-State or the two States and the District of Columbia, it is really critical that we are all issuing the same guidance and direction. That certainly was a stumbling block for us in the spring event.

Also, because the CDC, and I am not blaming or putting fault on them, but constantly changing the guidance for closing schools also created confusion in those areas. So I think we have a ways to go to ensure that the communication is across the board and going back to your idea of regional teams, I think that is a great idea. Part of it should be the whole communication package should go along with that.

Ms. JACKSON LEE. We don't want communication to be missing, and we don't want to dumb down the communication, in essence, to suggest that people should not be concerned.

Mr. MUTH. No. Absolutely not. I think the facts should come out as the facts are.

Ms. JACKSON LEE. Ms. Kelley, Federal employees are everywhere, and many times dealing with the public. Do you think it is crucial that, beyond the MOU you have, there be an immediate contact communication with our Federal employees and their leadership when there is a sign of a pandemic of the kind that H1N1 could have been?

Ms. KELLEY. I do.

Ms. JACKSON LEE. I thank you very much. I yield back.

Ms. CLARKE. I thank the witnesses for their valuable testimony and the Members for their questions.

Before concluding, I would like to remind our second panel of witnesses that the Members of the committee may have additional questions for you, and we will ask you to respond expeditiously in writing to those questions.

Hearing no further business, the committee stands adjourned.

[Whereupon, at 5:51 p.m., the committee was adjourned.]

APPENDIX

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR MS. JANE HOLL LUTE, DEPUTY SECRETARY, DEPARTMENT OF HOMELAND SECURITY

Question 1. During the hearing, various Members asked you about lessons learned from responding to the H1N1 outbreaks/pandemic. How is the Department of Homeland Security identifying lessons learned from its preparedness for, detection of, and response to the H1N1 outbreaks and pandemic influenza? Is this information being added to the DHS Lessons Learned Information Sharing (LLIS) system? If not, why not?

Answer. The Department of Homeland Security (DHS) has identified lessons learned from the response to the spring outbreak of H1N1, and has in fact implemented changes to improve our response for the fall wave. Specifically, while DHS found that the United States Government (USG) pandemic planning began in 2005 was of great value in responding to the H1N1 outbreak, DHS learned that much of what actually occurred in the spring was not contemplated by prior planning. First, contrary to planning scenarios, based upon the H1N1 spring outbreak, DHS learned that an initial outbreak with high mortality rate in one country does not necessarily mean that the same pattern will follow in the United States. In fact, the H1N1 spring outbreak in the United States proved to have a relatively mild or low mortality rate and relatively few hospitalizations. DHS also learned that contrary to our planning scenarios where outbreaks usually start overseas in Africa or Southeast Asia, a pandemic can start with little or no warning closer if not at home, here in the Americas. Fortunately, the USG was able to use the information developed over the years to adjust plans for community mitigation, for determining science-based border strategies, for vaccine prioritization, for pre-deploying antiviral medications quickly to States and for rapidly creating messages that helped the public understand what the Nation was facing. Also, very importantly, over the years, DHS developed close working relationships with interagency partners, which facilitated coordinated response and communications.

DHS was always planning for the “worst-case scenario” which is appropriate, but not enough attention was paid to adapting our policies and plans for a mild to moderate pandemic. Since the spring, the USG has been working on focusing our preparations on the current pandemic scenario. DHS found that, while the Department did an excellent job stockpiling personal protective equipment and antivirals for the DHS workforce, the Department must continue to review and update the policies that address workforce protection, communications, and training of employees.

These lessons learned became a major component of the Federal Action Matrix that is currently used to track and monitor aspects of the USG preparation and response to H1N1. Action items were developed for improvement in the following areas: DHS incident response coordination, DHS external communications, workforce protection and guidance, support of the Secretary as the Principal Federal Official, and in incident preparedness and continuity of operations. Coupled with the development of a four-pillared approach to preparedness, response, and recovery, the USG is in a much better position to deal with a future pandemic as a result of this after-action work.

LLIS currently contains pandemic influenza lessons learned. DHS intends to include updated information on lessons learned from the current H1N1 response on LLIS.

Question 2. FEMA Disaster Assistance Policy 9523.17 mentions the Federal Coordinating Official (FCO) for an influenza pandemic. Who is the FCO for the H1N1 pandemic?

Answer. There are pre-designated H1N1 team leaders and teams for each State and U.S. Territory. If a declaration is warranted and declared, the President would appoint an FCO for the declared State or territory to execute any appropriate Stafford Act programs. At this time, the plan is not for a single FCO for H1N1.

Question 3. In your testimony, you made reference to finalizing operational plans to ensure that DHS essential functions are maintained and personnel are protected during a sustained outbreak. Please forward these operational plans, the DHS strategic plan for pandemic influenza, and H1N1 and pandemic plans created by the DHS components and major offices to the committee.

Answer. The Department of Homeland Security, in coordination with Federal, State, local, Tribal, private sector, and non-governmental organizational (NGO) partners, continues to develop and execute pandemic influenza-related planning activities. Ensuring that all essential functions are maintained and protected during a sustained outbreak has been an integral component in all pandemic planning and operations. The second implementation plan is the *DHS 2009–H1N1 Influenza Implementation Plan*, which has been signed by Secretary Napolitano and is provided to the committee as requested as an attachment to this document.

The *DHS 2009–H1N1 Influenza Implementation Plan* identifies specific component roles and responsibilities, and it also directs all DHS components to develop plans that address key preparation and response actions, performance of mission essential functions, workforce protection, continuity of operations, and communications with key stakeholders during the H1N1 influenza pandemic. For example, FEMA developed a Pandemic Influenza Plan (April 19, 2009) that focuses on FEMA’s responsibilities to maintain essential functions and services, ensure the safety of its employees, coordinate Federal response and support interagency activities, and communicate with internal and external stakeholders. FEMA is also developing a FEMA H1N1 Plan to include guidance for workforce protection, mission sustainment, special considerations for response in an H1N1 environment, and support to other Federal agencies.

Question 4. When will the DHS strategic plan for pandemic influenza be posted on Flu.gov?

Answer. The DHS strategic plan for pandemic influenza is the *DHS 2009–H1N1 Influenza Implementation Plan*, which has been signed by Secretary Napolitano. This document establishes an integrated strategy for H1N1 preparedness and response based on the Framework’s four pillars as described in our response to question No. 6. The DHS plan is also “For Official Use Only”, and it will not be posted to the website.

Question 5. Please describe the “active engagement” of DHS with its tribal partners.

Answer. The Department of Homeland Security (DHS) via the Office of Intergovernmental Programs engaged in outreach during the Spring H1N1 outbreak and has on-going engagement with the tribal community in preparation for the upcoming H1N1 flu season. Working with the Department of Health and Human Services (HHS) and in particular, Indian Health Services (IHS) who has the lead, DHS coordinates directly with tribes, through national and regional tribal associations, and with the Bureau of Indian Affairs to provide guidance on H1N1 readiness efforts for individuals, communities, businesses, and schools. DHS is working with several HHS components—the Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), and the Office of the Assistant Secretary for Preparedness and Response (ASPR)—to ensure that we are communicating and coordinating our outreach to Tribes. DHS Intergovernmental Programs (IGP) send regular e-mail communications to Tribal leaders and Tribal organizations as new materials related to H1N1 issues are developed. DHS has engaged and is looking to engage with its other Federal partners at four of the largest Tribal stakeholder organizations at their annual conferences over the next 2 months concerning the latest information on H1N1, the Conferences are:

- a. September 9–11, 2009: National Native American Law Enforcement Association Annual Conference, Tulsa, OK;
- b. September 14–16, 2009: National Indian Health Board Annual Consumer Conference, Washington, DC;
- c. October 11–16, 2009: National Congress of American Indians Convention, Palm Springs, CA;
- d. October 22–25, 2009: National Indian Education Association Conference, Milwaukee, WI.

Question 6. In your testimony, you stated that, “we will be prepared and we will be ready” for the pandemic this fall. Please provide a timeline detailing activities that will be undertaken to reach a full state of readiness.

Answer. To achieve a full state of readiness, the Federal Government, through its various Departments and agencies, and the White House National Security Staff (NSS) are leading the effort to meet the preparedness and response challenges that the H1N1 virus presents to the Nation. Together, we are achieving substantive progress toward meeting the goals set by the White House. Our “whole of govern-

ment” approach to addressing these challenges compels Federal Departments and agencies to work collaboratively and under exceptionally tight timelines.

On August 5, 2009, the NSS published the *National Framework for 2009–H1N1 Preparedness and Response*. This document provides specified tasks and suspense dates assigned to Departments for action. The Framework also categorizes the tasks into four pillars.¹ DHS utilized the Framework’s pillars and leveraged previous pandemic influenza planning products to develop the *DHS 2009–H1N1 Implementation Plan*.

Additionally, after examining the effects of the first wave of H1N1, DHS collected lessons learned from the initial outbreak, and the Department provided guidance to components relating to their preparation for future waves of H1N1. This guidance outlined activities and timelines associated with the activation and deployment of component resources and the H1N1 Regional Coordination Teams.

Information from the Framework, DHS lessons learned from the initial H1N1 outbreak, and guidance to DHS components has been distilled into a Federal Action Item Matrix containing action items designed to track and manage the Federal Government’s approach to H1N1 response. These action items will address and ameliorate our collective preparedness and response requirements. We plan to have all action items resolved and in place by October 15, 2009.

Question 7. How has DHS worked with the coordinating councils to develop and provide pandemic influenza guidance, clarification of roles and responsibilities, possible actions (such as border closures), etc.?

Answer. The Department of Homeland Security’s (DHS) Partnership and Outreach Division (POD) has worked closely with representatives from the Sector-Specific Agencies, Sector Coordinating Councils (SCCs), and Government Coordinating Councils (GCCs) to develop planning guidance, and has conducted workshops to assist the private-sector business community within the critical infrastructure and key resources (CIKR) sectors in planning for a pandemic influenza outbreak.

In 2006, DHS released the *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources* (CIKR Pandemic Influenza Guide) and, subsequently, the individual sector-specific annexes. The CIKR Pandemic Influenza Guide may be found at www.flu.gov. Since the publication of that Guide in 2006, DHS and subject-matter experts provided by and coordinated through the respective CIKR SCCs have been drafting individual sector-specific guides aimed at preparing the sectors for a high-severity influenza pandemic.

In addition to the Guide, POD worked with the SCCs and GCCs to develop workshops targeting CIKR business owners and operators and their contingency planners across the United States. Nine web-based workshops were conducted during the fall of 2008 for the Commercial Facilities, Defense Industrial Base, Emergency Services, Energy, Food and Agriculture, Water, and Information Technology/Communication sectors. During these workshops, participants had opportunities to ask questions about the latest USG pandemic planning guidance.

At this time, POD, HHS, and other sector-specific agencies are reviewing and updating the draft sector-specific guides to ensure consistency with USG guidance for the 2009–2010 influenza season. When final, these guides will be disseminated to the sector partners, and POD will work with those partners on any upcoming activities and actions. Additionally, implementing a border closure is not part of the national strategy for responding to a pandemic.

Question 8. Please describe DHS efforts to plan for H1N1 occurring at the same time as other major incidents, including hurricanes and acts of biological terrorism.

Answer. The Department of Homeland Security has taken several steps to prepare for the possibility of a second wave of the H1N1 influenza occurring simultaneously with other major incidents.

The DHS Office of Operations Coordination and Planning (OPS) and the Office of Health Affairs (OHA) established an Operational Planning Team (OPT) to provide surge support to the planning and operational support efforts needed to augment our capabilities to prepare and respond to the challenges that 2009 H1N1 presents to the Nation. The OPT’s initial charter laid the foundation for a Federal Strategic

¹ The following are the four pillars established in the *National Framework for 2009–H1N1 Preparedness and Response: Surveillance*.—Enhanced efforts to achieve timely and accurate situational awareness of evolving disease and the impact on critical sectors to inform policy and operational decisions; *Mitigation Measures*.—Interventions to slow the spread of illness and reduce the impact of infection and illness on individuals and communities; *Vaccination*.—Actions to secure safe and effective vaccines and to ready a national vaccination program to enable the United States to begin voluntary immunization upon a recommendation that this approach is warranted; *Communications and Education*.—A coordinated campaign to foster a convergence of action across all levels of government, the private sector, the entire health care sector, faith-based and community-based organizations, and individuals.

Multi-Incident Plan, to be incorporated within the family of National Planning Scenarios in the Integrated Planning System, National Planning Annex I, to Homeland Security Presidential Directive-8.

In developing a draft of this multi-incident plan, the OPT took an all-hazards approach to address threats that may occur simultaneously with a 2009 H1N1 influenza outbreak. Special consideration was given to managing requirements for a major hurricane during an H1N1 outbreak.

Interagency cooperation led to the completion of the draft Federal Strategic Multi-Incident Plan on July 9, 2009. Participating agencies included DHS, the Department of Health and Human Services, the Department of Education, the Department of Transportation, the Department of Justice, the Department of Defense, the Department of Commerce, the U.S. Department of Agriculture, the Department of State, the Department of Labor, the Department of Treasury, and the Department of Veterans Affairs. Through the information analysis planning process, threat scenarios, objectives, and tasks were produced. The OPT developed and analyzed courses of action to address both common all-hazards threat characteristics and unique scenarios that may occur simultaneously.

In addition to the work undertaken by the OPT, DHS OPS and FEMA senior leaders conducted a multi-threat tabletop exercise on August 11, 2009, in which the leadership examined and analyzed the challenges and response requirements relating to simultaneous response to a second H1N1 wave and a hurricane in the southeastern United States.

In accordance with the FEMA Pandemic Influenza Plan, FEMA has activated its Headquarters and Regional Pandemic Response Teams (PRT). In anticipation of the potential impacts of a pandemic on FEMA, the PRTs will develop strategies to plan, manage, and coordinate the effects of a pandemic on our ability to carry out FEMA's mission.

Question 9. What responsibilities does the DHS Science and Technology Directorate have with respect to addressing pandemic influenza? Please provide information including specifics regarding all on-going research, including diagnostic tests.

Answer. The Science and Technology (S&T) Directorate addresses pandemic influenza by providing technical support for event planning and response efforts as well as conducting studies to better understand how disease spreads.

These studies include analyzing potential mitigation strategies to minimize the spread of influenza outside of the United States, assuming the outbreak starts in the United States; analyzing the benefits of various screening strategies for passengers leaving the United States and entering foreign countries; and analyzing social mitigation strategies such as social distancing and school closures when implemented in the United States. These studies seek to determine if the implementation of a layered approach can delay the peak outbreak in a foreign country.

S&T is also working on an all-hazards basis to promote resilient communities. This includes enhancing coordination and cooperation among first responders and between the public and private sectors; working to make the States' 211 help systems more effective; developing metrics to measure the psycho-social impacts of extreme events; and seeking to better understand and improve official communications regarding degrees of risk and best steps to mitigate risk.

During an event, the S&T Directorate provides on-call technical support as needed. In addition, the Biodefense Knowledge Center, funded by the S&T Directorate and operated out of the Lawrence Livermore National Laboratory, also supports planning and preparatory efforts by providing information and rapid response to queries regarding biological agents such as influenza.

The S&T Directorate is not currently involved in the development of pandemic influenza diagnostics assays; the Department of Health and Human Services is the lead for diagnostic-related activities as they pertain to pandemic influenza.

Question 10. How has the National Biosurveillance Integration Center maintained constant, real-time, dynamic biosurveillance of the H1N1 outbreaks/pandemic? Please provide specifics and examples of reports and products.

Answer. Specific examples include:

- NBIC continued/continues to issue reports including specific H1N1 data on a daily basis. From April 24—September 14, 2009 a total of 163 reports were prepared providing real-time, dynamic updates to NBIS Member Agencies (examples attached 20090915 NBIC report and 20090914 NBIC report).
- Through an aggressive daily production cycle that ensured 24-hour coverage, NBIC assembled and centralized individual domain data-feeds utilizing the Biosurveillance Common Operating Network (BCON).

- BCON provided automated data-feed scanning of 2009–H1N1 and related biosurveillance events (at a dynamically constant rate of approximately 790 sources every 2 hours).²

The NBIC aggressively pursued the development of additional biosurveillance related tools to enable it to provide more timely information to Federal, State, local, and Tribal leaders; with the express purpose of enhancing their decision-making in preparation for the return of H1N1 in the fall of 2009.

- Recognizing the potentially devastating consequences on multiple critical infrastructure areas of the United States, the NBIC engaged with the National Infrastructure Simulation and Analysis Center (NISAC) to model potential outbreak characteristics and infrastructure impacts of a resurgent novel-H1N1 virus. The results of the NISAC Modeling effort were analyzed and reviewed by an aggressive and thorough interagency process that engaged all NBIS Member Agencies and additional Federal participants (including the Departments of Energy, Education, and Labor). The impact-analysis was shared with all of the foregoing departments and agencies to provide additional insight into “most-likely scenario” effects regarding the anticipated resurgence of H1N1. This NBIC interagency assessment includes insights regarding the measurable dynamics associated with the impact of absenteeism, reduction of productivity and (for example) the perception of the safety of food commodities that could potentially limit the functionality of many critical infrastructures and key resources if there is a resurgence of the 2009–H1N1 novel influenza virus.
- With the goal of achieving accurate real-time interpretation of the output, NBIC hosted specific interagency collaboration and coordination meetings regarding the development of the Modeling effort and Assessment report with the Department of Health and Human Services (HHS) (including the Centers for Disease Control and Prevention (CDC)) on 22 July 2009 and the United States Department of Agriculture (USDA) on August 13, 2009.
- To garner specific subject matter and domain-specific insight, NBIC hosted an interagency collaboration and coordination conference regarding the development of the Modeling effort and Assessment report on July 22, 2009. Participants in the conference or post-conference discussions included representatives from: NBIS Member Agencies (State, Defense, Justice (FBI), Interior, USDA, Commerce, HHS (including CDC and FDA), Transportation, Veterans Affairs, U.S. Postal Service, EPA); the Departments of Education, Energy, Labor; and internal DHS offices including Infrastructure Protection, Intelligence and Analysis, and the Office of Health Affairs.
- Finalization of the assessment is pending the results of a second modeling run. The parameters for the second run are being finalized with HHS this week. The modeling run and subsequent assessment update should be completed by November 30, 2009.
 - This Modeling effort can be used to provide further focus to interagency biosurveillance efforts and associated analytic efforts regarding key indicators that may result in earlier cueing and more effective mitigation strategies as the 2009–H1N1 influenza season unfolds.
 - A briefing on the NBIC-led, interagency Assessment will be provided to the Department of Homeland Security Secretary and Deputy Secretary.
 - The Executive Summary of the DHS Secretary’s briefing will be shared with other Federal Departments and State and Local Government Representatives once cleared by DHS leadership.
- Throughout the emergence of the 2009–H1N1 pandemic, the compilation of biosurveillance information from the NBIS community continued on a daily basis, including daily interagency teleconference calls used to create an interagency cross-domain report.
- After receiving updates from interagency SMEs, NBIC analysts update 2009–H1N1 reports on its main visual and reporting tool, the Biosurveillance Common Operating Picture (BCOP).
 - The BCOP is a geospatial tool that allows users to review specific in-depth information/reports that are updated on a daily basis, including the various key dynamics associated with the likely return of H1N1 to include a timeline of events, State-by-State case counts, specific reports about local communities (at such time as they are developed) and links to the relevant SMEs in the NBIS community.
 - NBIC continued/continues to issue reports and update the BCOP to include specific H1N1 data on a daily basis. From April 24–September 14, 2009 a total of 163 updates were prepared providing real-time, dynamic

²Declared on 11 June 2009.

- information to NBIS Member Agencies (attached document 20090914 FED Worldwide H1N1 Influenza).
- To increase the situational awareness of State and local governmental agencies, the Secretary of DHS approved the development and deployment of an H1N1-specific BCOP (one that is accessible by State and local governmental representatives).
 - The H1N1-BCOP will be accessible to all validated State and Local officials through the Homeland Security Information Network (HSIN) by the end of September 2009.³
 - In coordination with the DHS/Office of Health Affairs (OHA) H1N1 Overarching Integrated Process Team (DHS/OHA H1N1-OIPT), the NBIC provides tailored inputs to a special 2009-H1N1 weekly Situation Report (SITREP). These H1N1-SITREPs inform the Secretary of DHS and, like the information posted to the BCOP, are interagency products. The H1N1-SITREP includes information regarding any potential mutation of 2009-H1N1 or any coinfection (normal seasonal flu plus H1N1 flu) that could suggest a change in the lethality or rate of infection among the population (attached document 20090911 NBIS Input to H1N1 Influenza SITREP).

Question 11. How has the National planning scenario for pandemic influenza informed DHS plans and response efforts for the H1N1 outbreaks/pandemic? Please provide specifics.

Answer. National Planning Scenario No. 03, Biological Disease Outbreak—Pandemic Influenza played a significant role in the development of Federal H1N1 plans and response efforts. The initial Federal Pandemic Influenza Operations Plan⁴ developed by DHS in coordination with interagency partners established a solid foundation that facilitated the rapid development of the 2009 H1N1-specific plans described in our responses to questions No. 3 and No. 6.

Question 12. What H1N1 guidance and training have been provided to DHS personnel in general and in the DHS components specifically (i.e., guidance for components, tailored for their specific operations and challenges)? Please provide copies of these documents to the committee with the specific dates they were released.

Answer.

Training

On August 20, 2009 Secretary Napolitano presented awareness information in video format that is available to all DHS employees via Component intranets as well as the DHS internet webpage. The video can be viewed at http://www.dhs.gov/files/programs/gc_1241202408781.shtm.

In 2007, the Office of Health Affairs developed a general awareness video for Pandemic Influenza. This was made available to all Components to use or include in their learning management system. While not H1N1-specific it does provide basic influenza prevention.

Multiple Components have developed and conducted specific training programs. A partial list of training follows:

Customs and Border Protection (CBP).—This Component had been conducting Pandemic Influenza training for over a year. A partial list of training classes and the number of employees trained is shown below.

Module Name	TRAEN Code	Number Complete
Avian Influenza Fundamentals	139700	50,267 employees.
Bird Handling Procedures	139704	32,479 employees.
PI for International Employees	139705	6,461 employees.
PI Safety—Protecting Yourself	139701	36,787 employees.
PI Safety—Protecting Your Family	139702	35,134 employees.
PI Safety—Protecting the Public	139703	35,972 employees.

³This differs from the Federal version of the BCOP which allows users to investigate multiple biological events outside of 2009-H1N1.

⁴DHS developed a draft of a Federal Pandemic Influenza Operations Plan (OPLAN) in 2007. This plan was not finalized due to the October 2007 compression of the 15 National Planning Scenarios into eight scenario sets by the Homeland Security Council Deputies Committee and direction by the Deputies that the pandemic influenza scenario would be last in order of development priority.

This list does not include additional respiratory protection, train-the-trainer for fit-testing, and personal protective equipment training that were also conducted since this training is also applicable to other hazards.

FEMA.—FEMA developed a basic training class that is being used at Presidentially-declared disasters as part of the basic safety orientation program. This training was completed in May 2009 and has been in use as needed since that time.

TSA.—Has conducted the class described in the table below: The Influenza Awareness and Precautions Briefing is estimated to be 40 minutes in length and covers general information on the common cold, flu and Avian flu, what precautionary steps you can take as well as outlines the TSA strategic plan and strategy for Pandemic Influenza.

Length: 0.75

Audience: TSA Employees

Contact: ***.*****@tsa.dhs.gov

CPEs: 0.00

Source: Vendor Developed

Contact Hours: 0.75

Goals: Differentiate among the common cold, the common flu, and the avian flu; Describe the treatment options for each type of ailment; Identify the preparedness and response measures you can take to protect yourself and your family; Describe the National Strategy for protecting the United States from a pandemic flu; Describe TSAs plan for communicating information about our on-going efforts; Describe the TSA response plan to a possible avian flu outbreak in the United States.

Credit Hours: 0.75

In addition, TSA posted N95 Respiratory Protection Training to the Online Learning Center it will be activated in the near future as other influenza training products are completed, including online H1N1 Awareness Training.

USCIS.—Collateral Duty Safety Officers have participated in formal training on the USCIS Pandemic Plan and their role in its implementation. Two special courses are in the final stages of development. The first course addresses illness in USCIS employees and a second course deals with ill applicants and visitors to USCIS offices.

USCG.—The USCG began conducting general awareness training on Pandemic Influenza approximately 2 years ago, using two different programs. One is the DHS developed program and the other is a USCG program that addresses specific USCG situations. In addition to these programs the USCG also has developed and conducted specialized training for their three most at-risk groups, Aids to Navigation (due to Avian Influenza), Boarding and Deployable Operations, and medical personnel and medical corpsmen.

FLETC.—FLETC has a half day of training planned for all FLETC management on Safety and Emergency Management. It will include the Pandemic flu and H1N1, as well as hurricane planning, etc. At present it is scheduled for Sept 22, though the date may move slightly.

USSS.—Train the trainer for respirator training and for accomplishing fit-testing at field locations. Approximately 100 personnel initially trained as the trainers. Program will be increased significantly to accomplish training and fit testing of N95 for our established mission essential personnel. The target for completion is training approximately 3,400 employees. Posters are being developed for deployment throughout the Service. The distribution will occur via e-mail allowing the field offices to print as many as they need and save on mail costs. A brochure was developed specifically for the United Nations General Assembly details. The information will be presented specifically to the shift leaders for distribution to their teams at the United Nations. USSS is working on the Avian Pandemic DVD done a few years ago and re-working it to a smaller content so it can play on the internal website. The goal is to deploy the program to all employees but the method and content are still being completed. A "Pandemic Info" link has been established on the USSS internal webpage.

ICE.—ICE began conducting non-mandatory, general awareness training, via ICE University on pandemic influenza approximately 2½ years ago. These courses remain available to ICE employees.

Avian/Pandemic Influenza.—This educational module teaches common ways to avoid catching and spreading the flu, whether pandemic flu or seasonal flu. This courseware is for FYI purposes only.

Pandemic Influenza Educational Series.—While this course was originally developed as an awareness training for avian influenza (H5N1), these training modules present an opportunity to increase awareness and gain greater understanding of the implications of and personal protective measures for all types of pandemic influenza.

All ICE employees are encouraged to complete each module in the series and supervisors are invited to use the modules for roll call training or similar group training opportunities.

At the outset of the H1N1 influenza outbreak, ICE addressed the use of facemasks and respirators as a mitigation strategy to decrease the exposure to the virus for at risk personnel. Specifically, ICE launched a fit-testing program throughout the United States, training fit testers. To date, ICE has trained over 10,000 law enforcement and mission-essential personnel in the use of N95 respirators. The cadre of over 300 fit testers, located throughout the United States, is well-positioned to ensure continued protection of the ICE workforce.

In addition, ICE will be conducting a hybrid H1N1 Table Top Exercise (TTX) over a 3-day session to include senior leadership from all ICE Program and Field Offices throughout the United States. The ICE H1N1 TTX is designed to provide an opportunity for every ICE program to reinforce leadership roles, responsibilities, and authorities while responding to the current H1N1 event and to engage in discussions about how ICE will manage its missions and its people in preparation for the next wave of H1N1.

Guidance

A variety of guidance documents for use Department-wide were developed by the Office of the Chief Human Capital Office, Office of Health Affairs, and the Office of the Chief Administrative Officer. These documents were fully coordinated within DHS and then used to develop a DHS Employee H1N1 information page. These documents address risk exposure, personal protective equipment, disinfection, time and attendance, personnel guidance for managers and supervisors and a host of H1N1-related topics. The documents and webpage were developed and constructed during August 2009 with the official announcement of the page occurring on August 17, 2009. Availability of this information was highly promoted via Pandemic Planning, occupational safety and health, and human resources groups. Announcement of the page was the lead story on the DHS intranet for approximately a week in mid-August. This guidance provides the basis of workforce protection for all DHS employees and is being used by Components to develop or refine their own Pandemic Influenza plans. It should be noted that this page is undergoing constant review and update as additional information and guidance becomes available. These documents have been attached to the main workflow.

Question 13. What exercises have been conducted by DHS regarding pandemic influenza (including intradepartmental pandemic influenza tabletops and workshops)? Please provide specific dates, information regarding attendees, scenarios upon which these exercises were based, how/whether the Homeland Security Exercise and Evaluation Program (HSEEP) was used, how the National Exercise Program provided support, after-action reports, and how information from these exercises (including after-action reports) were put into LLIS.

Answer.

DHS PI Exercises	Type	Dates	Attendees	Scenario	HSEFP Compliance	NEP Support?	LLIS Reporting?
Intra-DHS	Table Top (TTX).	Oct 28, 2008	DHS Component representatives.	Overseas outbreak spreads to US Focus on DHS incident management.	Yes; standard planning conferences and documentation.	NEP staff liaison provided for technical contributions to exercise development.	Used as central information repository during planning and hosts the after-action report.
Intra-DHS	TTX	Apr 3, 2009	DHS Component representatives.	Overseas outbreak spreads to US; Workforce protection focused.	Yes; standard planning conferences and documentation.	NEP staff liaison provided for technical contributions to exercise development.	Used as central information repository during planning and hosts the after-action report.
Intra-DHS	TTX	Sept 10, 2009 ..	DHS Assistant Secretaries/Component leadership.	Real-world H1N1 threat; Focus is Continuity of operations and Workforce protection.	Yes; standard planning conferences and documentation.	NEP staff liaison provided for technical contributions to exercise development.	Used as central information repository during planning and hosts the after-action report.
Principal Level Exercise 1-08.	TTX	Feb 2008	Interagency Deputy Secretaries.	International outbreak.	Yes; standard planning conferences and documentation.	NEP sponsored	No; the White House maintains control of the Summary of Conclusions.

DHS PI Exercises	Type	Dates	Attendees	Scenario	HSEFP Compliance	NEP Support?	LLIS Reporting?
Through the Regional Exercise Support Program, DHS/FEMA has sponsored exercises across the US at various levels of government.	Workshops, Seminars, TTX's Functional, Full scale.	All levels/jurisdictions; including senior officials.	Various	Yes; especially those utilizing DHS funding.	Sponsor of exercise support—primarily through the Regional Exercise Support Program.	Various means of information management.

Question 14. How do the recently created Regional Coordination Teams for pandemic influenza differ from the previously established teams? Please provide specifics.

Answer. The previous National Pandemic Influenza Principal Federal Official (NPI-PFO) team included a national Principal Federal Official for a pandemic event, as well as NPI-PFO field teams. For the H1N1 influenza outbreak, Secretary Napolitano elected to serve as the sole Principal Federal Official and replace the NPI-PFO field teams with reconfigured H1N1 Regional Coordination Teams (RCTs). To reflect these modifications, the pandemic “regions,” their associated staffing, and responsibilities as outlined in the NPI-PFO structure have been renamed and reconfigured to reflect Secretary Napolitano’s intent. The H1N1 RCT structure and mission reflect those necessary changes.

Secretary Napolitano has outlined the following seven missions for the RCTs:

1. Serve as a conduit between the many Federal agencies engaged in H1N1 response efforts and DHS’s various partners in the States;
2. Identify, and respond, through previously established incident management architecture, to critical information requirements, enabling the Secretary to make decisions related to the Secretary’s role as the Principal Federal Official for the H1N1 Pandemic;
3. Serve as the Secretary’s primary source in the field for awareness of strategic issues related to the H1N1 pandemic and help broker resolution of significant disputed issues;
4. Identify and help reconcile regional conflicts involving varying social distancing policies and national resources, especially those affecting commercial activities outside of a single *Robert T. Stafford Disaster Relief and Emergency Assistance Act*, Public Law 100-707, declaration “affected area” and during a compressed time cycle;
5. Report through the FEMA Regional Administrator and the Federal Coordinating Officer (FCO). This will ensure that the FEMA Regional Administrators can focus on emergency management and regional administration functions and the FCOs can focus on and lead the administration and coordination of relief at the operational and tactical levels as required by law;
6. Assist DHS component and other Federal interagency leaders in the field to coordinate and collaborate to achieve nationally directed strategic objectives, including those related to entry and exit screening, quarantine, isolation, vaccination, continuity of operations, and continuity of government;
7. Coordinate with the Designated Agency Safety and Health Official within DHS, Components, and other Department and Agency safety officers in the field through the chair and appropriate members of the DHS Safety and Occupational Health Committee, on all action affecting personnel regarding personal protective equipment and distribution of anti-viral medications.

Question 15. In your testimony, you stated that personal protective equipment has been prepositioned at 120 DHS locations and field offices Nation-wide. Where are these locations and to which offices are they assigned?

Answer.

U.S. Immigration and Customs Enforcement (ICE)

ICE National Capitol Region

ICE Alternate Operating Facility

ICE SAC Atlanta, GA; ICE SAC Baltimore, MD; ICE SAC Boston, MA; ICE SAC Buffalo, NY; ICE SAC Chicago, IL; ICE SAC Irving, TX; ICE SAC Denver, CO; ICE SAC Detroit, MI; ICE SAC El Paso, TX; ICE SAC Honolulu, HI; ICE SAC Houston, TX; ICE SAC Los Angeles, CA; ICE SAC Miami, FL; ICE SAC New Orleans, LA; ICE SAC New York, NY; ICE SAC Newark, NJ; ICE SAC Philadelphia, PA; ICE SAC Phoenix, AZ; ICE SAC San Antonio, TX; ICE SAC San Diego, CA; ICE SAC San Francisco, CA; ICE SAC San Juan, Puerto Rico; ICE SAC Seattle, WA; ICE SAC St. Paul, MN; ICE SAC Tampa, FL; ICE SAC Washington, DC; ICE FOD Atlanta, GA; ICE FOD Boston, MA; ICE FOD Buffalo, NY; ICE FOD Chicago, IL; ICE FOD Dallas, TX; ICE FOD Denver, CO; ICE FOD Detroit, MI; ICE FOD El Paso, TX; ICE FOD Houston, TX; ICE FOD Los Angeles, CA; ICE FOD Miami, FL; ICE FOD Newark, NJ; ICE FOD New Orleans, LA; ICE FOD New York, NY; ICE FOD Philadelphia, PA; ICE FOD Phoenix, AZ; ICE FOD Salt Lake City, UT; ICE FOD San Antonio, TX; ICE FOD San Diego, CA; ICE FOD San Francisco, CA; ICE FOD Seattle, WA; ICE FOD Saint Paul, MN; ICE FOD Washington, DC. Total—51 ICE Locations.

CBP Air Cargo, Humble, TX; CBP Laredo, TX; CBP Price Main (ATCET) Carson, CA; CBP—Miami International Airport; CBP New Orleans, Louisiana 70112; CBP Newark, NJ 07102; CBP Jamaica, NY; CBP Portland, OR; CBP San Diego, Otay

Mesa Commercial Facility; Area Port of San Francisco; CBP San Juan Puerto Rico; CBP Seattle, WA; Area Port of Tampa; Area Port: Orlando; Area Port: Jacksonville; Mariposa Port of Entry. Total—23 CBP locations.

DHS TSA Warehouse
GSA Distribution Center
Springfield, VA 22150
Total—TSA

DHS STOCKPILE

Cumberland Logistics Center (FEMA)
USCG central warehousing operations:
Harrisonburg, VA
USCG Locations the PPE Push Packs were pre-positioned:
Charlevoix, MI 49720-9999
Duluth, MN 55802-2492
USCGC ASPEN (WLB-208)
San Francisco, CA 94130-5013
USCGC CYPRESS (WLB-210)
Mobile, AL 36615-1390
USCGC ELM (WLB-204)
Atlantic Beach, NC 28512-5633
USCGC FIR (WLB-213)
Astoria, OR 97103
USCGC HICKORY (WLB-212)
Homer, AK 99603-0101
USCGC HOLLYHOCK (WLB-214)
Port Huron, MI 48060
USCGC JUNIPER (WLB-201)
Newport, RI 02841-1716
USCGC KUKUI (WLB-203)
USCGC MAPLE (WLB-207)
Sitka, AK 99835-9454
USCGC OAK (WLB-211)
Charleston, SC 29405-2421
USCGC SEQUOIA (WLB-215)
USCGC SPAR (WLB-206)
Kodiak, AK 99619-0651
USCGC SYCAMORE (WLB-209)
Cordova, AK 99574
USCGC WALNUT (WLB-205)
Honolulu, HI 96819
USCGC WILLOW (WLB-202)
Newport, RI 02841-1716
USCGC ABBIE BURGESS (WLM-553)
Rockland, ME 04841-3417
USCGC ANTHONY PETIT (WLM-558)
Ketchikan, AK 99901
USCGC BARBARA MABRITY (WLM-559)
Mobile, AL 36615-1390
USCGC FRANK DREW (WLM-557)
Portsmouth, VA 23703-2703
USCGC GEORGE COBB (WLM-564)
San Pedro, CA 90731-0208
USCGC HARRY CLAIBORNE (WLM-561)
Galveston, TX 77553
USCGC HENRY BLAKE (WLM-563)
Everett, WA 98207-5001
USCGC IDA LEWIS (WLM-551)
Newport, RI 02841-1716
USCGC JAMES RANKIN (WLM-555)
Baltimore, MD 21226-2703
USCGC JOSHUA APPLEBY (WLM-556)
St Petersburg, FL 33701-5099
USCGC KATHERINE WALKER (WLM-552)
Bayonne, NJ 07002-5041
USCGC MARCUS HANNA (WLM-554)
South Portland, ME 04106-0007
USCGC MARIA BRAY (WLM-562)

Atlantic Beach, FL 32233
USCGC WILLIAM TATE (WLM-560)
Philadelphia, PA 19147
USCGC BLUEBELL (WLI-313)
Portland, OR 97217-3992
USCGC BUCKTHORN (WLI-642)
Sault Ste. Marie, MI 49783-9501
USCGC BAYBERRY (WLI-65400)
Seattle, WA 98134-1192
USCGC BLACKBERRY (WLI-65303)
Long Beach, NC 28465-8443
USCGC ELDERBERRY (WLI-65401)
Petersburg, AK 99833-0550
USCGC ANVIL (WLIC-75301)
Charleston, SC 29401-1817
USCGC AXE (WLIC-75310)
Morgan City, LA 70380-6030
USCGC CLAMP (WLIC-75306)
Galveston, TX 77553-3001
USCGC HAMMER (WLIC-75302)
Mayport, FL 32233
USCGC HATCHET (WLIC-75309)
Galveston, TX 77553-3001
USCGC HUDSON (WLIC-801)
Miami Beach, FL 33139-5101
USCGC KENNEBEC (WLIC-802)
Portsmouth, VA 23703-2199
USCGC PAMLICO (WLIC-800)
New Orleans, LA 70117-4698
USCGC SAGINAW (WLIC-803)
Mobile, AL 36615-1390
USCGC SLEDGE (WLIC-75303)
Baltimore, MD 21226-2704
USCGC SMILAX (WLIC-315)
Atlantic Beach, NC 28512-5633
USCGC VISE (WLIC-75305)
St. Petersburg, FL 33701-5030
USCGC CHENA (WLR-75409)
Hickman, KY 42050-1132
USCGC CHEYENNE (WLR-75405)
St. Louis, MO 63118-3284
USCGC CHIPPEWA (WLR-75404)
Buchanan, TN 38222-7181
USCGC CIMARRON (WLR-65502)
Buchanan, TN 38222-4201
USCGC GASCONADE (WLR-75401)
Omaha, NE 68112-0337
USCGC GREENBRIER (WLR-75501)
Natchez, MS 39122-8909
USCGC KANAWHA (WLR-75407)
Pine Bluff, AR 71611-7627
USCGC KANKAKEE (WLR-75500)
Memphis, TN 38105-1502
USCGC KICKAPOO (WLR-75406)
Vicksburg, MS 39180-0031
USCGC MUSKINGUM (WLR-75402)
Sallisaw, OK 74955-0626
USCGC OBION (WLR-65503)
Owensboro, KY 42303-0277
USCGC OSAGE (WLR-65505)
Sewickley, PA 15143-2093
USCGC OUACHITA (WLR-65501)
E. Chattanooga, TN 37416-2825
USCGC PATOKA (WLR-75408)
Greenville, MS 38701-9584
USCGC SANGAMON (WLR-65506)
East Peoria, IL 61601-2039
USCGC SCIOTO (WLR-65504)

Keokuk, IA 52632-5851
 USCGC WEDGE (WLR-75307)
 Demopolis, AL 36732-9999
 USCGC WYACONDA (WLR-75403)
 Dubuque, IA 52001-7652
 USCG total buoy tenders: 66.

Delivery locations for prepositioning of surgical masks:
 CBP Warehouse

Indianapolis, IN 46278

USCG 1: Attn: USCG Pandemic Stockpile

DHS 1: Attn: DHS PPE Stockpile Program

Cumberland Logistics Center (FEMA)

USCIS 1: Attn: USCIS Pandemic Stockpile

FEMA 1: Distribution Center—Atlanta

FEMA 2: Distribution Center—Ft. Worth

FEMA 3: Distribution Center—Moffett Field

FEMA 4: Distribution Center—Frederick

FEMA 5: Cumberland Distribution Center

MTW 1: Mount Weather Emergency Operations Center

USSS 1: U.S. Secret Service

Beltsville, MD 20708

NCR 1: DHS National Capital Region

Question 16. Please provide copies of all of the employee messages that were distributed by DHS and its components regarding H1N1 guidance.

Answer. Attached to the main workflow are copies (15) of the employee messages that were distributed to DHS.*

Please note that some of the early guidance has been revised and superseded based on advice from OSHA and CDC as more was learned about H1N1.

Question 17. Has the Department established vaccine priorities for which employees will receive H1N1 immunization first? If so, please describe these priorities and the criteria used to develop these priorities.

Answer. Based on HHS/CDC H1N1 vaccine target group recommendations, the Department of Homeland Security (DHS) has prescribed vaccine prioritization for its Federal employees who fall into the five priority groups of health care and emergency medical services workers, pregnant women, those employees 24 years of age or younger, persons aged 25–64 years of age with underlying health conditions associated with higher risks of medical complications from influenza, and household contacts and caregivers for children under 6 months of age.

DHS will follow HHS, CDC, and the Office of Personnel Management's (OPM) publication, "Preparing for the Flu: A Communications Toolkit for the Federal Workforce" at http://www.flu.gov/professional/federal/workplace/federal_toolkit.pdf and will determine the prioritization of its employees for H1N1 vaccine in accordance with the groups recommended at <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>. OHA has taken measures to ensure DHS operational components identify both mission critical and emergency personnel.

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR WILLIAM CORR, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question 1. When will clinical trials for the H1N1 vaccine be completed?

Answer. With its sister agencies in the Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), has designed and is in the process of implementing clinical trials for the novel H1N1 2009 influenza vaccine through the Nation-wide network of NIAID Vaccine and Treatment Evaluation Units (VTEUs). Data from these trials will provide knowledge to help inform public health policy decisions and provide guidance for the 2009–H1N1 immunization plan. The initial NIAID-supported H1N1 trials are designed to answer three primary questions:

- Are these vaccines well-tolerated in healthy people of various ages?
- How large of a vaccine dose, and how many doses of vaccine, are needed to induce an immune response that is predictive of protection?
- Can 2009–H1N1 influenza vaccine be safely administered at the same time or sequentially with the seasonal influenza vaccine, and will both vaccines induce protective immune responses?

*The information has been retained in committee files.

These studies are assessing the vaccines in multiple age groups, including children aged 6 months and older, healthy adults, and healthy elderly adults over 65 years of age. Complete immune response data from the first trials—those studying two doses in healthy adults—are expected in late October. Preliminary data indicate that the vaccines are safe and that a single 15-microgram dose induces what is likely to be a protective immune response in healthy adults between the ages of 18 and 64. For adults aged 65 and over, the preliminary data indicate that the immune response to the 2009–H1N1 influenza vaccine is less robust, as is the case with seasonal influenza vaccine. Data on how the pediatric populations respond immunologically following a first and second dose of H1N1 vaccine are expected in mid-November. Early data from the pediatric trials suggest that one dose of vaccine in older children, aged 10 to 17 years, may be adequate to induce a robust immune response. Younger children may require a second dose, as is the case with seasonal influenza vaccine. Complete immune response data from studies of administration of the 2009–H1N1 influenza vaccine with the seasonal influenza vaccine in both adults and children are expected to be available by mid-December. Preliminary data are expected to be available in October.

In addition to these initial trials, NIAID is supporting additional studies in populations who may be at higher risk of complications from influenza. For example, the first clinical trial of 2009–H1N1 influenza vaccine in pregnant women began on September 9; preliminary data are expected in late October. Additional trials in pregnant women are expected to begin in late October. Clinical trials of the vaccine in other populations are in development.

Finally, NIAID is supporting trials of 2009–H1N1 influenza vaccines with adjuvants, which are additives that help create a more vigorous immune response to a vaccine. These trials are expected to begin in mid-September, with the first preliminary immune response data expected in mid- to late October.

In addition, five manufacturers licensed by FDA to produce seasonal influenza vaccine for the United States are also conducting clinical studies with the H1N1. These studies were designed with guidance from FDA to evaluate the immune response to the vaccine, and determine the optimal dose. The populations studied by the various manufacturers include children 6 months of age and older, adults, and the elderly. The preliminary results from the manufacturers' clinical studies regarding the number of doses and the immune response induced are consistent with the results of the NIH studies discussed above. The trials are on-going.

Question 2. Please describe HHS efforts to plan for H1N1 occurring at the same time as other major incidents, including hurricanes and acts of biological terrorism.

Answer. Multiple simultaneous events are always a possibility, and over the years the Department has responded to co-occurring events. There are playbooks to guide the response for each type of event, and the Secretary's Operations Center coordinates the response to each event. To plan specifically for an H1N1 outbreak occurring at the same time as a hurricane, the Office of the Assistant Secretary of Preparedness and Response (ASPR), the Office of Preparedness and Emergency Operations (OPEO) conducted four 3-hour tabletop exercises, titled "HHS Preparation to Respond to Multiple Events Tabletop Exercise—Steps to Responsiveness" between May and July 2009.

Our purpose in conducting this series of tabletop exercises was to share knowledge and gain an understanding of how each ASPR organization would respond and integrate into the overall ESF No. 8 response. Our method was to build each exercise on the previous exercise discussions, focusing on OPEO considerations in response to an impending hurricane and on-going influenza outbreak, relationships between Emergency Management Group entities, and team preparedness, and readiness considerations. The exercises assisted in achieving the following objectives:

- Identify command and control procedures and structures when dealing with multiple ESF No. 8 events.
- Understand capabilities and expectations for resource and volunteer management.
- Identify and establish expectations for evacuation, mass care, and patient movement.

Question 3. Will the antivirals in the National stockpile be replenished on an on-going basis? If so, how often and what are the challenges in doing so?

Answer. All of the antiviral drugs that were released in the spring from the Strategic National Stockpile (SNS) have been replenished. Future decisions to replenish antiviral drugs will be made based on need for product, available manufacturer supply and available funding.

Question 4. Which traditional surveillance systems were and are used by the Centers for Disease Control and Prevention to track the progress of the novel H1N1 outbreaks/pandemic?

Answer. The Epidemiology and Prevention Branch in the Influenza Division at CDC collects, compiles, and analyzes information on influenza activity year-round in the United States and produces a weekly report from October through mid-May. The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in State and local health departments, public health and clinical laboratories, vital statistics offices, health care providers, clinics, and emergency departments. Information in five categories is collected from nine different data sources.

- *Viral Surveillance.*—About 80 U.S. World Health Organization (WHO) Collaborating Laboratories and 70 National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories, located throughout the United States, participate in virologic surveillance for influenza. All State public health laboratories participate as WHO collaborating laboratories along with some county public health laboratories and some large tertiary care or academic medical centers. Most NREVSS laboratories participating in influenza surveillance are hospital laboratories. In 2007, human infection with a novel influenza A virus became a nationally notifiable condition. The 2009 influenza A (H1N1) virus is a novel virus. Novel influenza A virus infections include all human infections with influenza A viruses that are different from currently circulating human influenza H1 and H3 viruses.
- *Outpatient Illness Surveillance.*—Information on patient visits to health care providers for influenza-like illness is collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet).
- *Mortality Surveillance.*—Rapid tracking of influenza-associated deaths is done through two systems:
 - 122 Cities Mortality Reporting System. Each week, the vital statistics offices of 122 cities report the total number of death certificates received and the number of those for which pneumonia or influenza was listed as the underlying or contributing cause of death by age group. The percentage of all deaths due to pneumonia and influenza (P&I) are compared with a seasonal baseline and epidemic threshold value calculated for each week.
 - Surveillance for Influenza-associated Pediatric Mortality. Influenza-associated deaths in children (persons less than 18 years) was added as a nationally notifiable condition in 2004. Laboratory-confirmed influenza-associated deaths in children are reported through the Nationally Notifiable Disease Surveillance System.
- *Hospitalization Surveillance.*—Two systems monitor hospitalizations with laboratory confirmed influenza infections.
 - Emerging Infections Program (EIP). The EIP Influenza Project conducts surveillance for laboratory-confirmed influenza related hospitalizations in children (persons less than 18 years) and adults in 60 counties covering 12 metropolitan areas of 10 States (San Francisco, CA; Denver, CO; New Haven, CT; Atlanta, GA; Baltimore, MD; Minneapolis/St. Paul, MN; Albuquerque, NM; Las Cruces, NM; Albany, NY; Rochester, NY; Portland, OR; and Nashville, TN).
 - New Vaccine Surveillance Network (NVSN). The New Vaccine Surveillance Network (NVSN) provides population-based estimates of laboratory-confirmed influenza hospitalization rates for children less than 5 years old residing in three counties: Hamilton County, OH; Davidson County, TN; and Monroe County, NY.
- *Summary of the Geographic Spread of Influenza.*—State health departments report the estimated level of spread of influenza activity in their States each week through the State and Territorial Epidemiologists Reports. States report influenza activity as no activity, sporadic, local, regional, or widespread.

For a more detailed explanation of these influenza surveillance systems visit: *Flu Activity and Surveillance*.

Question 5. Which vaccine manufacturers are providing bulk components for the H1N1 vaccine? Are these the same manufacturers who already produce U.S.-licensed seasonal vaccine? If not, please provide the list of these manufacturers as well.

Answer. Six manufacturers are licensed to manufacture seasonal influenza vaccine in the United States: CSL Limited, GlaxoSmithKline Biologicals, ID Biomedical Corp of Quebec, MedImmune, LLS, Novartis Vaccines and Diagnostics Limited, and sanofi pasteur Inc.

On September 15, 2009, FDA-approved supplements to the existing Biologics License Applications from four of these licensed influenza manufacturers to include Influenza A (H1N1) 2009 Monovalent Vaccine. These vaccines are made by CSL Limited, MedImmune LLC., Novartis Vaccines and Diagnostics, Limited, and sanofi

pasteur, Inc. These manufacturers make their own bulk components; however, they will provide the monovalent Influenza A (H1N1) 2009 in final finished containers, not in bulk form.

QUESTIONS FROM RANKING MEMBER PETER T. KING OF NEW YORK FOR WILLIAM CORR, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question 1a. While a vaccine is a critical component of the National strategy to mitigate pandemic influenza, other non-pharmaceutical tools also have the potential to limit disease and play an important role in a dynamic influenza strategy. In terms of a point-of-care diagnostic that can determine a pandemic strain for the coming influenza season, does HHS: See value in, and

Answer. Yes, HHS/ASPR sees value in point-of-care diagnostics.

Question 1b. Plan to procure such a piece of technology?

Answer. HHS/ASPR and HHS/CDC together invested in development of point-of-care influenza diagnostic detection systems. It was an investigational test of such a system that was used as part of a clinical evaluation in the first case of 2009–H1N1 in California.

Question 2a. In terms of personal protective equipment (PPE): What is HHS' response to the claim that the National stockpile contains only enough face masks to provide for the American population for 3 days?

Answer. The Strategic National Stockpile (SNS) includes respirators and facemasks, but they are not intended to be used to help protect the general American population. The respirators and facemasks in the SNS are intended to be provided to States to help protect health care workers in accordance with published guidance for use. CDC's guidance recommends the use of respirators primarily for health care workers in close contact with patients with influenza-like illness (ILI) and the use of facemasks by patients with ILI while they are in a health care setting to limit the spread of influenza. CDC's guidance generally does not recommend the use of respirators or facemasks for workers in non-health care occupational settings for general work activities or in community and home settings except in certain circumstances for persons at increased risk of severe illness from influenza.

Question 2b. Has HHS considered procuring advanced but commercially available PPE technologies, such as masks and gowns that neutralize virus particles?

Answer. Issuing contracts for the purchase of PPE is a competitive process. HHS contract requirements for the purchase of PPE are set according to Federal acquisition regulations and do not exclude the purchase of PPE with antimicrobial properties. To date, HHS has purchased respirators for critical workforce from three vendors on the GSA supply schedule competitive process.

Question 3. Lastly, can BioShield funds be used for pandemic influenza procurements, whether pharmaceutical or non-pharmaceutical in nature?

Answer. No. BioShield funds support the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents.

QUESTIONS FROM THE HONORABLE MICHAEL T. MCCAUL OF TEXAS FOR WILLIAM CORR, DEPUTY SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question 1a. In your testimony, you stated that the number of antiviral courses States have on hand is 35 million and the size of the Strategic National Stockpile (SNS) is between 75–100 million. According to information obtained from the Department of Health and Human Services, however, the SNS currently holds over 48 million regimens of antiviral drugs, with States holding an additional 23 million regimens (prior to the H1N1 response).

Can you please clarify the discrepancy in these figures?

Question 1b. Will the supplies on hand be sufficient for a second wave of pandemic flu occurring concurrently with seasonal flu? Or do you plan to purchase more antivirals?

Answer. Prior to H1N1, States bought 23.5 million treatment courses of antivirals for their stockpiles and HHS had 50 million treatment courses of antivirals in the SNS. In May 2009, with the H1N1 outbreaks in the United States, 11.5 million treatment courses of antivirals were deployed pro-rata to the States. Additionally, nearly 1 million treatment courses were provided to Mexico and other countries. Subsequently, HHS replenished the antiviral stockpile by purchasing 13 million treatment courses of antivirals. Additionally, States purchased another 2.1 million treatment courses of antivirals for their stockpiles, bringing the total amount of antivirals in States to about 37.1 million treatment courses.

HHS is awaiting delivery of an additional 1 million treatment courses of antiviral drugs and has plans to procure more antiviral drugs upon availability of contingency funds.

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR Ms. BERNICE STEINHARDT, DIRECTOR, STRATEGIC ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE

Question 1. Which recommendations from GAO's work on pandemic influenza remain open? What is the current status, given recent changes (e.g. the combining of the Homeland and National Security Councils, the new DHS regional coordination teams)?

Answer. As of July 2009, GAO has made 24 pandemic preparedness recommendations that Federal agencies have generally agreed to. There have been 11 recommendations, however, that have not yet been fully implemented. Several of these open recommendations are particularly relevant to planning and preparedness for the 2009 H1N1 pandemic in the coming months.

- First, given the change in administration and the associated transition of senior Federal officials, the shared leadership roles that have been established between HHS and DHS for a pandemic, along with other responsible Federal officials, should be rigorously tested and exercised.
- Second, the 3-year period covered by the National Pandemic Implementation Plan is now over and it will be important for the White House National Security Staff (NSS), which supports the Homeland Security Council (HSC) in this administration, to establish a process for updating the National Pandemic Implementation Plan so that the updated plan can address the gaps we have identified, as well as lessons learned from the 2009 H1N1 pandemic.
- Third, DHS should continue to work with other Federal agencies and private sector members of the critical infrastructure coordinating councils to help address the challenges of coordination and clarify roles and responsibilities of Federal and State governments.
- Fourth, although HHS, DHS, Education, and the White House hosted an H1N1 summit in July 2009 to aid State and local governments in pandemic planning, DHS and HHS could also hold additional meetings with States to help them address previously identified gaps in their pandemic planning.
- Finally, greater monitoring and reporting of agencies' progress in plans to protect their workers during a pandemic are needed to insure the readiness of agencies to continue operations while protecting their employees in the event of a pandemic.

QUESTIONS FROM RANKING MEMBER PETER T. KING OF NEW YORK FOR Ms. BERNICE STEINHARDT, DIRECTOR, STRATEGIC ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE

Question 1a. GAO has found that there is no mechanism in place to monitor agencies' progress in developing workforce protection plans. DHS was charged with this responsibility, but the Homeland Security Council has not mandated this.

Why do you feel DHS is the right agency to handle this responsibility?

Answer. The National Security Presidential Directive/NSPD 51 designates the Secretary of Homeland Security to serve as the President's lead agent for coordinating overall continuity operations and activities of executive departments and agencies. Among other responsibilities, the Secretary is directed to "Coordinate the implementation, execution, and assessment of continuity operations and activities". As we reported in June 2009, the primary threat to continuity of operations during a pandemic is the threat to employee health.

Agencies' protection of its workforce from infection is a key element of pandemic influenza operational plans. As originally envisioned under the Homeland Security Council's (HSC) *Implementation Plan for the National Strategy for Pandemic Influenza*, DHS was charged with, among other things, monitoring and reporting to the Executive Office of the President on the readiness of departments and agencies to continue their operations while protecting their workers during an influenza pandemic. Although DHS officials said they were subsequently informed that they did not have to prepare a report, having DHS monitor and report on the status of agencies' pandemic plans to protect the safety and health of their employees while maintaining essential operations could enhance agencies' accountability for this responsibility and serve as an effective way of tracking agencies' progress in making their pandemic plans operational by planning for the protection of their workforce.

Question 1b. What office within DHS should handle this?

Answer. The scope of our report did not include an assessment of which DHS office or offices should be selected to lead or manage the assessments.

QUESTION FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR MS. COLLEEN M. KELLEY, NATIONAL PRESIDENT, NATIONAL TREASURY EMPLOYEES UNION

Question. Does NTEU have a position on which Federal workers should get vaccinated against H1N1 first?

Answer. NTEU's position is that Federal employees whose jobs necessitate their close interaction with and proximity to the public, such as Customs and Border Protection (CBP) Officers, CBP Agriculture Specialists, and Transportation Security Officers in inspection positions at domestic airports and U.S. air, sea, and land ports of entry, should be among the first to be provided with the vaccine, if agencies distribute it to workers. The choice to get vaccinated, however, should be the choice of the Federal employee and not mandated.

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR MR. RICHARD G. MUTH, EXECUTIVE DIRECTOR, MARYLAND EMERGENCY MANAGEMENT AGENCY

Question 1. In your testimony, you refer to the need for greater consistency between public health and emergency management planning guidance so that the various agencies can work together seamlessly. What guidance were you referring to? Please provide specific examples.

Answer.

- Guidance for emergency management planning generally is directed by the Comprehensive Planning Guidance and other paradigms, such as NUREG for nuclear planning.
- Planning guidance differs as MEMA uses standard emergency management planning guidance while other agencies including the Maryland Department of Health and Mental Hygiene are required to use CDC guidance.
- NIMS/ICS is Federally required but this is not adhered to by all entities.
- Scalability and flexibility is essential. Unfortunately, these were not found in all State flu planning; the Strategic National Stockpile Plan (SNS) especially needs to have these characteristics.

Unintended consequences:

- Plans must be integrated in similar formats with all State hazard events in mind. When these commonalities do not occur, operational staff using the plans, those committing resources and decision makers at the highest levels are unable to fulfill their responsibilities. Thus, resources can be wasted, decisions poorly drawn and, most critically, citizens can be put at risk.

Question 2. What criteria will the State use to determine activation of the Emergency Operations Center in response to the H1N1 influenza pandemic?

- The State Emergency Operations Center (SEOC) at MEMA is always at Level 1 through its 24/7 Maryland Joint Operations Center (MJOC). This capability is available for all-hazard efforts.
- Pursuant to criteria in State law, when more than two State departments are involved in an incident, the Level of the SEOC may be raised to accommodate the incident.
- State staff is called in via an automated call-down system.
- While H1N1 may have some unique features, it will be treated as a "Notice Event" meaning that MEMA is aware of its occurrence, similar to a hurricane and Levels will be increased as required.
- As with other health incidents, DHMH is the lead State agency, the subject matter experts as it were and MEMA coordinator of operations and State resources.

Consequence/benefits:

- Maintaining standardized levels and adherence to State law and procedures in an all-hazards posture allows for the most efficient and reliable means of operation before and during an incident.
- Standardization further creates an atmosphere of "no surprises" or as few as possible when dealing with emergencies.
- Staff from MEMA and any other involved State agency has been trained on and is knowledgeable of procedures and anticipated actions.

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR DR. MARK B. HORTON, DIRECTOR, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

Question 1. Do you believe there is a need for greater consistency between public health and emergency management planning guidance so that the various agencies can work together seamlessly? If so, please provide examples specific to the State of California. If not, why not?

Answer. In California, the California Emergency Management Agency (CalEMA) recognized that the H1N1 outbreak was a public health disaster and that an effective response required public health to lead California's efforts. CalEMA provided (and continues to provide) support to the State's public health infrastructure which includes our sister department, the Emergency Medical Services Authority (EMSA).

We do believe there is a need for greater coordination between public health and emergency management functions at the Federal level. From the State perspective it often appeared that was not a clear articulation of roles and responsibilities between the Health and Human Services Agency and the Department of Homeland Security. For example there appeared to be overlap between the two organizations with respect to public communications, requests to States for information and reporting requirements. From a public information standpoint, the first issue has been recently resolved with the institution of jointly-hosted conference calls. To sustain an adequate response to the continued outbreak, it will be necessary to ensure that there is a common understanding of roles and responsibilities, coordination of timelines, consistency of public information and guidance, and integration across funding streams. Absent that understanding by all concerned it will be difficult to mount an integrated medical response if public health first responders are faced with reporting within multiple command structures.

It is important to note that this outbreak has clearly demonstrated the need to identify specific funding to ensure that emergency preparedness policy and funding decisions continue to include all-hazard preparedness for public health in addition to first responders such as police and fire.

Question 2. What criteria will the State use to determine activation of the Emergency Operations Center in response to the H1N1 influenza pandemic?

Answer. In California, the Joint Emergency Operating Center (JEOC) is currently operating at a moderate level of activation to coordinate response efforts across Federal, State, and local agencies for the on-going H1N1 emergency State-wide. CDPH and EMSA are coordinating with CalEMA to identify trigger points for more intense activation status.

The State response in April, 2009 was guided by The Pandemic Influenza Preparedness and Response Plan, as adopted by CDPH (then the Department of Health Services) in September 2006. The Plan indicates that the first case of laboratory-confirmed novel influenza virus human infection in California or elsewhere in the United States, or evidence of sustained human-to-human transmission anywhere in the world, will result in activation of the relevant components of the emergency management organization and may trigger a Governor's proclamation of a state of emergency. On Friday, April 17, 2009, the Centers for Disease Control, through laboratory data supplied by the Federal Border Infectious Disease Surveillance (BIDs) program office located in San Diego, determined that two California influenza cases had a unique combination of gene segments not previously reported among swine or human influenza viruses in the United States or elsewhere. CDPH staff worked through the weekend with CDC staff to collect additional information. Although human-to-human transmission had not yet been verified, on Monday, April 21, 2009 the CDPH Joint Emergency Operation Center (JEOC) went to full activation. On April 28, 2009, the Governor declared a state of emergency.

Operational levels are commensurate with the level of H1N1 activity in the State and appear adequate at this time. Activation status is regularly reviewed by emergency support personnel and staffing and resources are constantly reassessed. Given that we are at a higher stage of alert and in a proclaimed State of Emergency for public health, activation status will remain elevated throughout the pandemic, even as State Operations Center (SOC) and JEOC staffing levels fluctuate based on demand from differing disciplines.

QUESTIONS FROM CHAIRMAN BENNIE G. THOMPSON OF MISSISSIPPI FOR DR. THOMAS A. FARLEY, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Question 1. How is New York City modifying its pandemic influenza plan to address the H1N1 pandemic?

Answer. Response was not received at the time of publication.

Question 2. What specific lessons were learned by New York City in addressing the H1N1 cases at Rikers Island and to protect those that may have come into contact with these patients?

Answer. Response was not received at the time of publication.

Question 3. What guidance was developed and distributed by New York City for how to deal with H1N1 in institutional settings?

Answer. Response was not received at the time of publication.

Question 4. How is the New York City Department of Health and Mental Hygiene working with the New York State Department of Health to respond to the H1N1 outbreaks/pandemic?

Answer. Response was not received at the time of publication.

