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PANDEMIC FLU: CLOSING THE GAPS

HEARING

BEFORE THE

AD HOC SUBCOMMITTEE ON STATE, LOCAL, AND PRIVATE SECTOR PREPAREDNESS AND INTEGRATION

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

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PANDEMIC FLU: CLOSING THE GAPS

WEDNESDAY, JUNE 3, 2009

U.S. SENATE,
AD HOC SUBCOMMITTEE ON STATE, LOCAL, AND
PRIVATE SECTOR PREPAREDNESS AND INTEGRATION,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:05 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Mark L. Pryor, Chairman of the Subcommittee, presiding.

Present: Senator Pryor.

OPENING STATEMENT OF SENATOR PRYOR

Senator PRYOR. I will go ahead and call our meeting to order. I want to thank everyone for being here today. This is the Subcommittee on State, Local, and Private Sector Preparedness and Integration and it is time for us to update our efforts on pandemic influenza.

The Centers for Disease Control (CDC) has described pandemic flu as both inevitable and as one of the biggest threats to public health in the Nation. In October 2007, I chaired a hearing entitled, "Pandemic Influenza: State and Local Efforts to Prepare." At that hearing, HHS, DHS, and State and local health officials testified. The witnesses cited efforts underway that included national strategies, plans, and exercises. Now less than 2 years later, we are faced with the reality of a pandemic threat.

In late March and early April 2009, the first cases of a new flu virus, the H1N1, were reported in Southern California and San Antonio, Texas. So far, the CDC has confirmed 10,053 cases in 50 States and in the District of Columbia. This includes seven cases in my home State of Arkansas according to the CDC. The CDC reports that most of the influenza viruses being detected now in the United States are of the strain. Further, CDC's Dr. Anne Schuchat has said this will be a marathon and not a sprint, and even if this outbreak is a small one, we can anticipate that we may have a subsequent or follow-up outbreak several months later and we need to stay ready.

One of the things we have talked about in this Subcommittee before is hurricane preparedness. Years ago, there was an exercise authorized and then for whatever reason, the money wasn't available to conduct the Hurricane Pam exercise, which was almost identical to the scenario we saw when Hurricane Katrina struck.

We find ourselves today in somewhat of a similar situation in that we have had this flu scare already this spring and now it looks like, if flu behaves like it normally does, we will have a few months where it won't be that active, and then I hope I am wrong, but it looks like it may come back in the fall. We just need to make sure that we are ready, that we are doing everything that we can do, and that the State, local, and private sector are working together on this.

So what I would like to do is introduce the panel and ask each of you to make a 5-minute statement. We may be joined by some other Senators. I know Senator Ensign has been trying to change his schedule to get here. We will keep the record open after the conclusion of the hearing for a couple of weeks and let Senators submit questions, and if there are follow-ups that we need to work with you on, we will do that.

Let me introduce the panel. First, we have Bernice Steinhardt. She is Director of the Government Accountability Office's Governmentwide Management Issues. She has led the preparation of 11 GAO reports, the most recent, "Sustaining Focus on the Nation's Planning and Preparedness Efforts." It synthesizes 23 recommendations that we should be working on now. Ten of them have yet to be acted on.

Our second panelist will be John Thomasian. He is the Director of the National Governors Association's Center for Best Practices.

Next, we will have Dr. Paul Jarris. Dr. Jarris is the Executive Director of the Association of State and Territorial Health Officials (ASTHO).

Finally, we will have Dr. Ostroff. Dr. Ostroff is the Acting Physician General and Director of the Bureau of Epidemiology for the Pennsylvania Department of Health.

What I would like to do is open it up, 5 minutes each, and then we will ask questions. Go ahead.

TESTIMONY OF BERNICE STEINHARDT,[1] DIRECTOR, STRATEGIC ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. STEINHARDT. Thank you very much, Senator Pryor. I really appreciate the chance to be here today. I wanted to talk to you about the report that you mentioned a moment ago that we issued this past February which synthesized the results of close to a dozen reports that we have issued since 2006. In that February report, we pointed out that despite the economic crisis and other national priorities that had become top priorities for the country, a pandemic influenza is still a very real threat and requires continued leadership attention. When the H1N1 virus emerged 2 months later, that warning was dramatically underscored.

Before I go into the findings of our reports, I want first just to acknowledge the important progress that we have made in the last few years. In addition to the National Pandemic Strategy and Implementation Plan that was developed by the Federal Government, all 50 States and the District of Columbia now have pandemic plans, as do many local governments and private companies, and we have clearly benefited from all of this planning.

[1] The prepared statement of Ms. Steinhardt appears in the Appendix on page 24.

But that said, there are still some significant gaps in our planning and preparedness. For one thing, the leadership roles in a pandemic, the "Who is in charge?" question, have not been clearly worked out and tested. Under the National Pandemic Plan, the Secretaries of Health and Human Services and the Secretary of Homeland Security are supposed to share leadership responsibilities along with a system of Federal Coordinating Officials and also Principal Federal Officials and the FEMA Administrator. And all of these positions may be vital in a pandemic, but how they will work together has not been tested yet.

So in 2007, we recommended that HHS and DHS work together to develop and conduct national tests and exercises, and the Departments agreed with our recommendation, but since that time, there still has not been a national exercise for this purpose. Now that we have new people filling some of these leadership positions, the need to clarify these relationships in practice is only heightened.

Beyond the lack of clarity on leadership roles, the National Strategy and Plan have a number of other missing pieces, and I will mention just a couple. First of all, key stakeholders, like State and local and tribal governments, were not directly involved in developing the plan, even though the plan relies on them in a number of instances to carry out some key elements of the plan.

Second, there were no mechanisms described in the plan for updating the plan and reporting on its progress, and this issue of updating the plan is particularly timely since this is a 3-year plan and it was developed in May 2006.

To fill these gaps, we recommended that the Homeland Security Council establish a process for updating the plan that would, first of all, involve key stakeholders and incorporate lessons learned from exercises and other sources. We made that recommendation in 2007, but the Homeland Security Council didn't comment on it, nor did they indicate whether they would act on it. But I would say that it is especially pertinent today as we try to learn from the experiences of the H1N1 outbreak.

As we go forward, it is also essential for the Federal Government to share its expertise and coordinate its decisions with other levels of government and the private sector. A number of mechanisms were developed for these purposes, but they could be used even more, and I will mention one example.

In a 2008 report that we did on State and local pandemic planning, we pointed out that an HHS-led assessment of State plans found many major gaps in 16 of 22 priority areas that included policies related to school closures and community containment. At that same time, a number of the State and local officials that we were talking to told us that they would welcome additional guidance from the Federal Government in these same areas, and I know the National Governors Association found many of the same kinds of issues.

DHS and HHS at that time had earlier convened a series of regional workshops with State officials to help them with their planning efforts and we thought that the two Departments could use additional workshops to help States address the gaps in their pandemic plans. The two Departments, HHS and DHS, agreed with

our recommendation, but they haven't held any additional meetings since then.

In closing, I just want to point out that it's important to bear in mind that while the current H1N1 outbreaks seem to have been relatively mild, the virus could return, as you pointed out, Senator. It could return in a second wave this fall or winter in a more virulent form. So given this risk, the Administration and Federal agencies should be turning their attention to filling some of the gaps that our work has pointed out, while time is still on our side.

Thanks very much.

Senator PRYOR. Thank you. Mr. Thomasian.

TESTIMONY OF JOHN THOMASIAN,[1] DIRECTOR, NATIONAL GOVERNORS ASSOCIATION CENTER FOR BEST PRACTICES

Mr. THOMASIAN. Thank you, Mr. Chairman. As you pointed out, my name is John Thomasian and I direct the National Governors Association Center for Best Practices and I appreciate the opportunity to testify before you today on pandemic influenza and how we can close potential gaps in our capacity to respond. My comments today are based on the work we have done over the past several years with the States on pandemic planning that began in 2006 with a Governor's Guide. It included training workshops, nine regional training workshops for all 50 States and four territories in 2007 and 2008, and our work continues today as we assist the Governors' Homeland Security Advisors in responding to the recent outbreak.

I am going to focus on five key areas very quickly: Information sharing, interagency coordination, school closings, continuity of government and coordination with the private sector, and communication with the public. Each of these were identified as problems in our previous work and I will discuss how each of them were handled in the current outbreak.

Information sharing—information sharing during the recent flu event demonstrated that systems worked much better than we anticipated. The flow of information between the Federal Government and the States was nearly constant during the initial weeks of the outbreak and case counts were updated daily. Morbidity and mortality figures were readily available. And the Federal Government did a good job pushing information down to State and local government.

That being said, there is room for improvement. Both CDC and DHS began to hold independent daily briefings for State officials in the early weeks. These briefings often contained the same information and often contained the same Federal officials. But States were never sure if all the information was new, so they put time aside for all the briefings. As a result, State officials spent several hours each day monitoring conference calls instead of response activities. In the future, DHS and CDC should hold a single daily briefing with States on all essential information.

Interagency coordination—when we held our workshops in 2007 and 2008, many State teams were meeting for the first time. They were not clear on their own responsibilities, much less those of

[1] The prepared statement of Mr. Thomasian appears in the Appendix on page 48.

their Federal counterparts. Three years later, with additional planning and exercises, the situation has improved. I think the Centers for Disease Control and Department of Homeland Security worked well together during the recent outbreak and provided a relatively seamless portal to Federal resources and technical assistance. At the State level, homeland security agencies began coordinating immediately with their health departments and many States enacted emergency declarations and other orders to begin mobilizing broader State resources, if needed.

Looking ahead, we must recognize that good interagency coordination deteriorates without practice. To maintain performance, States must be given encouragement and resources to conduct preparedness exercises with multiple agencies and levels of government. This is a capacity that will go away over time.

School closures—school closure policy was a topic of intense discussion at each of our national workshops with little consistency in approach. It was not a surprise, therefore, when the recent outbreak led to a patchwork of school closure decisions. One issue was that the Centers for Disease Control's written guidance suggested that closures should be based on laboratory-confirmed cases, while public comments by some Federal officials suggested decisions should be based on suspected or probable cases or even when students had a family member with the disease.

Also missing was advice to parents and students on actions to be taken outside of the classroom to limit the spread of the disease. In many cases, dismissed students simply recongregated at shopping malls or other venues to share potential infections. More precise advice will be needed from CDC in the future to help States and districts implement a more consistent approach to school closure. Guidance should also address prevention actions beyond school grounds.

Continuity of government and coordination with the private sector on critical services—in our workshops, we asked States to envision a rate of absenteeism that could approach 40 percent. To cope with this possibility, States needed to develop detailed continuity of government plans and work with the private sector to ensure the availability of critical goods and services. This mild outbreak simply did not test these contingencies. They remain among the unknowns of our preparedness and should be revisited before we enter the next flu season.

Finally, communication with the public. In the recent outbreak, government and the media did a good job informing the public on the spread of the disease and what individuals should do to avoid infection. However, the Federal Government did not adequately explain the type of response options they had at their disposal, what was being considered or rejected, and why. This led to a great deal of confusion in the early stages regarding what might happen next. To address this gap, the public must be given information on the appropriateness and implications of specific actions, such as quarantine, social distancing, travel bans, school closings, and the use of personal protective equipment.

In conclusion, the spring outbreak has so far resulted in less than 9,000 confirmed cases nationwide. In contrast, we must remember that a severe pandemic would produce tens of millions of

infections. Before the onset of the next influenza season, we should take the time to address the weaknesses this initial outbreak exposed. We should clarify the guidance on school closures to ensure consistency. Information exchange should be improved so that responders can allocate their time more efficiently. The public must be educated on the benefits and costs of mitigation strategies. And States should be encouraged and supported to conduct periodic pandemic exercises with Federal agencies, local governments, and the private sector.

Thank you, Mr. Chairman. I am pleased to answer any questions later.

Senator PRYOR. Thank you. Dr. Jarris.

TESTIMONY OF PAUL E. JARRIS, M.D., MBA,[1] EXECUTIVE DIRECTOR, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Dr. JARRIS. Mr. Chairman, thank you for the opportunity to speak. I would like to make a couple of points that have not been made before.

One is that this is not over. We still have an outbreak and an epidemic going on in this country. Just over the last day, the cases have increased to 11,000, which is a tremendous undercount, and your State of Arkansas is now nine rather than seven. You have been relatively spared, but other States have been hit much harder, including New York and currently Massachusetts has a dramatic outbreak ongoing. So this has never gone away. It is really not a matter of if it comes back in the fall. It hasn't left yet. The question will be, when it comes back in the fall, will it have evolved to a more severe pandemic or epidemic than the epidemic we are having right now?

Furthermore, it is not just another seasonal flu, as we hear people saying. This is not the time of year you have a flu outbreak. That is one of the ways we search for new viruses and find them.

Second, this is primarily young people being affected. The average age of individuals being affected is between 11 and 19 years old. The average age of someone in the intensive care unit is 23 years old. And the average death rate is in the 40s. That is not seasonal influenza, which largely affects the elderly and otherwise people with immune compromise. So this is a novel virus, and what we have to understand is we do not know how this is going to behave.

In 1918 at this time, it was behaving very similar to this. Now, whether or not it will come back as severe a category four or five in the fall, we simply don't know. But the prudent thing is to plan for a range of an outbreak consistent with what we have now all the way to a severe pandemic worldwide. The World Health Organization is right now considering whether to raise it to a pandemic level six, but frankly, that is not that important to this country because we already have an epidemic ongoing. Pandemic just means the epidemic has spread around the world. We have it already.

The response to date, I believe, has been a good response. The Federal Government, State government, and local governments

[1] The prepared statement of Dr. Jarris appears in the Appendix on page 62.

have acted in concert with each other and as a National Government response. Harvard did a study which showed 80 percent of Americans were satisfied with the response. Eighty-eight percent were satisfied with the information they were getting. That was the result not only of the Federal Government giving us guidance, but the State public health officials and homeland security officials going back to the Federal Government to say, here is what is happening on the ground and giving them situational awareness.

We also have learned that there is much to be done with our planning. There were many assumptions made which proved not to be true. There were many planning plans that were made which were not nearly granular enough. So now that we are in a response, much more so than just a drill, we have learned about the shortcomings in our planning and what has to be happening. We have now a window of 12 to 16 weeks before this thing would escalate, as the 1918 virus did, before the return of the seasonal influenza, which will come on top of this current influenza outbreak.

The reason I say it is not scalable, there has been about a 25 percent cut in State and local emergency preparedness funding over the last several years. We have had about a 20 to 25 percent cut in hospital preparedness funding. And the single appropriation of pandemic influenza funding in 2006 was completely spent by August 2008. There is no money from the Federal Government to state and local government, public health, to respond and plan for the fall and we simply have no alternative. So we must take advantage of this window of opportunity now to protect the American people.

And let me give you the orders of magnitude here because frankly, I think we are all having a little bit of sticker shock when we think about what it will take to respond and protect the American people. For one, we are asking for $350 million, another bolus, if you will, of planning money to carry the State and local governments not only through the response right now, but to plan and work on transitioning from planning to implementation for the fall.

But importantly, there has been much talked about vaccine, the single most effective thing we can do to protect our population. Our plans call for protecting the entire U.S. population. That is 300 million people. We do believe that it will be two doses per person. By the time we know different, it is too late to produce the extra doses. So if conservatively that is $5 per dose, we are talking about $6 billion just to buy the vaccine.

Now, vaccine isn't a good luck charm. It has to be given to people. We can give you the numbers and the information, but conservatively, it is $15 a dose to provide vaccine under the government-run program. That is less than the private sector. But much of the workforce giving this will be private sector. So we are talking about $15 billion to give those 600 million doses. So just there alone, we are in the $14 to $15 billion range. So we really have to come to grips very rapidly with how serious are we as a Nation in protecting the people of the United States and will we make those resources available now or will we stare the American people in the eye come the fall and say, when we had an opportunity, we didn't do it. Thank you, sir.

Senator PRYOR. Thank you. Dr. Ostroff.

TESTIMONY OF STEPHEN OSTROFF, M.D.,[1] DIRECTOR, BUREAU OF EPIDEMIOLOGY AND ACTING PHYSICIAN GENERAL, PENNSYLVANIA DEPARTMENT OF HEALTH

Dr. OSTROFF. Thank you, Senator. Influenza is unquestionably one of the most unpredictable public health issues we face. Just when you think you understand what is going on, it always throws you a curve ball.

For several years, we have been focused on the emerging threat of bird flu in Asia, and rightly so. It is highly lethal, it has continuously circulated for 6 years, and it has devastating consequences for agriculture. Most of our planning assumptions have been based on a scenario that a pandemic would start in Asia, that it would be noticed there, and that we could delay its introduction and spread.

And then out of nowhere, a new virus lands right on our doorstep, isn't noticed until it is already here, and renders many of our planning assumptions irrelevant. Fortunately, so far, its public health impact as measured by illness and death has been modest, but its overall impact has been anything but. It has caused tremendous disruption to individuals, families, schools, and communities, and we don't know what the future holds for this virus.

Like the other States, we in Pennsylvania immediately ramped up our disease monitoring and response as soon as we learned of this new flu strain. Over the last 2 months, despite the fact that we have not had that many cases in Pennsylvania, it has been enormously labor intensive and challenging to address the myriad of issues that it presents.

We have established a State-wide task force that includes our public health and emergency response partners. We have partly activated our emergency operations center. And we set up an internal health department task force. We have reached out to the education and agriculture sectors, migrant centers, medical societies, the rich array of academic centers in our State, the pharmaceutical sector, and the State's major vaccine manufacturer. And most importantly, we have closely integrated our work with that of our network of district and local health departments who form our frontline eyes and ears through daily group phone calls to discuss cases and disease clusters.

We have greatly relied upon the excellent work done by the CDC, including their guidelines, lab support, the pharmaceutical stockpile, and their technical back-up. We in the States have had an ongoing dialogue with CDC about all aspects of this event, and sometimes we have disagreed, like in the school closure area. But CDC has been very willing to listen and change course when appropriate.

Some aspects of our response have gone quite well. These include risk communications, disease monitoring and investigation, and applying control measures to limit disease spread. Other areas have been more challenging, especially lab support, where backlogs quickly developed when specimens had to go to CDC.

We in Pennsylvania continue to individually count, investigate, and respond to each identified case of illness due to this new virus.

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[1] The prepared statement of Dr. Ostroff appears in the Appendix on page 69.

With less than 300 cases, even this has been very resource intensive and has strained our disease investigators and our laboratory. Like most States, we have been impacted by the economic situation. We have hiring freezes in place and our bench strength is not very deep at all.

Because in general we don't count individual cases of seasonal influenza, many of the most heavily impacted States are now no longer doing it for this new flu strain, either. Instead, they only count severe cases and those in special circumstances, like health care workers and pregnant women. This makes the national numbers that you are hearing now being reported very tough to interpret, since States are counting cases differently.

In Pennsylvania, because many parts of the State have still been minimally affected by this virus, we think it is important to understand where the virus is, how it is spreading, and who it is affecting, so we will continue to count until it is no longer feasible for us to do so.

So far, many aspects of our preparedness efforts have not been engaged. As examples, we have not dipped into our pharmaceutical stockpile. We have not mass distributed vaccines or antivirals. We have not handled large numbers of sick or dying people. And we have not implemented full community mitigation efforts, and hopefully we won't have to do so. But it is important to be prepared in case we need to.

So we in Pennsylvania have just initiated a process to review our efforts to date and see what has gone well and where we need to improve. We are also embarking on a planning effort to prepare for what the virus has in store for us in the coming months. This includes doing better monitoring, planning for distribution and administration of stockpile material and vaccines, and dealing with health care surge needs.

The flu is just one of a long line of emerging infectious disease threats. Others include SARS, MRSA, West Nile, foodborne outbreaks, and vaccine-preventable diseases. All of these highlight the need for a robust and a well-trained public health workforce and for flexible resources that allow us to best apply the resources that we have where they are needed.

At the State and local level, the same people address all these problems in the field and in the lab. While our preparedness resources have helped, they do not cover nearly all of our needs and our resources for emerging infections have dwindled in recent years. Despite these problems, all of us are firmly committed to continue to address this new flu virus while continuing to confront the other public health threats that we face.

I will be happy to answer any questions.

Senator PRYOR. Thank you.

Let me start with you, Ms. Steinhardt. In your GAO report, you have several criticisms of the state of affairs right now. One of those is that the roles are not very clear between State, Federal, local, and who makes the decisions on certain things. What would you recommend that State and local officials do to clarify their roles?

Ms. STEINHARDT. Well, the important thing, and this is the lesson that we learned, I think, most vividly from Hurricane Katrina,

the important thing is to test and exercise. It has often been said that you don't make friends in the middle of a disaster. People need to know each other and figure out how they are going to work together in advance of a true emergency, and that is what needs to happen here, as well.

Senator PRYOR. OK. I notice that the GAO, the NGA, and the ASTHO have reports that say that you need more guidance in school closures, you mentioned, and several other areas, like private sector workforce, situational awareness, etc. Do you think the Federal Government could distribute policies on these issues by this fall or is it too late for this year?

Ms. STEINHARDT. I would hope that the Federal Government could do that. As my fellow panelists have said, there is a lot that we are still learning about this virus. But certainly there is more—some of those lessons learned can and should be shared with States and local governments, as well.

Senator PRYOR. Mr. Thomasian, in your experience in terms of defining roles and some of the gaps that Ms. Steinhardt has identified, how has the Federal Government been to work with?

Mr. THOMASIAN. In the past Administration, I would say the lead agency was clearly HHS. Secretary Leavitt took it on himself. Under his watch, he was going to try to avoid not having these roles defined. So I think we got one strong but one siloed lens looking at that.

Senator PRYOR. He wanted to not define the roles?

Mr. THOMASIAN. No, he did want to define the roles, but since he represented a single agency, he had certain boundaries.

Senator PRYOR. I see.

Mr. THOMASIAN. So I think we got halfway there. I think we still have a ways to go. I was pleased to see that the Department of Homeland Security worked well together with HHS during this initial crisis. Again, we have not been fully tested, so all the roles have not been fully defined or explored and the tensions have not been exposed to a large degree. But it was an initial good first step.

So I do believe they have tried to do a good job and I will reiterate my panelist assertion that the best way to define a role is to initially put some aspects down on paper, but you have to exercise. You have to test it. Relationships need to be built.

Senator PRYOR. OK. Let me follow up on that. When the National Response Framework and the National Pandemic Implementation Plan were being put together, there was a lot of criticism that the Federal Government did not work with and talk to the State and local governments effectively. Now they have been working on the First Responder Health Surge Capacity Action Directive. Have they been working with the States and with the local folks as they are putting that together?

Mr. THOMASIAN. They are. We work very closely, I should say, with the Governors' Homeland Security Advisors. In fact, we have formed an association within our association called the Governors' Homeland Security Advisors Council, and it is our understanding they are working together with them. Again, though, it does take a while for all this to trickle down through the States. This has been a constant refrain from the Governors' Homeland Security community, that the Federal Government needs to fully advise and

work through issues with the States. I believe we are on the right path. It is too early to tell that it is taking place in all cases, though.

Senator PRYOR. Dr. Jarris, did you have any comments on that?

Dr. JARRIS. Yes. I think it is worth questioning the model. The model that the Federal Government will sequester itself and develop guidance for the Nation is a model that doesn't work well. There is a certain amount of expertise, whether it is scientific or law enforcement, in the Federal Government. But actually, the people who implement this guidance are at the State and local levels, and what we fail to appreciate is the expertise in implementation. So a model that will work much better is if Federal, State, and local all work jointly on guidance. Right now, what we do is we play ping-pong. The Federal Government comes out with something, lobs it over the table. We say it doesn't work. We lob it back. We don't have time for that in 14 to 16 weeks.

What worked well in this response to date is that we really were working together, information flowing up and down, modifying what each other was doing. Now we seem once again to be flipping back into the old model of the Federal Government will come up with guidance for the fall. It simply won't work.

For example, school closure. That is primarily a public and political decision to close schools. It is not fundamentally a science-based decision. So what we need to do is to work with the mayors, the governors, and those who make the school closures, and the health officials who will make recommendations to them, to truly understand all the issues there so we can do, if you will, a cost-benefit analysis. There is no way that the Federal Government guidance can come out without true involvement of the local and State officials making these decisions and have it work.

Senator PRYOR. So are you recommending that we get some sort of summit together?

Dr. JARRIS. Well, a summit would be helpful, but an ongoing working relationship would be far more helpful.

Senator PRYOR. And does that not exist right now?

Dr. JARRIS. The tendency is for Federal Government to develop guidance. There may be input sought, but then it goes back into a sequestered environment and the guidance comes out. And I think it is much more efficient, actually, if we could sit down as Federal, State, and local and jointly work on guidance.

Senator PRYOR. OK. This is a little bit of a follow-up to something I think you said in your opening statement. There are a lot of assumptions about the flu and the H1N1 did not really follow those assumptions.

Dr. JARRIS. Yes.

Senator PRYOR. It didn't start in Asia. It didn't go from a bird population to human population. What do you recommend, or how do you recommend that we build in flexibility to all this planning so that if a different scenario presents itself, like H1N1 has so far, it doesn't really follow the textbook example, how do you build in the flexibility?

Dr. JARRIS. Yes. I think with a novel virus, it is a mistake to assume there is a textbook. They all operate differently. So really what we need is to have much more robust planning. It is not just

a matter of scientifically planning for it. We need to have modelers in there. We need to have systems engineers come in and figure out what is going to happen. So, for example, we should plan for a best case, a worst case, and a most likely case scenario and hope that covers the bases. Of course, something out of the blue will happen.

But, for example, if we look at the vaccination campaign for the fall, we will have an initial bolus of vaccine coming out probably sometime around October, but we don't know how fast it is going to grow. That vaccine will come out with an initial bolus. We don't know how much that will be. It will then come out with weekly numbers, so a certain amount per week. We don't know how much that will be. That will be distributed on a per capita basis to the country and we have to go down a priority list, which incidentally the priority list we have is for H5N1, not H1N1.

So you see how many unknowns there are here. What will the adjutant do? We haven't gone through the safety studies yet. We actually don't know if it is one dose or two doses. So there are so many complexities here and we will not know ahead of time enough information to make the decisions. So at the outset, we have to come up with operational assumptions and plan around those assumptions with different scenarios.

Senator PRYOR. And you had mentioned the costs of providing a vaccine to every American. What is your overall estimated cost on that?

Dr. JARRIS. Well, we don't quite know again, what the vaccine is going to cost. It hasn't been developed yet. We don't know the cost of the adjutants that may be in it. So probably between $5 and $10 a dose, $10 is what it normally costs for regular seasonal flu. And we assume 600 million doses, so we are talking somewhere in the $6 billion range. It could be more, could be less.

But then we actually have to give the vaccine, and we estimated this a number of ways. We had dozens of States and local health departments who did a cost basis for them to give a vaccine. Medicare pays $18 to $20. Medicare pays costs. We checked with Visiting Nurse Associations. We checked with private sector. So the ranges are anywhere from about $12 to $30. We picked $15, which we think is a reasonable dose. So $15 times 600 million, we are talking about another $9 billion.

Senator PRYOR. And how does that square with your thoughts on planning, though, because at some point, you have got to pull the trigger on the vaccine, about whether you are going to go with this particular vaccine or not. And if the strain changes, like down in the Southern Hemisphere it could be a different strain this fall or whatever the case may be. So when is that point where you have to pull that trigger?

Dr. JARRIS. There is seed stock developed now, it is my understanding—and I am not Dr. Fauci—that the variation has not been tremendous around the world yet. So we think we will have a vaccine that will probably cover all the options unless there is a major mutation. So that seed stock will then have to go into production. At the same time, we need 2 to 3 months to do the scientific testing for safety, for response, for dosage, and things like that.

So we will have to make a decision soon to purchase—we have already put a purchase order in for this country—not only because

we need the lead time to develop the vaccine, but because other countries are already in line, Great Britain, France, things like that. So in order to put our place in line, we are going to have to make a purchase decision very soon.

Now, it is one decision to purchase. That, we will have to do early. It is another decision to give it. We are going to have to look in the fall, based on the safety studies, to say, OK, given what we know, we have this vaccine. Should we actually give it to people? And I think we have to carefully consider that, because all vaccine has side effects and we will have to weigh the severity of the illness in the fall versus potential side effects of the vaccine. So that is a later decision, I would guess, that is going to be made probably in the August to September time frame.

Senator PRYOR. Mr. Thomasian, let me ask you a follow-up to what Dr. Jarris was talking about. We have talked about a lot of different scenarios about administering a vaccine and how to distribute it around the country, around the various States. From your standpoint, how should that be done? Should you let the various States make that decision on how it is distributed, or should there be one national policy that the States just follow?

Mr. THOMASIAN. Well, the way it is currently laid out is the States have prepared plans on how they would distribute vaccines and antivirals and they have priority lists that match up to a good extent to the Federal senses of priority. So I don't think there is a huge variation out there. So I would say, let the States administer it with a joint discussion between the Federal Government and the States on the type of priorities.

I am saying that because I am assuming, and I think it is safe to assume, that we would not have vaccines for everybody, so we would have to be focusing on the essential service individuals and the most vulnerable populations. Otherwise, I think we can probably go to the open market distribution of the vaccines.

Senator PRYOR. Dr. Ostroff, do you have any thoughts on that?

Dr. OSTROFF. Specifically about the vaccine? There is obviously a lot of unknowns, I think, as Dr. Jarris pointed out.

Senator PRYOR. And let me just interrupt there. It seems to me that you can do a lot of planning and you can be prepared in some ways, but because the vaccine needs so much lead time, that is sort of a separate question that just makes it hard to figure out what the best way to go is, but go ahead.

Dr. OSTROFF. Well, I think a couple of other points just to consider—one of them is, I think as Dr. Jarris rightly pointed out, we shouldn't look at the current situation as being in the past tense. We in Pennsylvania, our numbers have gone up by a third just since I put my testimony together this weekend, so it is quite active right now in Pennsylvania. It shows no signs of abating. I think that we all anticipated that it would dampen down over the summer months. The virus may not have read the textbook and may decide not to do that.

The other thing that we have to remember is that in 1918, which is the model that we have all been looking at, the virus came back very early. It came back in September and it came back with a vengeance in September. It didn't wait until the usual winter influenza season. And so in terms of our thinking about what to do re-

lated to vaccine, I think that we have to really put our decision making on the fast track about what to do because by the time we make decisions over the next couple of months, the virus may have jumped out ahead of us and it could come back in a form that is more severe than it currently is.

The other, I think, issue to also keep in mind is that we are relying quite heavily on antiviral drugs. The antiviral drug of choice, if you look at the seasonal strain that was just floating around the country, that was resistant to that particular drug. And so if this particular virus decides to get together with that one and transfers its resistance, then that is a program for our assumptions and planning.

And so I think as far as the vaccine, I am not sure that we have a lot of time to be able to make these decisions. I think the virus is telling us, because right now, virtually all influenza in the United States—and again, it is a very unusual time to be seeing this disease—is this virus. And so it may not be an option, the regular one versus this one. I think that we have to look seriously at what the virus is telling us right now and make our decisions relatively quickly.

Senator PRYOR. OK. Given all the circumstances that we are in right now and also given the fact that in the supplemental appropriation that is working its way through the Congress and hopefully will get to the President's desk in the next couple of weeks, we put $1 billion in there for pandemic flu issues and preparedness. Do you have an idea on how that money should be prioritized, what the most critical needs are to get us ready for this?

Dr. OSTROFF. Well, there are a lot of needs and I think many of them have been pointed out. Again, we have not been fully exercising the full gamut of things that we would need to do for a full-fledged pandemic. I think that we do need to very quickly come up with our plans as to how we would distribute the vaccine. I think when the vaccine becomes available, there is not going to be enough for everybody and we are going to have to make decisions about how to prioritize who gets it and who doesn't, and we generally do that based on what we see about the patterns of disease.

I think that we have to work out much better than we did how to distribute antiviral medications. In addition to that, I do think that we have to very quickly figure out what we are going to do about the medical surge issues, because again, most of us haven't had to exercise that part of our pandemic plan.

And the last thing that I will say is that for us, if there is a lot of disease, both being able to monitor what is going on as well as do the diagnostic work in our laboratory—I mean, Pennsylvania is a large State. We are the sixth largest State in terms of population. We only have 300 cases, and it has been all we could do to be able to count what we are seeing and to make the diagnoses in our laboratory. We are sort of relying on two people in our laboratory to do all this work, and if one of them gets the flu, then we are down by 50 percent. So we need to, I think, pretty quickly figure out how we deepen our bench strength between now and the fall because I think that these will all be serious gaps for us.

The last thing that I will say is that in terms of the Federal guidance, one of the things I think that is important—and I have a fair-

ly unique perspective, because I worked at the CDC for 20-some years, so I was on the giving end rather than the receiving end for all that time period—is that we don't like it to be so prescriptive that there is not a lot of wiggle room. We in Pennsylvania, as far as school closures, we set up our policy right from the very beginning. We have held to that policy all along. We didn't think that the initial recommendations from the CDC were quite correct and we didn't think the revised recommendations were quite correct, either.

So we don't want them to be so prescriptive that it looks like we are not following what other people are doing. Each State has to take that guidance and interpret it and translate it to their local circumstances. That is what is being done in Arkansas and that is what we are doing in Pennsylvania.

Senator PRYOR. Let me ask about this medical surge question that you brought up. It is really just for the panel at large. Given the economic downturn and given that certain hospitals, first responders, you name it, there have been some layoffs and some cutbacks, a lot of cities and counties and States are having to do cutbacks and this can be very painful. But it seems to me this is the worst time that they could be cutting back on these type of health-related services, but the reality is what it is. So any advice for this fall? Dr. Jarris.

Dr. JARRIS. Yes. It is an excellent question, Senator. We have looked at the State and local public health agencies, and due to the budget constraints in the States, we have lost over 11,000 positions in the last year and that pace is continuing. Given an outbreak, and we have already seen this in the last several weeks, we have taken a drastically diminished workforce and put them on two shifts from one shift. There is only so much people can do, and that really strained the system. On top of that, of course, we have had certain States who have actually run out of places to build the pandemic response so they are actually ramping down in the face of an escalating outbreak. So this is again the reason why we need some Federal assistance to mount the response and protect the American people.

Senator PRYOR. Mr. Thomasian, do you have any thoughts on that?

Mr. THOMASIAN. Well, it is an excellent point. I will say that in our work at NGA, we projected even after the recovery dollars are spent that States will be facing over the next 2 years somewhere between $170 and $230 billion in deficits across the States, so it is a tough time. It is very difficult to build a government around a peak event that may not occur.

I do feel, though, that if further resources were available to States, there are some critical areas that would certainly help. It may not address all the surge capacity, but certainly one is laboratory capacity is sorely needed in the States. Also, assistance again on exercising. Clearly, States will need to build as much capacity as they can afford to do in these areas, but honestly, I think this is an area that we have not been tested in and we will probably find that we will be sorely behind if a large event does come.

Senator PRYOR. Yes, Mr. Steinhardt.

Ms. STEINHARDT. Just to add to the comments that have already been made, looking at vaccine production, at best, at least from my understanding, if we begin today, we are looking at November for the initial production lines for this virus. So we still have this long period between now and then in which communities have to be able to respond to the continuing epidemic or a resurgence in a more virulent form. And so the kind of planning, the kinds of activities that have to take place before we even have a vaccine are really our first—need to be our first considerations here. What kinds of capacities do we need to build into communities? And I think as we look at priorities for funding and allocations of funding, we need to keep that very much in mind.

Senator PRYOR. OK. As I understand it, the World Health Organization is deliberating whether to move this from a Phase Five to a Phase Six. First, I don't understand the complete significance of that. And second, I guess, Dr. Ostroff, if they move from a Phase Five to a Phase Six, what does that mean for the United States? How does that change things here?

Dr. OSTROFF. I think in practical terms, it really doesn't change very much for us. Our planning, our thinking, our activities are all predicated on what we think the appropriate things to do in the United States are. I do think that part of the difficulty and why World Health Organization (WHO) has been having such struggles around this particular issue is that when you move to Phase Six, it sort of trips off a whole lot of activities in other parts of the world, some of them appropriate and some of them inappropriate based on their particular circumstances. And so I think it does make a difference.

I think that we have seen many countries do things that, in terms of entry and exit screening, etc., that may not necessarily be the best application of resources and if this would give them further reason to do some of those things, then I think it would be somewhat problematic. But in terms of the way that we would approach what needs to be done here in the United States, I don't really think it makes that much of a difference, which level they define it as.

Senator PRYOR. Dr. Jarris.

Dr. JARRIS. Yes. I would agree with my colleague that in terms of our response in the United States, within our borders, it probably doesn't change what we do because we have the epidemic. But as a global leader, it may very well change what we do.

One is as this continues to spread around the world, which it has been, and frankly, it is almost academic whether they declare it Phase Six or not because I think they met the criteria a month or more ago but there have been political discussions. But the issue is what role will the United States play in terms of a health diplomacy role worldwide if we have outbreaks hitting undeveloped countries or developing countries who do not have an infrastructure for public health and we see many more deaths because some of these countries have high rates of HIV, what will the United States do? Will we feel a responsibility to go and assist these nations?

And what is our responsibility to the rest of the world with regard to things like vaccine and antivirals? If we were producing

antivirals with our domestic capacity only for the United States, we might produce it one way without the vaccine sparing adjutants. However, the whole world needs the vaccine, and if we need to help other parts of the world, we probably do have to put adjutants to stretch the supply that we can produce even further.

So I would suggest that our political leadership involved and scientific community involved with global health issues will have some significant questions to address in terms of the U.S. leadership.

Senator PRYOR. That is fair enough.

Let me ask about this map that we have here.[1] You can see the confirmed cases around the world. When you see a map like this and when you look at the numbers, the quantity of this around the world and the fact that it is spread out geographically, from a scientific perspective, does that increase the chance of mutation or does that have any bearing on the chances of mutation?

Dr. JARRIS. Every infection increases the chance. Viruses do mutate rapidly, and as they travel around the world and are exposed to different populations of humans, of animals, there is an increased chance of resortment. So yes, the more it spreads, the more the chance of resortment.

Now, one thing to consider is since this is a novel virus, there isn't a heavy evolutionary pressure on it to evolve. In and of itself, it is making people sick and surviving. So we can't conclusively say whether it will resort or not. The great fear, of course, is that it does mix with someone with an H5N1 or mix with a seasonal influenza that is Tamiflu-resistant and then we are in trouble. But that really is another one of the unknowables.

Senator PRYOR. Mr. Thomasian, let me ask you about the Medical Reserve Corps. Can the States activate that, and what is that process?

Mr. THOMASIAN. I am not completely familiar with the activation process. I believe they can, but I would have to get back to you on that.

Senator PRYOR. Dr. Jarris, did you——

Dr. JARRIS. Yes. There is a Medical Reserve Corps that has been very helpful in certain limited disasters around the country. What we have found in areas severely hit, in Texas and Louisiana during their hurricanes, though, is the Medical Reserve Corps are people who have other jobs, and so when you are mounting a sustained response, they can't be counted on to be there day in and day out in shifts, so the doctors have to go back to their office to practice and nurses have to go back to the hospital or the health departments to their shift.

So what Texas has found, in fact, is that although they welcome them and like to work with them, they have actually had to go out and contract for paid professionals to come in and work for them because then you have performance standards that you can maintain. That again will be important with the vaccinations in the fall as well as if we have to do mass dispensing of Tamiflu. We are going to have to hire in contract nurses or hospital nurses or VNA

[1] The map referred to by Senator Pryor appears in the Appendix on page 93.

nurses, which means with them having other jobs, time-and-a-half, weekend pay, and things like that.

Senator PRYOR. OK. Let me ask this. I am getting down to the end of my questions, and like I said, we will keep the record open and some other Senators will probably have other questions. But given the last few months where the flu was first discovered in North America and it was almost wall-to-wall coverage there for several days on the cable news channels, etc., how did the media do and how did the public health officials and the elected officials do in getting the word out to the public and communicating the nature of this? Can you all grade that? Is that one of the lessons learned that we can improve?

Mr. THOMASIAN. Well, in my comments, I addressed—I think I would give them high marks. I would give the Federal officials and the public officials at the State and local level high marks for communicating to the public and communicating to the media, and the media did a good job, I think, reporting on the nature of the disease and where it was. Again, I think where the breakdown began in some areas was, well, so what do we do? What is the appropriate government response? And I think there was some initial hesitancy at the opening to talk about issues like quarantine and why you should and why you shouldn't use it and issues like travel bans so that we got into this situation for a while where there was a discussion of, should we block the borders in Mexico, and that percolated for a few days. But initially, I do think that the communication was very good and I think the public had a sense that this disease was existing out there, it wasn't a disaster, and they were getting up-to-date information.

Senator PRYOR. Does anybody else want to add to that?

Dr. JARRIS. There was a study done by Harvard University, a sample of the American people, and as I mentioned briefly before, 88 percent of Americans that were surveyed expressed satisfaction with the information they were getting. So I think we did a good job. I think it was clear, and Dr. Besser should be commended. He did a wonderful job, the Acting Director of the CDC.

The one place I think we are falling down right now is we have shut it down. I mean, you can't find anything in the media anymore. We should be using this time to let people know that now is the time to prepare. Now they should figure out in the fall if their kids' school is canceled, how are they going to take care of the kids? How are they going to telecommute? What if their elderly parent gets sick? We are missing an opportunity now, ahead of time, to have people think about the fall.

Ms. STEINHARDT. If I can add to that——

Senator PRYOR. Yes, go ahead.

Ms. STEINHARDT [continuing]. I think I would agree that the response and the communications were first-rate. But I think from our experience, looking at what happened several years ago when we first began to see cases of bird flu and outbreaks of H5N1 virus in humans, there was an enormous amount of attention, and then it fell off, and for most of the public, it seemed as though this issue went away completely. Unfortunately, what the public loses interest in, government often loses interest in, as well. I think within the public health community, members of the public health commu-

nity never lost sight of this problem, but otherwise, we let other issues take priority, and we know this from conversations we had with people in the private sector. Other food safety issues, whatever the issue of the day was, that is what took attention. So we need to, I think, somehow keep sight within government of our priorities and what the real dangers to the public are, whether it is covered in the media or not.

Senator PRYOR. Dr. Ostroff.

Dr. OSTROFF. Yes. I will just add a couple of comments, because I agree with everything that was said. I think that over the last few years, it has been ingrained in the public's mind that when something happens related to flu, it is going to be like the big bang. When that didn't quite happen right at the very beginning, I think there was a tendency for everyone to shrug their shoulders, saying, what is the big deal here?

What you heard was a lot of descriptions of this as being mild. Flu is never mild, and we tried very vigorously to say that this is not a mild disease now and it could be even more severe in the coming months. And so I do think that there is a segment of the population who feels that this was sort of like oversold to them when, in point of fact, I think that many of us are very concerned about what we are seeing right now and we are awfully concerned about what is going to happen in the fall. So I do think that I would echo the comment that we have to continue to reinforce the message that what you have seen so far might not necessarily be what you see later on.

But having said that, I would fully concur. I think that the Federal officials, in particular, did a fantastic job conveying information to the public. It was a transitional group of people, and given the circumstances and the amount of attention that this initially got, I think they did a wonderful job.

Senator PRYOR. Let me follow up on that. Ms. Steinhardt, you may be the best one to ask. There is sort of a lull period right now in terms of public awareness on this. If it comes back this fall, the lull will be over. A lot of people will be looking back and saying, why didn't we do something different? What would you recommend right now to the private sector in terms of the things they can be doing? It sounds like the government is going to continue to plan and work and try to coordinate, and there is a lot of work that we have talked about that needs to be done, but we haven't talked a lot about the private sector yet. Do you have any suggestions for the private sector?

Ms. STEINHARDT. Well, I have suggestions for the government in working with the private sector. We have this system of coordinating councils for critical infrastructure sectors. In fact, in work that we did here, we found that they could be used much more than they currently are. There are a lot of questions that the private sector has within these critical sectors that they have about how government policies are going to work. How are States and the Federal Government going to handle State border closings? These are vital issues for commerce. And those discussions should be happening today between private sector and government. We are not in this alone and these are issues that have to be resolved in tan-

dem, and that is one area where we certainly would urge greater attention.

Senator PRYOR. I have one last follow-up question. It is really a two-part question. I want to ask each of you this, and that is what is the single most important step that we can take to increase our preparedness in the next 3 months, from now until the fall? What is the single most important step we can take, and how do you suggest that we do it? Dr. Ostroff.

Dr. OSTROFF. Well, I wish I could tell you that there was a single step, because there isn't. There is a series of steps that I think we need to deal with.

Senator PRYOR. Is there one thing, though, that——

Dr. OSTROFF. Well, I think that the two areas that I really think that we need to focus on is we need to get our house in order for issues related to vaccination because we know for influenza that is the single best preventive measure we have available. And I do have concerns that we will see more morbidity and certainly more mortality for this as we go along and I do think we have to think about how we deal with medical surge issues.

Senator PRYOR. And so you are thinking vaccine, even though it could mutate, but you are saying, place your bet on what you know——

Dr. OSTROFF. I think not placing your bet on what we currently know would be a significant mistake.

Senator PRYOR. OK. Mr. Jarris.

Dr. JARRIS. Limited to one, it is a very difficult question because there is so much that has to be done. But I would think that if I was in the shoes of Congress and the Administration, the single most important thing to do is to appropriate sufficient resources in the next 2 weeks with this supplemental. There is so much that needs to be done. We don't have time to catch up later.

Earlier, you asked how to prioritize the $1 billion, and that is a very difficult question because just the vaccines are $15 billion.

Senator PRYOR. That sounds like a lot of money, but it is not——

Dr. JARRIS. Yes, in the old days. But frankly, if we appropriate less than what is needed, for example, the $15 billion for vaccines, and we need more than that, then the question that makes sense would be, well, if we appropriate $1 billion, which one-fifteenth of the American public are we willing to vaccinate and which fourteen-fifteenths are we not willing to vaccinate?

Senator PRYOR. Mr. Thomasian.

Mr. THOMASIAN. Thank you. Well, this is an excellent question and I will take mine beyond the public health arena. The one thing that we need to keep in mind is that this was not really a test. This was not really even a pop quiz. When we did our workshops, we asked States to envision a scenario where 90 million people came down with the disease and we had 1.5 million people needing intensive hospital care and an estimated 1.9 million deaths.

And I would have the States, if they received resources for exercises and further planning, to consider how they would maintain continuity of society under those situations. How would public safety react? How would we handle the high degree of absenteeism in both State government as well as our critical services, such as food services, electricity, etc. So I would use these intervening months

to examine what would happen if this became the true pandemic and the scenarios that we thought we would be looking at under the 1918 scenario and go beyond the public health aspects and look at the public safety, as well.

Senator PRYOR. OK. Ms. Steinhardt.

Ms. STEINHARDT. Well, I would certainly support that. I would say this is our time now to take a look at what our plans are, what our plans have been, what we have learned from what has happened over this last month. What assumptions do we need to revisit? This is our opportunity to learn from a real live test, and it is also our opportunity to actually pull in the results of a number of different tests that have happened over the last few years. I don't think we have learned nearly as much or incorporated the lessons learned from the various tests and exercises that have been done around the country and incorporated that into our thinking, but now we have this opportunity to just take that pause and think about what we know and what we need to change in our plans going forward.

Senator PRYOR. Good. I want to thank all four panelists. I hope I didn't grill you too much. We are going to leave the record open, as I mentioned, and I know Senator Ensign and others will submit some questions for the record. We would appreciate you getting those back to us within 14 days.

Thank you very much for your attention, and I appreciate all the work you have done in your various capacities. You are playing a very important role in saving American lives and we just appreciate everything you are doing.

So with that, we are going to conclude the hearing and leave the record open for 14 days. Thank you.

[Whereupon, at 3:14 p.m., the Subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR ENSIGN

While the media attention for the H1N1 virus has subsided, this hearing is no less important. Health officials believe that this virus could come back stronger during flu season this fall, and we have to be prepared for that. Right now, Federal officials are beginning to track this virus as it heads to the southern hemisphere to gain a better understanding of what it does in populations that are just entering the winter flu season. I am hopeful that whatever characteristics are identified will help us in our preparedness efforts.

While the number of confirmed cases of H1N1 in Nevada is on the low end at 102, a combination of guidance from the Federal Government and decisions made at the local level helped mitigate the spread of the disease. Two weeks ago, in Washoe County, Nevada, surveillance procedures revealed an increased absenteeism rate at Mendive Middle School. Local health district officials awaited word from the State laboratory as to whether or not the children were sick with H1N1. Upon confirmation, the Joint Health and Education Authorities Influenza Oversight Committee met quickly and decided to close the school. The decision was made when only five tests had come back positive for H1N1; however eight additional cases from the school have since been confirmed. State officials have noted that the guidance on school closures has been successful and the closure of Mendive is an excellent example of how the policy worked.

Today we will hear from a number of witnesses who will help us understand how States have responded to this virus over the last month. Their testimony will highlight successful responses and areas that need improvement. As with any emergency, lessons learned can be invaluable. Ideally, the discussion we have here today will provide information for States as they update their State preparedness plans to address the potential for a more potent strain of H1N1.

Approximately 36,000 people die as a result of influenza each year. Should this virus re-emerge as a stronger strain than we are seeing today, citizens should continue to exercise precaution and personal responsibility. While we can't predict the severity of a possible mutation, we can do our best to minimize its effects.

United States Government Accountability Office

GAO

Testimony before the Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration, Senate Committee on Homeland Security and Governmental Affairs

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INFLUENZA PANDEMIC

Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential

Statement of Bernice Steinhardt
Director, Strategic Issues

GAO-09-760T

June 3, 2009

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Highlights

Highlights of GAO-09-760T, testimony before the Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration, Senate Committee on Homeland Security and Governmental Affairs

INFLUENZA PANDEMIC

Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential

Why GAO Did This Study

As the recent outbreak of the H1N1 (swine flu) virus underscores, an influenza pandemic remains a real threat to our nation and to the world. Over the past 3 years, GAO has conducted a body of work to help the nation better prepare for a possible pandemic. In a February 2009 report, GAO synthesized the results of this work, pointing out that while the previous administration had taken a number of actions to plan for a pandemic, including developing a national strategy and implementation plan, much more needs to be done, and many gaps in preparedness and planning still remain.

This statement is based on the February 2009 report which synthesized the results of 11 reports and two testimonies covering 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

The February 2009 report made no new recommendations. This statement discusses the status of GAO's prior recommendations on the nation's planning and preparedness for a pandemic.

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 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 has occurred at the federal, state, and local government levels, but important planning gaps remain at all levels of government.
- 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 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.

The recent outbreak of the H1N1 influenza virus 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 23 recommendations, 10 of the recommendations that GAO has made over the past 3 years are still not fully implemented. With the possibility that the H1N1 virus could return in a more virulent form in a second wave in the fall or winter, the administration and federal agencies should turn their attention to filling in the planning and preparedness gaps GAO's work has pointed out.

View GAO-09-760T or key components. For more information, contact Bernice Steinhardt at (202) 512-6543 or steinhardtb@gao.gov.

Mr. Chairman and Members of the Subcommittee:

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 outbreak of the H1N1 (swine flu) virus. 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 preparedness and planning still remain. At the same time, national priorities have been shifting as a global pandemic has yet to occur, and the nation's financial crisis and other national issues have become more immediate and pressing. 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 11 reports and two testimonies on influenza pandemic planning.[2] We synthesized the results of this work in a February 2009 report, which I will discuss in more detail today.[3] We have made 23 recommendations based on the findings from these reports and testimonies, thirteen of which have been acted upon by the responsible federal agencies. While the responsible federal agencies have generally agreed with our recommendations and some actions are underway to address them, 10 recommendations have not yet been fully implemented. While our February 2009 report made no new recommendations, we updated the status of recommendations that had not yet been implemented as of February 2009. Many of the recommendations that remain unimplemented have become even more pressing in light of the very real possibility of a more serious return of the H1N1 virus later this year. Lists of our open recommendations and related GAO products that

[1]GAO's 2009 Congressional and Presidential Transition Web site: http://www.gao.gov/transition_2009.

[2]We also have three pandemic-related reviews underway on the following topics: (1) plans to protect the federal workforce in a pandemic; (2) the status of implementing the *National Strategy for Pandemic Influenza Implementation Plan* (National Pandemic Implementation Plan); and (3) 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, D.C.: Feb. 26, 2009).

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 has occurred at the federal, state, and local government levels, but important planning gaps remain at all levels of government.
- 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 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.

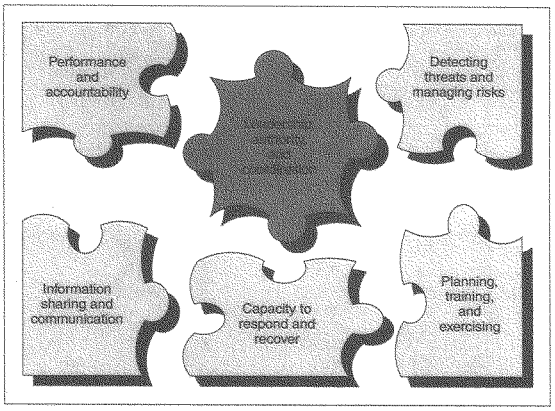
This statement is largely based on our prior work, which was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient,

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 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. While the current H1N1 outbreak seems to have been relatively mild, the history of an influenza pandemic suggests it could return in a second wave this fall or winter in a more virulent form. 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.[4] In addition, an influenza pandemic could result in 200,000 to 2 million deaths in the United States, depending on its severity.

The 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.[5] The National Pandemic Strategy is intended to provide a high-level overview of the approach that the federal government will take to prepare for and respond to an influenza pandemic. It also provides expectations for nonfederal 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 nonfederal 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. At the request of the House Homeland Security Committee, we have ongoing work assessing the status of implementing this plan.

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

[5]On May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The HSC will be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as an influenza pandemic.

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 HHS 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.[6] 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.[7] 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

[6]Pub. L. No. 109-295, Title VI.

[7]GAO, *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, D.C.: July 31, 2007).

challenges.[8] 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 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.[9] One of these was a lack of clarity about 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

[8]GAO-07-781.

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

agriculture, telecommunications, transportation, and water.[10] 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.[11] 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, D.C., 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 FEBs' 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

[10]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 healthcare; 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.

[11]GAO-08-36.

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.[12] 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)[13] in January 2008 as one of 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.

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

[13]Issued in January 2008 by the Department of Homeland Security (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 catastrophic incidents. The NRF builds upon the National Incident Management System, which provides a national template for managing incidents.

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

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.[14] As a result, assessments of the risks of the emergence of an 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

While the National Pandemic Strategy and National Pandemic Implementation Plan are important first steps in guiding national preparedness, 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.[15] The documents fully address only one of the six characteristics, by reflecting a clear description and understanding of problems to be addressed. Further, the

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

[15]The 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, D.C.: Feb. 3, 2004).

National Pandemic Strategy and Implementation Plan do not address one characteristic at all; they contain no discussion of what it will cost, where resources will be targeted to achieve the maximum benefits, and how benefits, risks, and costs will be balanced. 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 nonfederal 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 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.

State and Local Pandemic Planning

We reported in June 2008 that, according to CDC, all 50 states and the three localities that received federal pandemic funds have developed influenza pandemic plans and conducted pandemic exercises in accordance with federal funding guidance. A portion of the $5.62 billion that Congress appropriated in supplemental funding to HHS for pandemic preparedness in 2006—$600 million—was allocated for state and local planning and exercising. All of the 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.[16] However, an HHS-led interagency assessment of states' plans found on average that

[16]We conducted site visits to the five most populous states—California, Florida, Illinois, New York, and Texas—for a number of reasons, including that these states constituted over one-third of the United States 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 five urban areas and five rural counties.

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 six 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.[17]

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. 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. HHS and DHS indicated at the time of our February 2009 report that while no additional meetings had been planned, 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. 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.[18] NGA also reported that states generally have very little awareness of the status of disease

[17]DHS and HHS and other agencies, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council* (Washington, D.C.: Jan. 2009).

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

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.[19] 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);

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

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

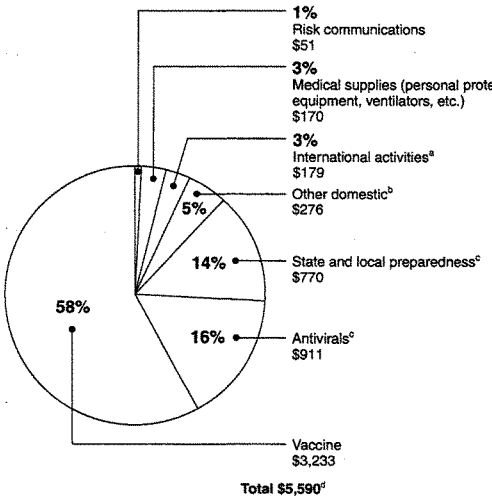
Improving the nation's response capability to catastrophic disasters, such as an influenza pandemic, is essential. Following a mass casualty event, health care systems would need the ability to adequately care for a large number of patients or patients with unusual or highly specialized medical needs. 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 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.

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. Figure 2 shows that 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 for state and local preparedness—$170 million—was allocated for state antiviral purchases for their state stockpiles.[20]

[20]Supplemental funding for pandemic preparedness and response is provided in both the Senate- and House-passed versions of a 2009 supplemental appropriation currently under consideration. The Senate bill includes $1.5 billion as requested by the administration and the House bill provides a total of $2.05 billion.

Figure 2: HHS Influenza Pandemic Supplemental Appropriations, Fiscal Year 2006

Dollars in millions



Source: GAO, HHS.

Notes: Data are from HHS, *Pandemic Planning Update III: A Report from Secretary Michael O. Leavitt* (Washington, D.C.: Nov. 13, 2006).

[a]International activities includes: international preparedness, surveillance, response, and research.

[b]Other domestic includes: surveillance, quarantine, lab capacity, and rapid tests.

[c]State and local preparedness includes funding for state subsidies of antiviral drugs.

[d]This figure does not include $30 million in supplemental funding that was transferred to the U.S. Agency for International Development.

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.[21] 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 and 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.[22] 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.[23]

[21]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.

[22]GAO-08-668.

[23]GAO-08-539.

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 Web sites, 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 Web site (www.pandemicflu.gov) and disseminated pandemic preparedness checklists for workplaces, individuals and families, schools, health care and community organizations, and state and local governments.

However, state and local officials from all of the states and localities we interviewed wanted additional federal influenza pandemic guidance from the federal government on specific topics, such as implementing community interventions, fatality management, and facilitating medical surge. Although the federal government has issued some guidance, 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. 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 for 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 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. This lack of clear linkages 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 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.

Concluding Observations

The recent outbreak of H1N1 influenza virus 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 many of our recommendations, almost half the recommendations that we have made over the past 3 years are still not fully implemented. For one thing, 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.

Pandemic influenzas, as I noted earlier, differ from other types of disasters in that they are not necessarily discrete events. While the current H1N1 outbreak seems to have been relatively mild, it could return in a second wave this fall or winter in a more virulent form. Given this risk, the administration and federal agencies should turn their attention to filling in some of the gaps our work has pointed out, while time is still on our side.

Chairman Pryor, Senator Ensign, and Members of the Subcommittee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

Contacts and Staff Acknowledgements

For further information regarding this statement, please contact Bernice Steinhardt, Director, Strategic Issues, at (202) 512-6543 or steinhardtb@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this testimony include Sarah Veale, Assistant Director; Maya Chakko; Melissa Kornblau; Susan Sato; Ellen Grady; Karin Fangman; and members of GAO's Pandemic Working Group.

Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions, GAO-08-671, September 30, 2008	The Secretary of HHS should expeditiously finalize guidance to assist state and local jurisdictions to determine how to effectively use limited supplies of antivirals and pre-pandemic vaccine in a pandemic, including prioritizing target groups for pre-pandemic vaccine.	In December 2008, HHS released final guidance on antiviral drug use during an influenza pandemic. HHS officials informed us that they are drafting the guidance on pre-pandemic influenza vaccination.
Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning, GAO-08-539, June 19, 2008	The Secretaries of HHS and Homeland Security should, in coordination with other federal agencies, convene additional meetings of the states in the five federal influenza pandemic regions to help them address identified gaps in their planning.	HHS and DHS officials indicated that while no additional meetings are planned at this time, states will have to continuously update their pandemic plans and submit them for review.
Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination, GAO-08-36, October 31, 2007	The Secretary of Homeland Security should work with sector-specific agencies and lead efforts to encourage the government and private sector members of the councils to consider and help address the challenges that will require coordination between the federal and private sectors involved with critical infrastructure and within the various sectors, in advance of, as well as during, a pandemic.	DHS officials informed us that the department is working on initiatives, 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.
Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy, GAO-07-781, August 14, 2007 *Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning*, GAO-07-1257T, September 26, 2007	(1) The Secretaries of Homeland Security and HHS should work together to develop and conduct rigorous testing, training, and exercises for an influenza pandemic to ensure that the federal leadership roles are clearly defined and understood and that leaders are able to effectively execute shared responsibilities to address emerging challenges. Once the leadership roles have been clarified through testing, training, and exercising, the Secretaries of Homeland Security and HHS should ensure that these roles are clearly understood by state, local, and tribal governments; the private and nonprofit sectors; and the international community.	(1) HHS and DHS officials stated 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.

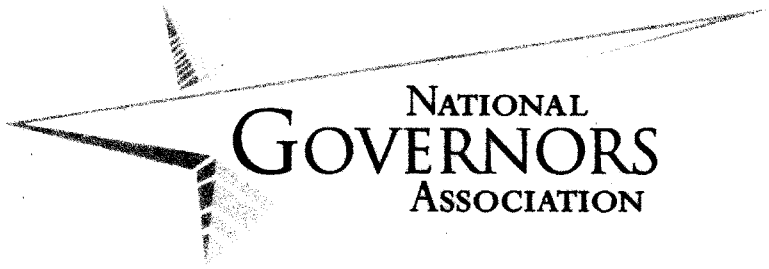
Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
	(2) The Homeland Security Council (HSC) should establish a specific process and time frame for updating the National Pandemic Implementation Plan. The process should involve key nonfederal stakeholders and incorporate lessons learned from exercises and other sources. The National Pandemic Implementation Plan should also be improved by including the following information in the next update: (a) resources and investments needed to complete the action items and where they should be targeted, (b) a process and schedule for monitoring and publicly reporting on progress made on completing the action items, (c) clearer linkages with other strategies and plans, and (d) clearer descriptions of relationships or priorities among action items and greater use of outcome-focused performance measures.	(2) HSC did not comment on the recommendation and has not indicated if it plans to implement it.
Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response, GAO-07-652, June 11, 2007	(1) The Secretaries of Agriculture and Homeland Security should develop a memorandum of understanding that describes how the U.S. Department of Agriculture (USDA) and DHS will work together in the event of a declared presidential emergency or major disaster, or an Incident of National Significance, and test the effectiveness of this coordination during exercises.	(1) Both USDA and DHS officials told us that they have taken preliminary steps to develop additional clarity and better define their coordination roles. For example the two agencies meet regularly to discuss such coordination.
	(2) The Secretary of Agriculture should, in consultation with other federal agencies, states, and the poultry industry, identify the capabilities necessary to respond to a probable scenario or scenarios for an outbreak of highly pathogenic avian influenza. The Secretary of Agriculture should also use this information to develop a response plan that identifies the critical tasks for responding to the selected outbreak scenario and, for each task, identifies the responsible entities, the location of resources needed, time frames, and completion status. Finally, the Secretary of Agriculture should test these capabilities in ongoing exercises to identify gaps and ways to overcome those gaps.	(2) USDA officials told us that it has created a draft preparedness and response plan that identifies federal, state, and local actions, timelines, and responsibilities for responding to highly pathogenic avian influenza, but the plan has not been issued yet.

Attachment I: Open Recommendations from GAO's Work on an Influenza Pandemic as of February 2009

Title and GAO product number	Summary of open recommendations	Status
	(3) The Secretary of Agriculture should develop standard criteria for the components of state response plans for highly pathogenic avian influenza, enabling states to develop more complete plans and enabling USDA officials to more effectively review them.	(3) USDA told us that it has drafted large volumes of guidance documents that are available on a secure Web site. However, the guidance is still under review and it is not clear what standard criteria from these documents USDA officials and states should apply when developing and reviewing plans.
	(4) The Secretary of Agriculture should focus additional work with states on how to overcome potential problems associated with unresolved issues, such as the difficulty in locating backyard birds and disposing of carcasses and materials	(4) USDA officials have told us that the agency has developed online tools to help states make effective decisions about carcass disposal. In addition, USDA has created a secure Internet site that contains draft guidance for disease response, including highly pathogenic avian influenza, and it includes a discussion about many of the unresolved issues.
	(5) The Secretary of Agriculture should determine the amount of antiviral medication that USDA would need in order to protect animal health responders, given various highly pathogenic avian influenza scenarios. The Secretary of Agriculture should also determine how to obtain and provide supplies within 24 hours of an outbreak.	(5) USDA officials told us that the National Veterinary Stockpile now contains enough antiviral medication to protect 3,000 animal health responders for 40 days. However, USDA has yet to determine the number of individuals that would need medicine based on a calculation of those exposed to the virus under a specific scenario. Further, USDA officials told us that a contract for additional medication for the stockpile has not yet been secured, which would better ensure that medications are available in the event of an outbreak of highly pathogenic avian influenza.

Source: GAO.



Testimony of John Thomasian
Director, National Governors Association
Center for Best Practices

Submitted to the Senate Ad Hoc Subcommittee on State, Local & Private Sector Preparedness & Integration

"Pandemic Influenza: Closing the Gaps"

June 3, 2009

Testimony before the Senate Ad Hoc Subcommittee on State, Local & Private Sector Preparedness & Integration

"Pandemic Influenza: Closing the Gaps"

John Thomasian
Director
National Governors Association Center for Best Practices

June 3, 2009

Chairman Pryor, Ranking Member Ensign, members of the subcommittee, my name is John Thomasian and I am the director of the National Governors Association Center for Best Practices (NGA Center). I appreciate the opportunity to testify before you today on pandemic influenza preparedness and what remains to be done to close potential gaps in the nation's capacity to respond. My comments today are based on our previous work with states on pandemic planning as well as our recent experience helping states on issues concerning the H1N1 influenza virus.

The NGA Center develops innovative solutions to today's most pressing public policy challenges and is the only research and consulting entity that directly serves all of the nation's governors. The NGA Center's policy experts provide governors information, technical assistance, and best practices on a full spectrum of policy issues, including education, health care, the environment, homeland security, public safety, and economic development.

Background

The NGA Center has been at the forefront of state pandemic preparedness planning for several years, starting in 2006 with the publication of a primer for governors and senior state officials on the need for robust, cross-sector planning. We followed the publication of that primer with a series of regional workshops throughout 2007 and early 2008 (NGA Center materials on pandemic influenza may be found on our web site, www.nga.org). These workshops emphasized the institutional, governance, and public safety aspects of pandemic preparedness that were designed to ensure that society, government, and the economy continued to function. Issues we explored included:

- Interagency coordination;
- How to manage workforce reductions;

- How to maintain essential services such as law enforcement and fire fighting;
- Arrangements with the private sector to ensure the availability of food and other necessities; and
- Public education and communication.

The workshops, held in partnership with the Association of State and Territorial Health Officials and with funding from the Department of Health and Human Services, involved every state, the District of Columbia, and four of the five U.S. territories. Participants in the workshops consisted of 3- to 7-member teams from each state, selected by their governor. Team members represented diverse backgrounds and responsibilities, including emergency management, public safety, public health, education, local government, and the private sector.

The workshops challenged states to identify gaps in their own plans and used as a planning scenario a "worst case" event built around the example of the 1918 pandemic. Thus, we asked states to consider an infection rate of 30 percent of the U.S. population (approximately 90 million people), with 1.5 million people needing intensive hospital care and 742,000 requiring ventilators. This scenario also included an estimated 1.9 million deaths, with up to 40 percent of the workforce unavailable during each of three expected pandemic waves. Economic costs to the nation were estimated in the range of $500 billion in 2004 dollars—a reduction in GDP of approximately 5 percent. This scenario was consistent with federal guidance issued to assist states in developing their pandemic preparedness strategies.

I mention this because our workshops asked states to envision a far more catastrophic event than we have as yet encountered with the new H1N1 virus. In contrast to a 1918-type scenario, the H1N1 virus so far has proved to be relatively mild, with 8,975 cases and 15 deaths in the United States and, as of June 1, 17,410 cases and 115 deaths worldwide.

My comments today are based on our observations of state preparedness from our workshops as well as our more recent work assisting governors, state homeland security advisors, and other state agencies in managing the response to the H1N1 situation during this spring. I will focus on five key areas:

- Information sharing between states and the federal government;
- Interagency coordination within states and between states and the federal agencies;
- School closing decisions;

- Continuity of government and coordination with the private sector on critical services; and
- Communication with the public.

I will attempt to describe the preparedness status of each issue as we encountered it in our workshops and during the recent outbreak.

Information Sharing

Awareness of the presence or absence of disease at the local, state, and national levels is essential to implementing mitigation strategies that deliver optimum public health benefits while minimizing negative side effects. At the time of our workshops, we concluded that no system then existed to provide state officials with a clear picture of the situation in their states, in neighboring states, or in other parts of the country.

The recent experience with the H1N1 virus illustrates the improvement in information sharing since our 2007-2008 workshops. The flow of information from the federal government to the states, and from the states to federal agencies, was near-constant during the initial weeks of the outbreak. Case counts were updated daily, morbidity and mortality figures were readily available, and federal agencies—in particular the CDC but also the Department of Homeland Security—were proactive in their efforts to push information and guidance to state and local government officials. Similarly, interagency communications at all levels of government appeared to be robust: Health agencies were talking to the public safety and education sectors at the federal, state, and local levels, and federal agencies' plans and strategies appeared to be well-coordinated. States, overall, were very pleased with the quality and quantity of information they received from the federal government.

There were some early "glitches," however, that should be easy to correct. We did hear complaints that the briefings used to deliver information to the states were not well-coordinated and resulted in too much time spent hearing redundant information. Both CDC and DHS established daily conference calls to brief relevant state officials on new or updated information, and confusion existed as to whether each briefing contained new information or simply repeated an earlier briefing for a different audience. Early in the outbreak, the calls sometimes ran concurrently, which resulted in some federal officials being unavailable for one call because they were briefing state officials on another call. Later, the calls were scheduled to run consecutively. This, however, resulted in state officials spending several hours each day

monitoring conference calls to ensure they were up to speed on the latest information and guidance.

Moving forward, we would suggest that DHS and CDC coordinate a single or twice-daily briefing with states on flu developments. States, for their part, would urge all of their key agency officials to join that daily briefing. The purpose of the briefing would be to provide essential situation updates and suggested response actions. This daily briefing would not preclude other conversations, but would offer some assurance that all essential information could be obtained in one call and, thus, free up more time for in-state activities.

Another issue that arose was the need to support more information exchange *among* states. In our work to support the state homeland security directors, they stressed a desire for more information on what other states were doing. To help address this issue, we began issuing weekly updates to the governors homeland security directors on various state actions. Two examples of these updates are attached. We would plan on continuing this work if another outbreak occurred and would welcome working with DHS and other federal agencies to examine how to improve this type of cross-state information exchange.

Interagency Coordination

Interagency coordination within states and between states and the federal government is crucial for an effective pandemic response. At our workshops, we found that many of the state interagency teams were meeting for the first time and were not fully aware of what each team member's responsibilities were in a pandemic. Although state plans define the responsibilities of each agency, many states had not had the opportunity to practice their roles in an interagency exercise. In addition, many state teams were unsure what roles each of the federal agencies were to play in a pandemic.

Based on the response to the recent outbreak, we can report the situation today is much improved. For one, the key federal agencies—CDC and DHS—appeared to be working together and did a good job articulating their scope of responsibilities to the states.

At the state level, preparedness exercises, including our workshops, had given state agencies the opportunity to learn and practice their roles and establish relationships among agency officials. At the early stages of the outbreak, states quickly "stood up" their public health emergency response teams but, more importantly, state homeland security advisors were quickly engaged to begin coordinating an overall state response. Many states soon began to go beyond the walls of their health departments and lay the groundwork to mobilize broader state

resources through emergency declarations and other actions. Examples of these actions can be found in our weekly updates (attached).

As we look ahead, we must recognize that good interagency coordination can be ephemeral. It needs to be exercised regularly to work properly. To ensure that it not become a gap or challenge, states must have the opportunity to work through response actions periodically with other agencies and the federal government. A truism in state emergency preparedness is that states are most ready for a disaster right after experiencing the last one. States and the federal government are more prepared to address a pandemic event today because they responded to an actual outbreak in April and May. This type of readiness deteriorates quickly, however, and at this moment there are no designated resources available to all states to conduct multiagency preparedness exercises.

School Closure

The issue of school closure presents perhaps the most complicated pandemic-related challenge for officials at all levels of government. The issue was a topic of intense discussion at each of our regional workshops, and state officials obviously were struggling with the implications of a long-term closure early in their efforts to plan for a pandemic. The issue is multi-faceted:

- The disease-mitigation benefits of closure or class dismissal must be weighed against the impact on the availability of workers throughout the local economy, as some workers will need to care for school-aged children.
- School closures disrupt the school year and the educational continuity for affected children. They affect testing schedules and district budgets. They also disrupt school-based nutrition and counseling programs.
- Colleges and universities have particular challenges that also must be addressed, including dormitory-style living quarters that could facilitate the spread of disease and the presence of international students who may not be able to return home easily, particularly if limits on international travel are in place.

During the H1N1 event earlier this spring, the issue of school closure received significant attention from the national media and from government officials who were attempting to react swiftly to stop the virus from spreading. To their credit, officials at the federal and state levels began considering school closure almost immediately as a non-pharmaceutical intervention that promised to at least slow the spread of the virus until better information became available

about the nature of the threat. This was an entirely appropriate response given the information available at the time.

Inconsistencies soon arose when attempting to implement school closure policies. One issue was that CDC's written guidance directed state and local officials to consider closing schools based on laboratory-confirmed cases, while public comments by some federal officials indicated closure decisions should be made based on suspected or probable cases. This created confusion among state officials and resulted in divergent approaches, with schools in one state closing only when cases had been confirmed and schools in a neighboring state closing based on probable cases. How long to close also was an issue. Many used a two-week timeframe or even longer, but that may prove unnecessary if no further cases were discovered in the student body after five days.

Also missing from the equation was a public explanation of the potential costs, possible benefits, and expected limitations of school closure. Parents in some communities accused government officials of acting too precipitously and complained of lost wages and unscheduled absences. In other communities, parents complained that schools did not close quickly enough, or that they opened too soon after initial closing, resulting in further spread of the virus. Meanwhile, national media lost no time in heading to local shopping malls to photograph and interview high school students who simply swapped school hallways for mall food courts as a venue in which to share viruses.

A serious public discussion must take place around the issue of school closure to clarify its ultimate purpose: not to cure disease, but rather to slow the spread of the virus in a community, to "flatten the curve" of peak illness and, essentially, to buy time until a vaccine can be produced. School closure is not a "silver bullet," and the public must be made aware of both its benefits and its limitations.

More detailed advice from CDC would be welcomed by states so they could implement a more consistent approach to school closure. Such guidance could be flexible, and designed to adapt as more information is known. For example, in the early stages of a new outbreak, a higher infection rate (i.e., ratio of infection, or R0) might be assumed, thus suggesting aggressive closure policies. As more is learned and research suggests lower infection rates, guidance can shift to suggest closure only after a certain number of cases are confirmed. In any case, more work is needed in this area to craft good guidance.

Continuity of Government and Coordination with the Private Sector on Critical Services

Two issues emerged in our 2007 and 2008 workshops that were directly related to the expected high degree of absenteeism resulting from a pandemic: the need for improved continuity of government planning and the need for states to coordinate more closely with the private sector to ensure the availability of critical goods and services.

All states have continuity of government or continuity of operations plans for general emergencies, and in many cases states included annexes to agency continuity of operations plans to address the unique workforce shortages likely during a pandemic. In some cases, however, we found that states were relying solely on their traditional continuity plans, which do not reflect the specific challenges of maintaining government operations and protecting workers during a pandemic. We have recommended that states examine and, where necessary, develop or improve policies to increase the willingness and ability of personnel to perform their duties. States should consider expanded policies on telecommuting as well as condensed or amended schedules or operating hours for some agencies. Policies also must be developed to address the need of some workers to care for sick family members, or for children affected by school closures, for extended periods of time, and to balance those needs against government continuity requirements.

States also must work more closely with the private sector to ensure the availability of essential goods and services during a pandemic. The public sector relies heavily on the private sector for a range of products and services, including critical infrastructure such as water, electricity, food and telecommunications services. Similarly, the private sector's ability to weather a pandemic will require close collaboration with the public sector on policies that could affect worker availability, supply chain reliability, and the provision of public safety services. As a result, efforts to control the spread of disease at the community level—including closing schools, limiting public gatherings, and restricting public transportation services—must be implemented with recognition of their effect on the ability of the private sector to deliver critical services.

Because the H1N1 outbreak has so far been relatively mild, continuity planning and public-private coordination strategies were not tested and remain among the "unknowns" of our preparedness for a more serious event. We do know that some states had reviewed their continuity plans and were considering strategies for implementing those plans, at least in the early days of the outbreak, but the strategies were never tested in a real-world environment. Similarly, we still do not know whether states are engaging sufficiently with their private sector

employers to ensure their respective continuity efforts adequately reflect their interdependencies. Nor do we have a clear sense of whether the private sector in general is amply prepared. This is an area that requires attention as we move forward.

Communication with the Public

The key to any effective pandemic response is a fully engaged and educated public. During our workshops in 2007 and 2008, there was concern that the public was not engaged in the discussions about pandemic preparedness. The public seemed aware of the potential threat from a human-to-human transmittable version of avian flu, but confused about what they should do about it. In the two years since the last workshops, states and the federal government made strides informing the public and the media about the ramifications of a pandemic. Both levels of government have stressed general preparedness and focused on self-reliance strategies such as stockpiling food, water, medicines and other necessities. However, the public still is not sufficiently educated on the type of actions that might be undertaken to stop the spread of the flu, and this creates a great deal of confusion around such issues as school closings, quarantine, public distancing, and travel restrictions.

In the recent outbreak, the federal government did a good job keeping the public and media informed. In addition, the mainstream media provided good reporting to the public about the spread of the disease and what individuals could do to avoid infections. However, because clear explanations were not provided about the value (or lack of value) of such actions as school closures and travel restrictions, there was confusion in the early stages. Moreover, the lack of clarity from the World Health Organization on the definition of pandemic and the different levels it uses to identify a pandemic threat only added more confusion and anxiety.

At the state level, almost every state created or updated their pandemic Websites. The sites informed the public about the situation in the state and nation and provided steps that citizens could take to avoid infection or limit its spread. However, a full explanation on the type of actions states and the federal government might take to prevent further spread of the disease generally was lacking. CDC and DHS did an excellent job early in the outbreak describing the nature of the health threat and providing information on the status of the disease, but they did not explain well what type of actions might be used to stop the flu's spread. In these early stages, the federal government and states need to better explain what actions are being considered and why (e.g., school closings, voluntary isolation when sick, and cancellation of public events) and which actions likely will be avoided and why (e.g., quarantine and travel restrictions).

To address this gap, we recommend that the public be engaged in substantive discussions about issues with difficult ethical dimensions, including:

- The need for self-enforcement of community mitigation efforts, in particular to ensure that children dismissed from school do not simply re-congregate in other settings that are equally conducive to virus transmission;
- Triage and rationing of health care, including the prioritization of medicines and scarce medical equipment such as ventilators;
- Voluntary quarantine and isolation as disease-mitigation strategies; and
- The value, risks, costs, and limits of more aggressive actions, such as enforced quarantine and travel and trade bans.

The window for effective engagement is now open, as the public again appears to understand the threat posed by emerging diseases and the reality of influenza pandemics. However, the relative mildness of the H1N1 outbreak thus far may be causing some complacency among the public and may have reinforced the skepticism in some quarters that the pandemic threat is not as real or as significant as public health and other officials have warned.

Conclusion

In conclusion, states have made strides in the last three years to improve their ability to respond to the full range of issues they are likely to encounter during a severe pandemic. But significant work remains.

The H1N1 outbreak this spring was not a test of a worst-case or even moderate pandemic scenario, but it did serve as a strong wake-up call to officials and agencies at all levels of government—and hopefully to the public as well—that the threat of a pandemic is real, even if the severity of the disease is unpredictable. We should take advantage of this renewed attention to close the gaps still remaining and maintain a high level of readiness.

We are presented with a unique opportunity: we have several months before the onset of the next influenza season. Scientists warn that the H1N1 could return at that time in a more-potent form. We should use the intervening months to address the weaknesses the initial outbreak exposed:

- Federal agencies should clarify the guidance on school closures to ensure consistency and, to the extent possible, include a discussion of the impacts school closures could have on state and local economies.
- Information exchange mechanisms should be improved so that state and local officials are not required to monitor phone calls for several hours each day.
- The public absolutely must be engaged over the next several months in a concerted outreach effort to explain the benefits and costs of school closures and other mitigation strategies and to solicit their participation and cooperation so that maximum benefits accrue from any decision requiring a change in public behavior.
- The federal government should encourage and support state efforts to hold periodic pandemic exercises that practice response coordination with federal agencies, local governments, and the private sector, review communication strategies with the public, and engage multiple agencies in the state, including public safety and health.

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

Summary of State Actions and Selected Federal Actions to Address H1N1 Swine Influenza Outbreak

May 1, 2009

State Web Sites/ Pages
52 states and territories have set up web sites or pages on their state portals dedicated to the H1N1 influenza outbreak.

Public Health Emergency Declarations
New York Governor Paterson, Wisconsin Governor Jim Doyle and the Virginia State Health Commissioner have declared a Public Health Emergency in their respective states. In addition, Iowa Governor Chet Culver has prepared a declaration for a Public Health Emergency.

State of Emergency and Other Gubernatorial Declarations
Four states have issued various gubernatorial declarations:

- California Governor Arnold Schwarzenegger has declared a *state of emergency* to hasten government services by suspending non-competitive contract bids for services needed to combat the outbreak and by waiving certification requirements to expand lab capabilities in the state and to pursue federal assistance;
- Illinois Governor Pat Quinn has issued a *gubernatorial proclamation* to mobilization state assets and aid in the distribution of medical supplies;
- Maine Governor John Baldacci has proclaimed a *civil emergency* to activate the Maine Pandemic Influenza Plan, activate elements of the national guard and expedite funds; and
- Texas Governor Rick Perry has issued a disaster *declaration* to allow the state to implement emergency protective measures and seek reimbursement under the federal Stafford Act.

Activation or Partial-Activation of State Emergency Operation Centers (EOCs):
Eight states and territories have activated or partially activated their state EOCs or state public health EOCs. California, Delaware, Illinois, Indiana and Rhode Island have activated their state EOCs. Guam and Michigan have partially activated their EOCs. In addition, North Dakota activated the state's public health EOC.

Engagement with the National Guard
Four states—Illinois, Nevada, Vermont and Wisconsin--have activated their National Guard or requested their help in dispensing antiviral medication.

School Closures
According to the U.S. Department of Homeland Security, as of Friday, May 1, 2009 approximately 11 states have closed at least one school.

Other State Actions

- Maryland has opened the Maryland Swine Flu Command Center.

- Vermont Governor James Douglas ordered the Vermont National Guard to ship nearly 30,000 courses of antiviral medicine to hospitals around the state on Wednesday. Also, Vermont has issued guidance that migrant workers pose no significant flu threat, as migrant workers are already well-established in the United States.

- Indiana halted visits to prison inmates and at least two schools canceled classes Thursday in the state's latest steps to prevent the spread of the swine flu virus.

- Delaware Governor Jack Markell requested a CDC advisory team to assist the state in response to the H1N1 virus.

Selected Federal Actions

- Per CDC, 25 states have received their initial SNS allotment, 24 other states have received partial shipment, 7 shipments are en route and 6 shipments are moving from the SNS warehouses today. The first push of SNS to the states is to be completed by May 8th. (DHS Intergovernmental Affairs Call, May 1st, 2009)

- FEMA is developing guidance on how to use current UASI and SHSGP funds for response to the H1N1 virus. (DHS Intergovernmental Affairs Call, May 1st, 2009)

- CDC will release guidance to the states via their website at http://www.cdc.gov/h1n1flu/

- CDC is preparing interim direction for use of existing CDC Preparedness Grant funds for emergency response (CDC Daily Conference Call, Thursday, April 30th).

- Per HHS Secretary Sebelius, CDC will have updated interim guidance on K-12 school closings, higher education school closings and day care facilities. Guidance is current as of May 1st, 2009.

H1N1 Influenza: Summary of State Actions

For the week ending May 8, 2009

The following is a brief summary of state actions concerning the H1N1 influenza outbreak. NGA's research is based on state press releases and open source media, and this summary is by no means comprehensive. If you would like to add your state actions to this summary, submit corrections and updates, or would prefer NGA track additional information, please contact dhenry@nga.org.

State Web Sites/ Pages
52 states and territories have set up web sites or pages on their state portals dedicated to the H1N1 influenza outbreak.

Community Mitigation Strategies
States have instituted social distancing measures in state prisons. South Carolina has suspended person-to-person visits. In addition to prison visits, Louisiana Governor Bobby Jindal has suspended tours of prison facilities.

Mutual Aide Activations:
Tennessee has begun assisting Texas in lab testing of suspected H1N1 cases. Tennessee's outbreak and lab workloads have been light compared to a 3,500 case backlog in Texas. Tennessee received 400 samples this week to begin lab testing.

SNS Deployment
Colorado utilized a public/private partnership to distribute SNS medical supplies to 13 dispensing sites in the state. Additionally, Hawaii and Ohio National Guard units are tasked in their state pandemic plans to assist in SNS deployment[i]. The Michigan Volunteer Defense Force—an element of the State Militia under the command and control of the Michigan National Guard—was deployed to assist the Michigan Department of Community Health with antiviral logistics and distribution[ii].

State EOC Activations Update:
Utah made a partial activation of the state EOC on Monday April 27th, using WebEOC as a primary monitoring tool. The Utah Department of Health has an active departmental operations center and a Joint Information Center (JIC) that is coordinating public media and information to the state EOC[iii]. Ohio has followed a similar structure, and is issuing daily situation reports from the state EOC. As of May 4th, South Carolina's Health and Environmental Control Departmental Operations Center is open[iv].

School Closures
CDC issued updated interim guidance on school closings for K-12 this week. Additionally, CDC has issued updated interim guidance for higher education.

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[i] Per MG Robert Lee, Hawaii HSA; Ohio Emergency Operations Center
[ii] Per BG Mike McDaniel, Michigan HSA
[iii] Per Keith Squires, UT HSA.
[iv] Per Blair Goodrich, SC Governor Sanford's Washington Representative.

Association of State and Territorial Health Officials

U.S. Senate Committee on Homeland Security and Governmental Affairs

Ad Hoc Subcommittee on State, Local and Private Sector Preparedness and Integration

"Pandemic Flu: Closing the Gaps from Surveillance to Treatment."

Testimony of

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2231 Crystal Drive, Suite 450
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June 3, 2009
2:00 pm

Good afternoon, Chairman Pryor, Ranking Member Ensign and members of the Committee. Thank you for inviting me to testify before your Committee to update you on the state and territorial response to the novel H1N1 influenza A epidemic and the readiness of health agencies for a potential future influenza pandemic. States are working with federal and local governments and the private sector to effectively respond to this ongoing outbreak and prepare for continued response in the fall should this virus become more lethal.

I am Dr. Paul Jarris, Executive Director of the Association of State and Territorial Health Officials (ASTHO). ASTHO is the national nonprofit organization representing the state and territorial public health agencies of the United States, the U.S. Territories, and the District of Columbia. ASTHO Members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice.

A Strong Governmental Public Health System at Work

The Governmental public health system (federal, state, territorial, and local) is front and center as we prepare for, respond to, and recover from disease outbreaks including pandemics. States and territories have made significant progress in pandemic planning as evidenced by our effective response to the ongoing H1N1 epidemic. A recent Harvard School of Public Health survey showed that more than 80 percent of Americans are satisfied with the way public health officials have managed the response to the H1N1 outbreak. Eighty-eight percent of Americans are satisfied with the information public health officials provided to them.

Despite the challenges of the current economy, federal, state, territorial, and local governments have come together to serve the American people as a unified enterprise. Throughout the last month and a half, the Centers for Disease Control and Prevention (CDC), ASTHO, state, territorial, and local public health departments have stood up their emergency operations centers. In May, ASTHO detailed our preparedness specialists to the CDC's Emergency Operations Center in Atlanta to serve as a liaison officer at their State and Local Desk. CDC, ASTHO and the

National Association of County and City Health Officials moderated daily conference calls with state and local public health leadership to maintain real time situational awareness. ASTHO also facilitated regular regional conference calls between the states and their federal regional representatives to tackle and coordinate vexing planning and response issues. On a daily basis we shared best practices among states for the benefit and use of every agency. ASTHO provided a critical interface between state and territorial response and federal planning and coordination.

State and Territorial Public Health Preparedness

In FY 2006, Congress invested $600 million in state and local pandemic influenza supplemental funding to support three years of preparedness activities. This funding was fully expended in August 2008. The federal investment enabled state and territorial health departments to lead the development of comprehensive pandemic influenza operational plans. Health agencies have partnered with agriculture, homeland security and emergency management, education, justice, labor, transportation, treasury and commerce, and other state and federal agencies to drill, revise, and refine plans to meet the goal of continuous state operations during a pandemic or other disaster.

Since December 2005, when the first emergency pandemic influenza supplemental was appropriated, state and territorial public health agencies have developed and tested antiviral drug distribution plans; purchased medical and other response supplies including antivirals, ventilators, respirators, laboratory equipment, and personal protective equipment; and exercised their plans for mass vaccination. At this moment, states and territories are carefully considering, and carrying out community mitigation strategies such as closing schools as recommended by federal guidance.

Prior to the current outbreak, all states and territories had their pandemic influenza operational plans assessed by a team of U.S. Government experts and their findings were reported to the Homeland Security Council. The comprehensive, effective, and integrated response with the CDC to H1N1 is a result of the investment Congress made in state and territorial public health preparedness.

State and Territorial H1N1 Response

State and territorial health agencies are on the front line of our nation's response to this novel influenza epidemic. Disease investigators are on the ground 24 hours a day, 7 days a week to detect infectious disease outbreaks and our state laboratories stand ready to test specimens to identify new and seasonal influenza strains. Our top priority is to protect the public's health, no matter what the situation. State and territorial public health officials prepare for and respond to all health threats including infectious disease outbreaks, natural or man-made disasters, and food borne illnesses. Public health agencies also understand the complex and devastating effects of pandemics.

However, the current epidemic is occurring during a period of economic hardship. State, territorial, and local health departments are suffering the same effects of the current recession as other sectors of the economy. State, county and municipal budget shortfalls have resulted in the loss of over 11,000 public health workers in the past year, and additional job losses are expected during the remainder of this year. As more public health professionals are laid off to balance state and local budgets, health departments will become even more strained in the fall, should H1N1 turn out to be more lethal. There is no dedicated public health emergency reserve fund states can draw from to pay for the response.

We need to build our workforce now so that we can sustain the current response and prepare for the future. Health departments are stretched to the limit working long and extra shifts, while remaining ever vigilant to handle other emergencies as they occur. We do not have the personnel and financial capital to continue this level of response over a long period. Right now states must also be prepared to respond to other public health threats arising from flooding, hurricanes, tornadoes, and wildfires. Sustained investment is needed. But, federal public health emergency preparedness and hospital preparedness funding for states and localities declined approximately 25 percent since 2005 and state budget cuts prevent us from absorbing these losses.

Further, state and territorial health departments are committed to carrying out mandated essential functions such as conducting restaurant inspections, maintaining a safe water supply, providing

maternal and child health services, screening newborns, giving immunizations, and numerous other activities critical to the public's health. Even before the outbreak, over 60 percent of health departments had reduced public health services, and 30 percent had eliminated entire programs. Additional reductions may be required to balance state budgets. These cuts cannot continue while more and more people in the U.S. are relying on our health departments to provide critical, front line services to protect their health.

It is essential that the state and local public health workforce and infrastructure be reinforced to enable enhanced influenza surveillance, case detection, epidemiological investigation, laboratory testing, medical surge capacity, fatality management, and disease control measures in the event that this novel virus returns with increased deadliness in the fall of 2009, as occurred in 1918. The federal government can purchase enormous quantities of new H1N1 vaccine but without the public health workforce to distribute and administer it the vaccine will do no good.

Previous federal investments made possible the effective federal, state, territorial, and local response to H1N1 virus over the last six weeks. Nevertheless, gaps remain and existing resources dedicated to preparedness are insufficient to carry on our response to this novel virus. The current epidemic stressed our diminished public health workforce after only a few weeks of response. A severe epidemic or pandemic will require a three to six month mobilization. Sustaining a response of this magnitude is not possible given the current human and financial resources available to state, territorial, and local public health agencies. Moreover, during the fall, public health will need enhanced surveillance to detect influenza outbreaks and sort out illness caused by seasonal influenza versus illness caused by a return of the novel H1N1 virus.

We must be prepared to sustain a public health response should we face a pandemic with the severity and duration that requires rapid dispensing of antivirals to millions of sick or exposed individuals, launching a national vaccine campaign for hundreds of millions of Americans, and providing professional medical attention in the face of an overwhelmed health care system.

State and territorial health agencies will continue to work with the U.S. Department of Health and Human Services and U.S. Department of Homeland Security to continue to refine and improve

pandemic influenza plans and welcome additional federal guidance on the roles and responsibilities of health departments to enhance our readiness and best utilize scarce resources in the event of a pandemic.

Allow me to mention three key areas where we can improve our readiness:

Disease Surveillance – We need more epidemiologists on the ground to identify outbreaks, monitor the spread of a disease, and inform our response as the outbreak continues. We recommend investing in standardized electronic reporting systems and centralized databases to analyze and respond to geographically widespread outbreaks. It is essential that we have real time capabilities to monitor the prevalence of diseases and identify which populations are most susceptible to certain illnesses whether it is pregnant mothers, children, young adults, or the elderly.

Laboratory Capacity – During our response, public health laboratories quickly exceeded testing capacity. Not only were there not enough laboratorians to maintain three shifts seven days a week, but states also needed additional reagents and other equipment to run the large number of tests required throughout this outbreak. Going forward state health laboratories would benefit from increased investment in electronic health information infrastructure. We recommend increasing our nation's investment in bi-directional data exchange of laboratory test orders and results with CDC. Our country would also benefit from interoperable regional electronic laboratory information sharing networks among state laboratories and health departments. Stronger laboratory capacity will speed our detection of potential cases and enhance our understanding of the characteristics of novel viruses.

Public Health Nursing – State and territorial public health nurses make up 25 percent of a health department's workforce. They are a critical component of our public health infrastructure providing expert advice and guidance to the public and health professionals. Public health nurses frequently oversee crucial emergency response activities such as the mobilization of mass immunization clinics. They are instrumental in overseeing and training volunteer nurses on the safe administration of antivirals and vaccines which includes properly screening individuals for

contraindications to medicines or vaccines. During emergencies, we rely on our public health nurses to ensure that vaccines are distributed efficiently, administered correctly, and are properly handled (i.e. refrigerated). We applaud Congress for including funding for nursing workforce development programs in the American Recovery and Reinvestment Act of 2009; however, additional investments are needed to reduce the serious public health nursing shortage in our state, territorial, and local health departments.

We cannot be complacent. We cannot let our guard down. We must redouble our investment in the nation's public health system. Protecting America's health and effectively responding to emergencies, whether pandemics or terrorist attacks, requires sustained commitment and financial support.

STATEMENT BEFORE THE AD HOC SUBCOMMITTEE ON STATE, LOCAL, AND PRIVATE SECTOR PREPAREDNESS AND INTEGRATION
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
JUNE 3, 2009
STEPHEN M. OSTROFF, MD

Mr. Chairman and members of the subcommittee, let me express my thanks for the opportunity to take part in this hearing, and for your taking the time to discuss state and local preparedness for public health emergencies like the recently identified novel influenza virus. I am Dr. Stephen Ostroff, Director of the Bureau of Epidemiology and Acting Physician General of the Pennsylvania Department of Health. I am here representing not only public health practitioners throughout Pennsylvania, but also epidemiologists nationwide in my capacity as one of the officers of the Council of State & Territorial Epidemiologists (CSTE).

I've actually testified to Congress once before on influenza. The last time was before the Senate Select Committee on Aging and occurred a few years back prior to my retirement from the Centers for Disease Control and Prevention. The topic of that hearing was protecting the elderly from flu and the focus was to encourage seniors to be vaccinated. Of note, one of the other witnesses at that hearing was the CEO of one of the two major flu vaccine producers. He too touted vaccination. Less than a week later, his product was withdrawn from the market due to production lapses, abruptly eliminating half of that year's vaccine supply and plunging our public health system into turmoil.

I tell this story not to reminisce, but as a cogent reminder of the unpredictability and volatility of influenza. Uncertainty arises not only from the virus and the disease it causes, but also from the availability and utilization of our prevention and control tools, including vaccines and antivirals. Just this past flu season the predominant circulating strain became resistant to the major antiviral in our pharmaceutical stockpile. There are few other diseases that we deal with in public health that are so challenging to predict, that so often prove us wrong, and have such profound health consequences.

Our current situation is a great example. As you know, for the last several years we've all been focused on the evolving circumstances of bird flu in the other hemisphere, and rightly so. We've been watching closely because H5N1 is a new and dangerous virus, it causes human disease with fatality rates in excess of 60 per cent, and it has tremendous agricultural implications. Over the last few years the experts have virtually all predicted that it's the next pandemic strain. And it still may be. As a result, we've built many of our flu plans and exercises around the threat of avian influenza.

And then right in our own backyard, literally at our doorstep, a new flu strain sweeps out of nowhere and upsets many of our basic planning assumptions, including the possibility it would first be detected in animals, how long it would take to get to our shores once it appeared elsewhere, what type of disease to watch for, and how best to implement control measures such as quarantine and travel restrictions.

Like our public health colleagues throughout the country, we in Pennsylvania have been responding to the evolving situation with the novel influenza virus and adapting our planning and response to what we see. When the new flu virus was first identified only eight short weeks ago, we quickly established mechanisms to monitor and respond to this new public health threat. We've been doing so with an array of partners, including those at the federal level (primarily the CDC), with our local public health agencies, with our state emergency management structures, with other state agencies such as agriculture and education, with professional societies, with health care practitioners, with academic partners, and with the private sector. Our state is blessed with a number of strong academic centers that have been heavily engaged in pandemic modeling and viral studies. We also have in Pennsylvania one of the major flu vaccine producers and the headquarters of one of the companies making influenza antiviral medication.

While much of our response was built into our pandemic planning framework, we have had to adapt the plans based on the specific circumstances and the perceived threat. In Pennsylvania we immediately set up a Department of Health task force consisting of our

epidemiology unit, the state public health lab, the unit that operates our district and local health departments, our public health preparedness unit, emergency medical services unit, health care facility regulatory unit, and offices of communications, informatics, and legal counsel. Within my bureau, the Bureau of Epidemiology, we've had an ongoing working group with teams specifically devoted to disease surveillance, field investigations, responding to clinical inquiries and public inquiries, producing guidelines and recommendations, handling infection control issues, community mitigation strategies, and laboratory liaison. Right now the epidemiology team meets daily and the departmental task force meets several times per week. For this response our departmental emergency operations center was partially activated to coordinate activities, update the web site, prepare situation reports and other information, triage inquiries, and handle issues related to our strategic stockpile.

Within state government, our emergency management agency organized a statewide task force consisting of relevant state agencies and the local and regional emergency management agencies. The Department of Health actively participated on this task force to share information and assure adequate dialogue.

The Department of Health organized conference calls and briefings with major medical societies in the state (e.g. Pennsylvania Medical Society, pediatricians, hospital association, etc) to share information and answer questions. Briefings were also held for our legislature, repeated press events were held, and we participated in radio and TV call-in programs. These activities were led by our Secretary of Health and Director of Emergency Management. CDC's recommendations were tailored to our state and local circumstances and disseminated using the statewide Health Alert Network of over 3,000 users, plans were established for distribution of material from the stockpile, and specific communications were developed for the Department of Education regarding school monitoring and closures.

Crucial for us was the establishment of daily group calls with our local health departments, who function as our eyes and ears on the front line. As a state with large

relatively autonomous health departments like those in Philadelphia and Pittsburgh, coordination is essential. These calls occurred every morning to share the latest numbers, address clusters and special situations, and answer questions and concerns. We have required daily reporting of suspected, probable, or confirmed illness from each local jurisdiction even if the number is zero, along with hospitalizations for pneumonia, and school absenteeism rates.

Speaking for all of our CSTE membership, we in Pennsylvania have greatly appreciated the leadership and support provided by CDC. They acted rapidly to produce guidance and recommendations, supported lab testing, coordinated national surveillance efforts, conducted special studies, and spearheaded communications to the public. As someone who was in a similar role while at CDC during events like SARS, West Nile, and anthrax, I fully appreciate the pressure to perform and the intense public and media scrutiny, especially since this has occurred during a time of transitional leadership. The states and locals may not necessarily agree with everything coming out of CDC, but we have had ample opportunity to provide feedback and share our opinions. These discussions are spirited and frank, but our federal partners have listened closely and adjusted strategies and tactics based on our feedback.

The novel flu strain came a bit later to Pennsylvania than other parts of the country. To date, we have confirmed more than 200 cases statewide, most of them in the southeast around Philadelphia, although our numbers are now increasing more rapidly than they did early on. Our disease patterns have been similar to the rest of the country in terms of demographics and severity. Unlike other parts of the country which have modified their surveillance strategies, in Pennsylvania we continue to do individual case investigations, and encourage lab testing in order to identify problem situations, trends in illness, and to watch the spread of the virus into still relatively unaffected areas of the state. So far, we've closed only one school in the state because of virus transmission among the children. We've also taken advantage of this unique situation by inviting CDC to study this episode to assess the patterns of transmission, how long the school children will shed the virus to inform national policies on school closure duration, and to assess the

economic and social impact of school closure. A CDC team has been onsite now for more than two weeks.

Counting cases of the novel influenza virus has been challenging for epidemiologists around the country. For seasonal flu, we do not count individual cases of diseases. The numbers are far too large, and there is no individual public health response for most cases. Flu surveillance is geared towards identify trends – namely when the disease is occurring, how severe it is, which groups are most affected, and which viruses are circulating. We only estimate the overall burden of disease through well established systems like sentinel physician networks, mortality reporting from a network of city vital statistics offices, weekly estimates of activity, and monitoring of lab results of flu testing. Efforts to identify and investigate all cases of the novel influenza virus were appropriate during the early stages of the outbreak, especially because individualized interventions were implemented for these cases. But many of the highly impacted states have transitioned away from individual case counting, and are only testing in special circumstances, such as severe disease or populations such as health care workers and pregnant women. Thus the national case counts are increasingly difficult to interpret and should be viewed with caution when assessing disease burden and trends, since different states are counting in different ways.

Many aspects of our response have gone well. We believe our extensive pandemic planning efforts have helped to guide our response. Aspects that have gone well include risk communications, surveillance and reporting, statewide coordination, and clinical case management.

However, there have been challenges. This outbreak has happened at a difficult time. Like most other states, Pennsylvania has significant budgetary challenges, and our public health system is equally affected and stressed. We've been affected by hiring freezes which have left minimal bench strength and have been relying heavily on a small number of critical personnel, especially to conduct field investigations and laboratory testing. Many other public health priorities, including routine investigations and surveillance

activities, have been shortchanged to reposition staff to respond to novel influenza virus. Laboratory bottlenecks rapidly developed when specimens were being sent to CDC for confirmation. Even now our lab struggles to keep pace with the testing workload. These stresses have surfaced in the absence of substantial amounts of disease likely to be seen during a pandemic. We have not had to deploy stockpile elements, deal with large numbers of illnesses overwhelming our health care system, or worker absenteeism anticipated during a pandemic,

No one can predict what will happen in the coming months with this new virus and whether any of the above will need to be utilized. We in Pennsylvania, as in all states, are presuming that things will get worse before they get better. Either now or in the fall. This is a pattern seen in previous pandemics. The best case scenario more people will get sick but the severity will not change. However, there's nothing to say the virus won't evolve, become more virulent, or acquire antiviral resistance like the recent seasonal flu strain, rendering our stockpiles of antiviral agents useless. We must also plan for options for vaccine and antiviral distribution and administration.

To do so, we are currently embarking on a formal evaluation of our recent performance in order to inform our planning for later this year. We will clearly need to enhance our laboratory capacity and better automate our surveillance activities. We also need to streamline our monitoring for hospitalizations and hospital utilization, improve our mortality reporting, and create better situational awareness. We believe this is achievable if adequate resources are available. Our position is that it is better to be over-prepared than under-prepared. In this regard, our preparedness funds have been helpful, but do not fully cover the needs for optimal influenza surveillance and diagnostics. Also, there was little role in the current situation for our emergency management partners, who stood by waiting for assignments and activities. However, in a full-fledged pandemic, they will be critical to a successful response. We do not want them to think that our planning efforts to date were misguided or unnecessary.

Influenza is generally considered the prototypic emerging infectious disease. But it is only one in a long and continuing line of public health problems. At present we are dealing with large-scale foodborne outbreaks, antibiotic resistant pathogens like MRSA, and reemerging vaccine preventable diseases like measles and pertussis. A few years ago it was vectorborne agents like West Nile and respiratory pathogens like SARS. These problems all fall to the same groups of epidemiologists and laboratorians on the frontlines at the state and local level. They highlight the need for a robust and flexible disease surveillance, investigation and response infrastructure, and the need to build and strengthen the public health workforce. Public health is primarily for and about people, not databases and computers. Our federal support in these areas has declined significantly in recent years and has not been replaced through categorical programs. Hopefully this will change. Especially because we have much to do right now and over the coming months to meet this new challenge.

Subcommittee on State, Local and Private Sector Preparedness and Integration
Hearing entitled:
"Pandemic Flu: Closing the Gaps"
June 3, 2009

Senator Mark Pryor
Questions for the Record

For Mr. John Thomasian, Director, Center for Best Practices, National Governors Association

1. **The Medical Reserve Corps (MRC) program, which is sponsored by the Office of the Surgeon General, in cooperation with the Department of Homeland Securities' Citizen Corps, consists of community based, locally organized volunteers who donate their time and expertise to prepare for and respond to emergencies, supplementing existing emergency and health resources. We briefly spoke about this at the hearing, and I'm hoping you can provide further details for the record.**
   - **Do your stakeholders find the MRC a useful resource?**
   - **Are there drawbacks or limitations with the MRC as presently constituted?**

   Medical Reserve Corps is an essential asset to the states for organizing specialized medical volunteers—such as doctors and nurses—for an emergency response. In addition, MRC organizes non-medical volunteers who can assist with logistics, public messaging, call centers, and even financial management and records keeping to facilitate reimbursement for response activities through the Stafford Act. MRCs also have been used as a stop-gap measure in local and state public health planning to compensate for funding shortfalls in public health departments and to augment the workforce during routine public health activities. They also have been used to staff call centers to handle excess demand during disease outbreaks. MRC's ability to organize and maintain certified, licensed medical volunteers for emergency situations remains a useful resource to the states.

   As presently constituted, MRC units are heavily relied upon in pandemic planning to provide an ancillary workforce to assist local and state government agencies in mass vaccination and prophylaxis planning. Some MRC programs have ensured that their volunteer base is independent and available to serve the MRC during an incident. However, many MRC volunteers are likely to be called into service at the primary hospitals where they are credentialed for medical practice or at other non-profit organizations where they have made commitments. In this sense, their value as a "force multiplier" may be limited during a pandemic, as few communities will be willing to part with those assets.

2. **Recommendation Number 13 in the Graham-Talent Commission Report suggested that the next administration should work with a consortium of state and local governments to develop a publicly available checklist of actions that each level of government should take to prevent or ameliorate the consequences of a biological incident, whether man-made or natural. The checklist should include adequate support for first responders and health units. Please provide suggestions for implementation of this recommendation.**

   The Governors Homeland Security Advisors Council, staffed by the NGA Center for Best Practices and comprised of the top homeland security official from each state and territory, provides a forum through which federal officials can work directly with the states on priority homeland

security policies and issues. The development of the "checklist" recommended in the Graham-Talent Commission report is the type of activity the governors envisioned when they formed the Council within the NGA Center for Best Practices in 2006. The National Homeland Security Consortium, managed by the National Emergency Management Association, provides another forum for engaging with the homeland security community at the state and local levels. Both organizations are appropriate forums for the administration to work through in the development of such a checklist.

Any "checklist" should focus on strategies for enhancing existing WMD terrorism-prevention activities rather than on areas where additional financial resources will be required.

3. **Do you have data or recommendations on identification of alternate acute care centers or hospitals? How should state and local health officials and health facility owners coordinate with the Department of Health and Human Services or the Department of Homeland Security for planning alternate sites if a community has not designated or prepared any?**

   State pandemic preparedness plans developed with guidance from the Centers for Disease Control and Prevention in many cases include annexes or chapters focused on the identification and establishment of alternative care facilities. The Agency for Healthcare Research and Quality has published an issue brief discussing various aspects of alternative approaches to providing mass care during pandemics or bioterrorism events, and this guidance has been incorporated by several state and local agencies. A number of other jurisdictions, however, have decided against the use of alternate care sites due to the difficulty of adequately staffing, supplying, and providing adequate medical care using appropriate infection control procedures in those settings.

   States or communities that have not yet designated alternative care facilities should do so according to the guidance provided by federal agencies, including HHS and DHS, and should be encouraged to reference models used by other states, including the Rocky Mountain Regional Care Model. They also should keep in mind that any ancillary or alternate care facility will require medical professionals and administrative personnel to provide staffing; this could affect the availability of Medical Reserve Corps volunteers or, conversely, contribute to the need for MRC teams in a given community. The sites will have to be adequately supplied during a time when inventories are likely to be low and supply chains likely to be stressed. In addition, ad hoc care facilities established in community centers, high-school gymnasiums or other non-traditional settings must address questions involving acceptable standards of care, liability, accreditation, insurance coverage, etc.

4. **Can you provide suggestions or best practices for enhancing the Department of Homeland Security's Office of Infrastructure Protection's Critical Infrastructure Coordinating Council (CICC) efforts to integrate the private sector into pandemic planning?**

   The individual sectors appear to be working independently through the CICCs to develop pandemic-related contingency and continuity plans and guidelines. We are unaware, however, of any multi-sector effort led by DHS or the Office of Infrastructure Protection (OIP) to develop cross-cutting guidance that would result in a consistent approach to workforce policies, interaction and coordination with federal and state agencies, and fuller integration of the private sector into pandemic planning and response. The DHS Office of Health Affairs is spearheading the department's pandemic preparedness activities and should be encouraged to

work closely with OIP to more fully integrate the private sector into plans and policy development.

We also recommend convening cross-sector working groups, perhaps under the auspices of the State, Local, Tribal and Territorial Government Coordinating Council, to facilitate cross-sector coordination and to enhance the integration of the private sector with plans and response at the state and local levels.

5. **The Government Accountability Office, the Association of State and Territorial Health Officials, and the National Governors Association (NGA) all mention the need to improve disease surveillance and information sharing among federal and state entities. On May 18, 2009, the NGA's Center for Best Practices held a roundtable discussion to identify best practices for sharing public health information with state fusion centers and the greater homeland security community. When it is completed, please provide a copy of the issue paper to the Subcommittee.**

   We will be happy to do so. The issue brief currently is being drafted. We expect to make it publicly available later this summer and will provide with an advanced copy.

6. **A February 2009 GAO report (GAO-09-334) recommends that the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) convene additional meetings of the states in the five federal influenza pandemic regions to help address gaps in their planning. DHS and HHS have indicated that no additional meetings are planned, although states must continuously update their plans and submit them for review. In 2007 and early 2008, NGA and the Association of State and Territorial Health Officials (ASTHO) held workshops to identify gaps and allow peers to work together before a real pandemic occurs. If requested by DHS and HHS, could NGA and ASTHO facilitate more workshops this summer before the fall/winter flu season occurs?**

   Yes. The NGA Center has proposed a series of activities, including workshops and workgroups, to the Department of Homeland Security. The activities are designed to enhance state pandemic preparedness in a number of areas, including continuity of operations planning, implementation of community mitigation strategies, and the development of effective public engagement programs. The NGA Center also is proposing to convene a national influenza conference this fall to provide an opportunity to share information and, if necessary, to "recalibrate" the nation's response to the H1N1 virus to reflect the data and information developed since the administration's July 9 Flu Summit.

   We currently are working with DHS to identify the resources that will allow us to more fully engage with the states in preparing for a resurgence of the H1N1 pandemic this fall.

7. **The National Governors Association has noted that states generally have less than adequate awareness of the status of disease outbreaks. The Department of Defense's Northern Command provides some disease modeling capability, and some states are using pilot disease surveillance and modeling systems. Are you aware of surveillance, modeling, and information sharing systems that could be used to enhance disease situational awareness? Please provide information relevant to these capabilities.**

State officials rely on a variety of reporting mechanisms from local and regional authorities to develop an accurate picture of the disease situation in their states, track the spread of the outbreak and optimize the use of scarce health and medical resources. Data contributing to an accurate situational awareness for public health incidents includes up-to-date information on the statewide inventory of pharmaceuticals; symptoms and syndromes reported by local public health agencies; the availability of staffed hospital beds in the state; and information on outbreaks and responses in neighboring states. State capabilities, however, vary in this area although several states are employing quite sophisticated systems.

The growing use of Geographical Information Systems (GIS) to map the locations of hospitals, pharmacies and other assets has immediate applications during a pandemic or other public health emergencies. Additional GIS information would contribute to an overall pandemic situational awareness could include the location of closed schools, data on the availability of food, gasoline and other essential goods and services, public safety (fire, police, EMT, etc.) personnel strength.
Alabama's well-known GIS-based situational awareness tool, known as "Virtual Alabama," allows users to load their own data to create "layers" of information on a shared, statewide mapping database The tool allows state officials to streamline the delivery of emergency medications to the public by allowing them to view, for example, the route of every highway, the site of every transportation choke point, and the location of every gas station between Strategic National Stockpile (SNS) shipment receipt and storage sites and local points of dispensing for emergency anti-viral medications.

North Carolina, meanwhile, develops its situational awareness through the "NC DETECT" program, which incorporates data from numerous sources to develop an overall picture based on unusual patterns of activity. Reporting at least daily, NC DETECT utilizes data from:

- Emergency room reporting of certain symptoms or illnesses;
- Poison control centers;
- EMS dispatch patterns;
- Wildlife; and
- Veterinarian data.

Each data pool reports pre-determined trigger symptoms to NC DETECT. Using algorithms developed by the CDC, the data is analyzed and alerts are made once the collective symptoms reach a threshold for concern. For example, poison control centers report not just on exposure to chemicals, but on "clinical" symptoms—the result of adverse effects of a medication, for example—that can include cardio, dermal, gastro-intestinal, fever, neurological, or respiratory ailments. A surge in any category, measured against other data points, might indicate an incident is occurring.

North Carolina also uses its situational awareness tool during the response phase. Poison control centers have been designated to be the principal information source for adverse reaction advice once antiviral medications are administered to the public. The state's Poison Control Center collects data on the adverse effects or ineffectiveness of the antivirals in the public, which can be used by decision makers to determine whether to continue distributing the medication.

Finally, **New Jersey** manages multiple public health and emergency management resources through "Hippocrates," the state's web-based situational awareness portal. *Hippocrates* is a

high-level knowledge management and information brokerage system that incorporates GIS layering technology to present an operational picture of state public health before, during, and after an incident. The system combines real-time data on the location of EMS crews, the availability of hospital beds, and medical supply inventories with other web-based data streams, including weather, traffic, and plume models. This information is shared throughout the emergency preparedness community to facilitate a more efficient and effective response.

More importantly, "Hippocrates" is used by agencies outside of public health, including the New Jersey State Police, the regional U.S. Department of Health and Human Services office, and external health associations, allowing the situational awareness developed by the public health sector to be incorporated into a regional situational awareness that can inform decision-making and incident command.
We anticipate that state surveillance capabilities will grow as electronic health information exchange is implemented in the next several years.

8. **Federal Executive Boards (FEB) were created by President Kennedy in a 1961 Directive, as a forum for communication and collaboration among federal agencies outside of Washington D.C. GAO report (GAO-09-334) recommends that federal coordinating mechanisms like the FEBs could be better utilized for incidents like a pandemic. The Homeland Security Committee discussed the FEBs in hearings held in September 2007 and June 2009. Further, Senator Voinovich and Senator Akaka are sponsoring a bill, S. 806 in the 111th Congress, to provide statutory standing and funding for the boards. How does NGA coordinate with the FEBs? Any recommendations for the FEBs?**

   The National Governors Association has not coordinated directly with the Federal Executive Boards. The boards operate at the local level and coordinate directly with state and local officials in their service regions.

   The NGA recognizes the value that the FEBs could provide in coordination, communication, and capacity building. We recommend that as the FEBs develop a more-formal emergency preparedness role they be engaged as a full partner in all state-federal planning and preparedness activities, including exercises. The number of federal agencies directly involved in emergency response or in providing support to state and local officials requires that roles and responsibilities be clearly defined and tested prior to an event. In particular, the FEB's role as it relates to the Principal Federal Official for each region must be clarified. Agencies at the state and local level are accustomed to working with specific agencies (FEMA, DOE, DOD, etc.). The role of the FEBs in relation to those specific agencies also must be made clear to avoid unnecessary confusion during an event.

9. **Are you aware of training facilities belonging to the federal government or volunteer organizations, such as the American Red Cross' Clara Barton Center for Domestic preparedness at Pine Bluff, which could be ramped up to train health care personnel/ volunteers in the event of a pandemic?**

   We are aware of a few federal facilities that provide pandemic specific training to the first responder community. They include FEMA's Emergency Management Institute in Emmitsburg, MD, which has a pandemic-related curriculum and DHS' Center for Domestic Preparedness in Anniston, AL, which offers a three-day pandemic preparedness course. Other federal agencies,

including CDC, offer training courses in pandemic preparedness, but are not "facilities" akin to the Pine Bluff Center.

10. **Please describe the actual and potential types of interaction, if any, that members of your organization have had with the Metropolitan Medical Response System (MMRS). Were any difficulties encountered during the past interactions?**

MMRS serves a coordination role among first responders, medical and mental health personnel, emergency management, business, public health, and volunteers. Their primary focus has been in response to incidents involving weapons of mass destruction; as a result, MMRS has not played an active *response* role in the communities it serves. However, MMRS does contribute to the development of plans, conducts training and exercises, and acquires pharmaceuticals and personal protective equipment for the regions it serves. Overall, the MMRS serves as a lifeline for communities to maintain response capabilities with existing resources in the first hours of an incident until outside resources can arrive.

MMRS also serves a vital training and exercise role to keep localities prepared not just for WMD, but for all hazards that can occur in a community. For example, MMRS is involved with planning and response programs for the Louisville Metro Jefferson County Crisis Group in Kentucky, and works with federal, regional, state and local response partners to execute FEMA, DHS and CDC sponsored exercises and training in that region.

We are unaware of any significant difficulties encountered by governors during past interactions with the MMRS.

11. **GAO's report (GAO-09-334) notes that although state and local jurisdictions will play crucial roles in preparing for and responding to a pandemic, they were not directly involved in developing the National Pandemic Strategy's National Pandemic Implementation Plan. Please identify the entities that you think should be included in an ongoing working relationship to develop further pandemic preparedness and response guidance.**

Pandemics, like most natural disasters, will be handled primarily at the local level with assets and resources flowing down from states, regions and the federal government as appropriate. As a result, agencies and organizations from the local and state levels and from the private sector should be engaged in developing preparedness and response guidance. A sampling of those groups includes:

- The Association of State and Territorial Health Officials
- The National Association of City and County Health Officials
- The US Conference of Mayors
- The National Governors Association
- The Governors Homeland Security Advisors Council
- The National League of Cities
- The National Congress of Parents and Teachers (National PTA)
- The National Emergency Management Association (NEMA)
- The National Homeland Security Consortium
- The U.S. Chamber of Commerce
- Business Executives for National Security (BENS)

- The International Association of Chiefs of Police
- The International Association of Fire Chiefs
- The National Sheriffs Association

Obviously, involving every group in the development of every guidance document is unreasonable. We recommend that the makeup of working groups should reflect the communities or interests affected by the guidance in question. For example, guidance on school closures should be developed cooperatively by public health and education organizations and officials with meaningful participation by parent and teacher organizations (the National Congress of Parents and Teachers), and state and local associations including the National Governors Association, the US Conference of Mayors, the National League of Cities, and others.

Subcommittee on State, Local and Private Sector Preparedness and Integration
Hearing entitled:
"Pandemic Flu: Closing the Gaps"
June 3, 2009

Senator John Ensign
Questions for the Record

For Dr. Paul Jarris, Executive Director; The Association of State and Territorial Health Officials

1. **What steps do you feel are necessary to manage a successful immunization campaign at the State level? Do you feel that the nation is prepared to manage such a campaign?**

   As stated in my testimony on June 3rd, the governmental public health system (federal, state, territorial, and local) is front and center as we prepare for, respond to, and recover from disease outbreaks, including pandemics. Managing a successful immunization campaign of the magnitude required by an influenza pandemic requires immense coordination, collaboration, and cooperation among all levels of government, the private sector, and the public. Since pandemic influenza funding was initially appropriated in 2005, states and territories have exercised their pandemic influenza operational plans as well as their mass vaccination plans. These exercises have served to develop public health personnel with roles, responsibilities, and procedures for vaccinating the population, and assist them in identifying gaps in plans. These plans are continuously revised and improved based on these exercises.

   The outbreak of H1N1, however, has forced public health officials to reassess these plans. Assumptions were that a novel influenza virus would appear first in animals and then in humans overseas, providing the United States with time to prepare for its arrival. However, the virus we are dealing with was first identified in North America. Federal, state, territorial, and local governments have collaborated to adapt planning and response activities to appropriately address the current epidemic. As we continue to work together to monitor and respond to ongoing infections and deaths, federal, state, territorial, and local governments are working feverishly to refine mass vaccination plans to best support the current and evolving circumstances.

   While we await the availability of an effective vaccine against the novel H1N1 virus, states are working with the federal government to prioritize initial shipments of vaccine and develop procedures for how best to distribute it. Hindering this process are two issues that I mentioned in my previous testimony: available funding and a reduced workforce. State, county and municipal budget shortfalls have resulted in the loss of over 11,000 public health workers in the past year, and additional job losses are expected during the remainder of this

year. Previous federal investments made possible the effective federal, state, territorial, and local response to H1N1 virus this spring. ASTHO thanks Congress for putting in place emergency supplemental funding for Novel H1N1 planning and response in FY2009. The Public Health Emergency Response (PHER) Cooperative Agreement funding, along with CDC's offer of direct assistance, will certainly prove helpful in preparing for the fall. The more recent Preparatory Phase Contingency Funds will help boost health departments' ability to have the resources they need to jump-start an immunization campaign.

A national vaccine campaign will be immense and require efforts never seen before. State public health departments are working with local governments, health care and the private sector so that there are people to provide the vaccine throughout the state, as well as developing massive educational campaigns to advise the public to receive both the H1N1 flu vaccine and the seasonal flu vaccine this year. Never before has the United States attempted to conduct a vaccination campaign on this scale, and many unknowns remain as we prepare for the fall, such as the number of doses required, the quantity of available vaccine and the extent of public demand for vaccination. As we work towards addressing the unknowns that we can control, and await the outcome of those we cannot, we must plan to maximally protect the public's health and our nation's infrastructure. Vaccinating the entire population will require a vast and competent workforce supported by robust operational capability.

The nature of a pandemic is such that we can expect a third wave to occur, even before we have seen the second wave subside. It is possible that the campaign will extend well into 2010. This means the nation should maintain the capabilities – workforce, vaccination sites, and resources – to continue vaccinating the public and keep them educated about the realities and uncertainties involved in pandemic planning. This requires dedicated funding for a long-term response.

State and territorial health departments have been diligent in their planning and preparedness activities. Public health has not followed the belief of *if* a pandemic will happen, but has been functioning on the premise of *when* a pandemic will happen. We are committed to working across all levels of government to better protect the public.

2. **There has been discussion about closing the border should the situation merit it. Have border state public health officials been given a voice in the decision on whether or not to close the border? Do you think that you should play a role in that decision?**

The Centers for Disease Control and Prevention convened regional meetings in May 2008 to discuss the Risk-Based Border Strategy approach. Issues raised at that time include but are not limited to:

- What are the responsibilities of state and local public health? Who is responsible for providing resources? Our understanding is that federal assets will be provided for

screening, and we recommend these protocols be in place before widespread transmission.

In the spring outbreak of H1N1, many state public health departments, in partnership with their governors, released statements advising the public on how to assess the prudence of previously scheduled trips out of state.

ASTHO has been actively involved in this issue with its members and the federal government, and convened a meeting in March 2008 to discuss the *Draft U.S. Aviation Entry Screening Concept of Operations* (CONOPS) for travelers during a severe influenza pandemic. ASTHO also assisted CDC in conducting five regional meetings on the Risk-Based Border Strategy, and updated state and territorial health officials on the results of all six meetings.

ASTHO functions as the collective voice for the public health officials of all 50 states, the District of Columbia, and six territories, and facilitates communications between those members and the federal government. Protecting the public from communicable diseases via border protection requires an integrated public health approach and states must be involved. ASTHO recently initiated a project with the CDC's Division of Global Migration and Quarantine to support state and territorial border control and quarantine planning for pandemic influenza to formulate guidance documents and address policy issues. ASTHO plans to continue assisting its members with this complex decision.

3. **During the outbreak, public health officials were called in to examine people that were flagged at border crossings or airports. Were the lines of authority clear between the Centers for Disease Control and Prevention (CDC) and the Department of Homeland Security (DHS)?**

DHS has primary authority in border protection; however, the Secretary of Health and Human Services has statutory authority, through CDC, for preventing the entrance of communicable diseases into the United States. CDC advises DHS personnel on how to identify passengers who may need to be quarantined. During the H1N1 response this spring, CDC briefed the public and released travel guidance on the CDC website. DHS provides status reports on border restrictions related to health issues on their website while also providing links to CDC's website. In preparation for the anticipated escalation of H1N1 this fall, CDC and DHS need to ensure that their roles are clearly defined in controlling influenza transmission at US borders and airports, as well as ensure that state public health roles and responsibilities are delineated. It is imperative that public health maintain its position as expert regarding health protection.

Subcommittee on State, Local and Private Sector Preparedness and Integration
Hearing entitled:
"Pandemic Flu: Closing the Gaps"
June 3, 2009

Senator Mark Pryor
Questions for the Record

For Dr. Stephen Ostroff, Director, Bureau of Epidemiology, Pennsylvania Department of Health

1. The Medical Reserve Corps (MRC) program, which is sponsored by the Office of the Surgeon General, in cooperation with the Department of Homeland Securities' Citizen Corps, consists of community based, locally organized volunteers who donate their time and expertise to prepare for and respond to emergencies, supplementing existing emergency and health resources. We briefly spoke about this at the hearing, and I'm hoping you can provide further details for the record.
   - Do your stakeholders find the MRC a useful resource?
   - Are there drawbacks or limitations with the MRC as presently constituted?

   Like most states, Pennsylvania finds the Medical Reserve Corps (MRC) to be a very valuable resource that can be drawn upon during federal, state, or local emergencies and disasters. The MRC provides important surge capacity, especially when services are disrupted or personnel displaced. However, the MRC is less likely to be useful during an infectious disease outbreak of the nature of pandemic influenza in the coming months. First, medical surge will likely be needed for a period of weeks to months, not days to weeks. Second, disease is likely to be widespread in many areas at the same time, making it less likely there will be an abundant supply of excess personnel able to be moved to areas of higher need. In addition, available practitioners will likely to be in high demand in their usual area and will not be able to drop other responsibilities to work through the MRCs.

2. Recommendation Number 13 in the Graham-Talent Commission Report suggested that the next administration should work with a consortium of state and local governments to develop a publicly available checklist of actions that each level of government should take to prevent or ameliorate the consequences of a biological incident, whether man-made or natural. The checklist should include adequate support for first responders and health units. Please provide suggestions on implementation for this recommendation.

   Every biological incident (whether man made or natural) is unique due to the agent involved, and the response must be tailored to those circumstances. However, there are clearly commonalities in the types of actions necessary to respond to a biological incident. These include the need for disease surveillance, field investigations, laboratory diagnostics, clinical support, infection control, community mitigation, decontamination, and communications. Under the National Incident Management System (NIMS) handbooks and checklists have been developed that help emergency responders organize their activities. It should be similarly possible to bring together public health and clinical personnel to develop standardized tools for biological incidents. Possibly this could be

done under the auspices of a federal advisory committee such as the National Biodefense Science Board.

3. Do you have data or recommendations on identification of alternate acute care centers or hospitals? How should local health officials and health facility owners coordinate with the Department of Health and Human Services or the Department of Homeland Security for planning alternate sites if a community has not designated or prepared any?

   Every community should include planning for alternate care sites should they be necessary during a public health emergency, either because their facilities are unavailable or there is a need for medical surge capacity. In Pennsylvania, every county has undertaken planning in this arena. And the state has obtained a number of portable field hospitals to function as backups. The optimal way to coordinate these activities with both DHHS and DHS is through existing mechanisms, such as the Hospital Preparedness Program operated through the Assistant Secretary for Preparedness and Emergency Response, which target funding for such purposes. This is far preferable to creating new mechanisms.

4. Can you provide suggestions or best practices for enhancing the Department of Homeland Security's Office of Infrastructure Protections' Critical Infrastructure Coordinating Councils' (i.e. Sector Councils and Government Councils) efforts to integrate the private sector into pandemic planning?

   The DHS Critical Infrastructure Partnership Advisory Councils appear to incorporate a wide array of stakeholders. In some instances these are individual private sector entities, but in many cases these are representative associations or organizations. Such associations are likely in the best position to assure their membership and interests are best represented, and I would encourage working with and through these associations to identify appropriate representation, either at the national level or through equivalent state entities.

5. The National Governors Association has noted that states generally have less than adequate awareness of the status of disease outbreaks. The Department of Defense's Northern Command provides some disease modeling capability, and some states are using pilot disease surveillance and modeling systems. Are you aware of surveillance, modeling, and information sharing systems that could be used to enhance disease situational awareness? Please provide information relevant to these capabilities.

   Most states have developed systems to conduct real-time disease surveillance, as required under preparedness funding provided to states through DHHS. In Pennsylvania, we use the RODS (real-time outbreak detection system) in collaboration with the University of Pittsburgh. This system collects data streams from a variety of settings to provide situational awareness of disease syndromes (including data on emergency department

visits, pharmacy data, etc). Such relatively non-specific information, when coupled to more specific disease reports and lab testing, provide a relatively comprehensive picture of the patterns of illness throughout the state. These systems have proven quite valuable in the current outbreaks related to pandemic influenza. Efforts are underway to make such syndromic systems even more comprehensive by incorporating other data streams or sources, especially with the advent of electronic health records. However, to be useful such sources would require validation and assure a reasonable signal to noise ratio so that state resources are not distracted chasing down high numbers of false signals produced by the data.

6. Federal Executive Boards (FEB) were created by President Kennedy in a 1961 Directive, as a forum for communication and collaboration among federal agencies outside of Washington D.C. GAO report (GAO-09-334) recommends that federal coordinating mechanisms like the FEBs could be better utilized for incidents like a pandemic. The Homeland Security Committee discussed the FEBs in hearings held in September 2007 and June 2009. Further, Senator Voinovich and Senator Akaka are sponsoring a bill, S. 806 in the 111th Congress, to provide statutory standing and funding for the boards. Do you have any experience with the FEBs? Any recommendations for the FEBs?

   Although I worked for a federal agency (the Centers for Disease Control and Prevention) not located in Washington DC for more than 20 years, and for two additional years for DHHS in Honolulu Hawaii, I have no direct or indirect experience with the Federal Executive Boards. I have also not interacted with them since arriving in Pennsylvania in 2007. However, improved coordination among federal agencies at the local or regional levels, strikes me as a very useful endeavor, since there are times they can act in less than coordinated fashion. My only recommendation is that they should coordinate their activities with state and local officials to be most effective.

7. Are you aware of training facilities belonging to the federal government or volunteer organizations, such as the American Red Cross' Clara Barton Center for Domestic preparedness at Pine Bluff, which could be ramped up to train health care personnel/ volunteers in the event of a pandemic?

   Ideally, training for pandemic influenza should be done locally. The skills needed to address illness during a pandemic are not especially different from routinely provided healthcare. There may be benefit to training volunteers and medical personnel on mass dispensing of medications or vaccines, but this could also be conducted through local exercises rather than at specific facilities.

8. Please describe the actual and potential types of interaction, if any, that members of your organization have had with the Metropolitan Medical Response System (MMRS). Were any

difficulties encountered during the past interactions? Did you include the MMRS in your Pennsylvania State-wide task force of public health and emergency response partners?

In Pennsylvania, both Pittsburgh and Philadelphia participate in the MMRS. MMRS resources have been used predominantly to bolster and support existing infrastructure, particularly related to the emergency medical response system and the hospital settings, as opposed to creating parallel or stand-alone systems. Therefore MMRS has not been directly represented in task forces and planning around pandemic influenza, but rather has participated through the supported partner organizations.

9. GAO's report (GAO-09-334) notes that although state and local jurisdictions will play crucial roles in preparing for and responding to a pandemic, they were not directly involved in developing the National Pandemic Strategy's National Pandemic Implementation Plan. Please identify the entities that you think should be included in an ongoing working relationship to develop further pandemic preparedness and response guidance.

Since any national plan must be implemented through state and local jurisdictions, they should play an integral role in the development and review of such plans to assure they can be appropriately executed. However, it is not possible to have all 50 states and/or 3000 local health departments individually participate in such planning efforts. Rather, planners should act through relevant stakeholder organizations to assure appropriate representation. In the public health arena, this would involve the Association of State and Territorial Health Officers, Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, and National Association of City and County Health Officers.

Subcommittee on State, Local and Private Sector Preparedness and Integration
Hearing entitled:
"Pandemic Flu: Closing the Gaps"
June 3, 2009

Senator John Ensign
Questions for the Record

For Dr. Stephen Ostroff, Director, Bureau of Epidemiology; Pennsylvania Department of Health

1. Approximately 36,000 people die as a result of seasonal influenza each year. At the start of flu season in the fall, you will not only have to monitor seasonal flu, but also potentially a more potent strain of H1N1. Can you discuss the challenges to monitoring two simultaneous outbreaks?

   The coming 2009-2010 influenza season will indeed be unusual and complicated. When the novel influenza strain was identified in April 2009, the winter influenza season was largely over. Initially, some disease caused by seasonal strains was identified, but since mid-May, virtually all confirmed illness has been caused by the new influenza virus. This has made it relatively easy to monitor the situation without overtaxing epidemiologic and laboratory resources. This will change in the fall when seasonal strains are likely to return. It will be important to know when and where the various strains are circulating, the age groups affected by each of the strains, and how severe is disease associated with each strain. The pandemic strain may continue to mainly affect younger age groups, while the seasonal strains may mostly affect the elderly. This is important not only to target prevention and control efforts (such as antiviral medications) but to evaluate the need for, and success of, prevention measures such as vaccine. Unfortunately, at the present time very few states have sufficient laboratory capacity to monitor virus strain types and antiviral resistance patterns. Such capacity will need to be developed in the coming months.

2. You mention the limited role of emergency management partners during the latest outbreak. What role do you see them playing?

   During the first wave of disease due to pandemic influenza, the role of emergency management partners was indeed limited. This is because disease was relatively mild, and there was no need to activate aspects of pandemic response such as medical surge, widespread distribution of antiviral medications, vaccination clinics, and large scale community mitigation. These are all areas where in most states the emergency response infrastructure will be vital to accomplish these activities. Should it be necessary to do any of these things in the fall and winter, emergency management would be a crucial partner. It is

important that they not be complacent about pandemic influenza based on their relative lack of involvement in the response last spring.

3. The World Health Organization (WHO) recently moved to Pandemic Phase 6 (indicating that a global pandemic is underway). There is some concern that these phases can be misleading, since they only represent the spread of the disease and not the strength of the disease. How do you feel the WHO scale impacts public perception of a pandemic?

   The WHO pandemic phases were indeed built on a model of severe disease and did not adequately consider a situation where a novel influenza strain emerges but does not produce especially severe disease. The WHO pandemic phase did not greatly influence planning or response efforts in the United States, but this is because disease appeared here early and was well entrenched at the time of the WHO designation. If the situation had been different and disease first appeared elsewhere, the designation would likely have influenced preparedness activities here. As WHO has already recognized, future pandemic phasing will incorporate additional factors when arriving at pandemic threat levels. However, even in the present situation, the WHO phase 6 designation did afford public health authorities another opportunity to educate the public about the importance of developing household self-reliance plans should more severe waves of disease occur in the coming months.

Anticipated Cost for Novel H1N1 Vaccine Administration

June 2, 2009

The Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the Association of Immunization Managers (AIM) calculate that the cost to state and local public health agencies for administering the novel H1N1 vaccine will be **$15 per dose, excluding the cost of vaccine and medical supplies.** Accordingly, the cost to vaccinate the entire U.S. population, assuming two doses per person, will be at least $9 billion.

Several sources were used to develop this calculation:

- Costs of past mass seasonal influenza vaccination clinics ranged from $10 to $25 per dose, according to data received from 11 diverse state health agencies.[1]
- Visiting Nurse Associations estimate their costs average $17 per vaccine dose, where they administer at least 5,000 vaccines.
- Medicare reimburses influenza vaccine administration costs at an average of $18.
- Private sector reimbursement for influenza vaccine administration costs averages $18 to $20

$15 per administered dose is a conservative figure for the true cost of administering the vaccine.

- Compensation for a private workforce is not fully accounted for in the $15 calculation. During an extended vaccine campaign, the majority of the vaccine clinic workforce will consist of private sector employees, including contract nurses, visiting nurses, and healthcare nurses. They will be hired under contract specifically for the campaign and reimbursed at the private market rate, which will also include overtime pay.
- Some efficiencies were assumed, making the number lower than the $18 Medicare reimbursement or the $18 to $20 private sector reimbursement. However, clinics would be held on weekends and evenings, resulting in increased operating costs. Additionally, many doses may not be administered in true "mass vaccination" settings. Other offsets include additional and necessary costs associated with traffic control, site and vaccine security, other clinical services such as mental health counseling, and public education services at publicly run mass vaccination clinics.
- The $15 calculation does not include the cost to purchase any medical supplies, although current plans are for the federal government to supply needles and syringes only. State and local health agencies will be required to purchase other necessary supplies such as alcohol swabs, bandages, and gloves.
- The $15 calculation also does not include the cost of tracking the vaccines administered, maintaining reminder/recall systems to ensure second doses are administered, or following up with individuals who experience an adverse event.

[1] State data was received from AK, CO, ID, MI, NC, NH, NY, OH, SC, TX, and WV.

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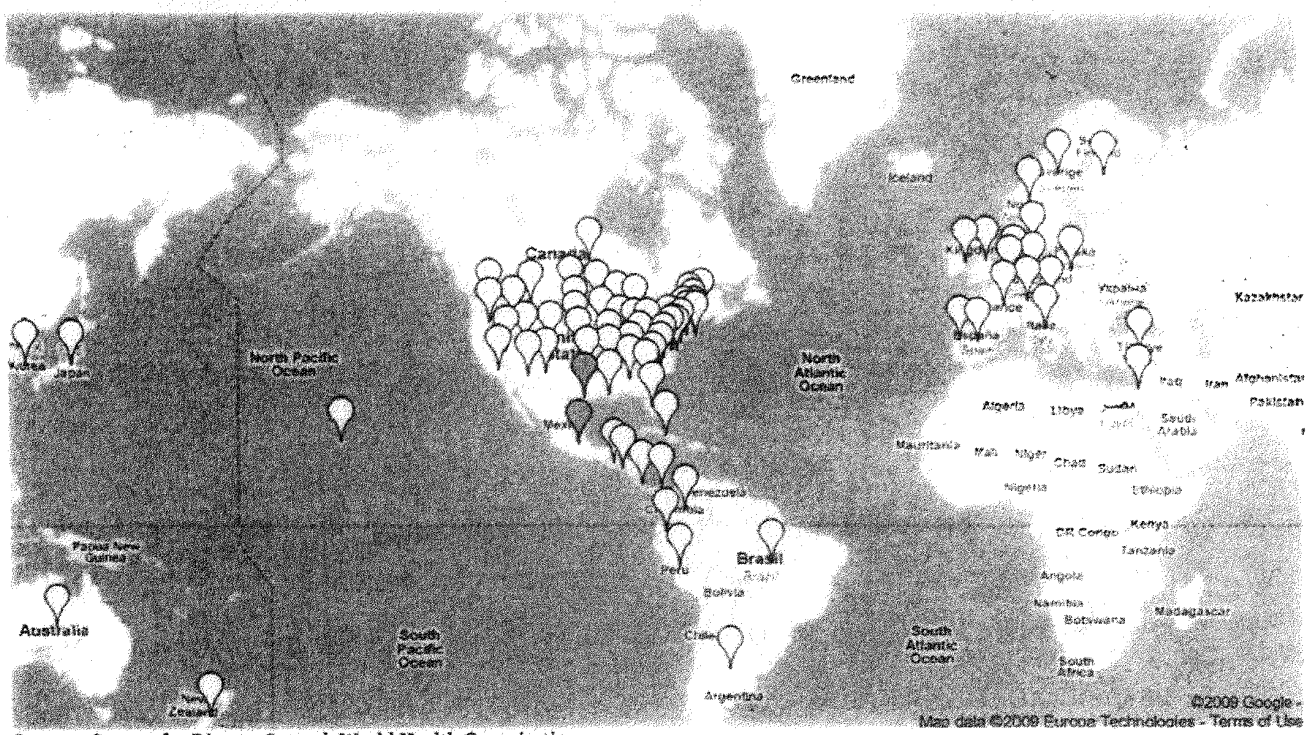
Confirmed Cases Of Swine Flu Across The Globe



Sources: Centers for Disease Control, World Health Organization