

PREPARING FOR PANDEMIC FLU

HEARING BEFORE THE SPECIAL COMMITTEE ON AGING UNITED STATES SENATE ONE HUNDRED NINTH CONGRESS

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PREPARING FOR PANDEMIC FLU

THURSDAY, MAY 25, 2006

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room SD-G50, Dirksen Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith, Kohl and Carper.

OPENING STATEMENT OF SENATOR GORDON SMITH, CHAIRMAN

The CHAIRMAN. Good morning, ladies and gentlemen. We welcome you to this hearing of the Senate Special Committee on Aging, and our hearing today is "Preparing for Pandemic Flu."

We have heard a great deal in the last several years about emergency planning and response. The tragedies of September 11 and Hurricanes Katrina and Rita showed us all just how vulnerable we can be to both man-made and natural disasters. Applying the lessons we learned from the past, we move forward with preparing to address the potential threats of tomorrow. While much may still be unknown about those threats, more and more indicators suggest that we may soon face a pandemic outbreak of a new influenza virus.

One does not have to look far back into history to see how devastating a severe pandemic flu can be to our society. In 1918, Spanish flu killed an estimated 2 percent of the world's population, mainly the young and the healthy. The milder Hong Kong flu outbreak in 1968 killed 34,000 in the U.S. alone, and caused between \$71 and \$166 billion in economic losses.

We have been fortunate not to experience a catastrophic flu outbreak for many decades, but the emergence of the highly aggressive avian flu virus in the late 1990's has generated a sense of urgency among the world's public health officials.

Just this week, a case of human-to-human transmission of the avian flu virus was reported in Indonesia. Reports such as these suggest that the next severe influenza outbreak could be looming on the horizon. In response to this threat, the United States has undertaken a significant effort to prepare for the next pandemic. Just recently, the Homeland Security Council released a lengthy pandemic influenza implementation plan. This report provides broad directives for all sectors of our society to follow in order to effectively prepare for the next flu outbreak.

I commend the efforts of the administration to put forward a comprehensive framework for pandemic flu preparedness, but it is clear we have much yet to do. Biotechnology and pharmaceutical companies continue to search for a safe and effective pandemic flu vaccine. Hospitals and other facilities are developing plans to ensure they have the necessary supplies and staff to handle a significant influx of patients.

As we move forward with this important work, it is essential that we keep the special needs of older Americans in mind. They may be more vulnerable to an infection due to preexisting health conditions or weakened immune systems. The more outreach we can do to the elderly in our communities before an outbreak occurs, the better protected they will be.

I hope we can use today's hearing to delve more deeply into what needs to be accomplished to safeguard all Americans from the harms of a pandemic, but especially those most vulnerable, such as the elderly, the disabled, the chronically ill and children.

I am very pleased to have my friend and our Secretary, Secretary Leavitt, with us here today, and I look forward to your testimony, Mike.

The witnesses we have assembled represent many of the key parties that will be involved in the initial response to a flu pandemic. If we have learned anything from the past, it is that all levels of public and private sectors must coordinate their efforts to successfully respond to an emergency.

While much is still unknown about the nature of the next influenza outbreak, we must press forward with implementing a comprehensive response effort. As Benjamin Franklin once said, an ounce of prevention is worth a pound of cure. That was true then and it still true, and it is certainly true as we look toward this horrible potential event.

In light of today's discussion of pandemic flu preparedness, I am pleased to join one of my Senate colleagues, Senator Evan Bayh of Indiana, in filing the All Hazards Public Health Emergency and Bioterrorism Preparedness and Response Act. This important legislation will help State and local communities better respond to the unique public health threats they might face, and creates new tools to encourage much-needed public health workforce development. I hope the Response Act will help guide Congress' discussion of how future public health planning and response efforts can better safeguard the health and well-being of our citizens.

So with that, I will turn to my friend and my colleague, Senator Kohl of Wisconsin.

OPENING STATEMENT OF SENATOR HERBERT KOHL

Senator KOHL. Thank you, Mr. Chairman, for holding this hearing.

Experts no longer ask if such a pandemic could occur. Rather, they question when it will occur. Earlier this month, the White House unveiled its plan for responding to a flu pandemic. This plan is a constructive first step with at least many serious questions unanswered, like which Federal agencies and officials will take the lead in responding to an outbreak emergency.

I am concerned that we are not prepared to care for the complex needs of our Nation's seniors, in particular. The elderly are among our most vulnerable members of society and they are far too often overlooked or even ignored in emergency preparedness plans.

Hurricane Katrina illustrated how we failed the seniors who need us most. Last week, we chaired a hearing in this Committee where we heard that 71 percent of those who died during Katrina were over the age of 60. We need to learn the lesson of those deaths and make sure that any strategy to prepare for pandemic flu incorporates the unique needs of seniors.

We need to do a better job in telling older people what supplies and plans they need to have in place in the event of a national emergency like pandemic flu. As a start, my office has developed a tip sheet, and HHS and DJS should follow with pamphlets, public announcements and specific direction for seniors and the agencies that serve them.

We also must direct States and local governments to include in all planning, training of first responders and practice exercises for national emergencies. Communities need plans to locate and help seniors who live at home if a flu pandemic occurs.

Federal, State and local governments are making progress in preparing for potential outbreak, but I believe we need to do more. Even if we are spared from a flu pandemic, the work that we do today will serve us all well in the event of any national emergency. We look forward to hearing from our panels today about the direction our Nation should follow and what it will take to deal with pandemic flu, including steps we must take to care for our seniors.

Again, Mr. Chairman, I thank you for this hearing and we look forward to hearing from our witnesses.

The CHAIRMAN. Mr. Secretary, thank you for being here, and your staff and others. We appreciate all that you and your Department have done. We have seen you a lot on TV, and you obviously know the subject well.

**STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY, U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASH-
INGTON, DC**

Secretary LEAVITT. Senator, thank you for holding the hearing. It is an important subject.

Pandemics happen. They are part of the biologic world. They are a biologic fact of life. They are part of the microbial world of viruses and bacteria that are constantly mutating, constantly finding ways to survive in more and more hosts.

The history of pandemics isn't so much the history of public health as it is humankind. As you pointed out, we have periodically throughout history had pandemics. You can go all the way back to the city of Athens in 430 B.C. and see the evidence of 25 percent of that great city's population being wiped out by a pandemic disease. It not only changed the city's health, but it changed their future. It affected their politics, it affected their prosperity. It changed the city in an irretrievable way.

That has been true almost entirely every century. We would see evidence of two or three of these. The 14th century may be the best-known—Black Death. Twenty-five million people across Europe died. Again, it did not just affect the health; it affected the culture and it affected the politics and the prosperity of that entire region.

You mentioned the fact that we have had 10 pandemics in the last 300 years. We have also had three of them in the last 100. You mentioned 1968 and 1957. They were what the scientists refer to as relatively small events by pandemic scale. They were highly efficient viruses; that is to say they spread quickly, but they were not particularly virulent. Not many people died.

1918 that you also referenced, on the other hand, was both efficient—it spread fast—and it was virulent. Lots of people died, and that, of course, is the type of event that we need to be prepared for. We hope and pray it will not occur, but that is the level at which we need to prepare.

We are today concerned properly, in my judgment. Scientists fear that the H5N1 virus that is spreading across the world on the backs of wild migratory birds could, in fact, be the spark of the next pandemic. No one knows with certainty, but the warning signs are there. We are seeing the capacity for this virus to jump the species barrier, clearly going from birds to people. We are also now seeing, and have throughout the history of this virus, very limited and highly inefficient transmission between people. You mentioned the circumstance in Indonesia. I am happy to respond during the questions if you would like to know more about that.

We are concerned not only because it is widespread; we are concerned because of its genetic similarity to the 1918 virus. It is clear by the course of events over the last several years that this is a aggressive killer once it gets into people, and so there is reason for us to be concerned. For that reason, the President has asked that we mobilize the country.

I have been moving throughout the country, having summits in every State, including Wisconsin and Oregon; in fact, almost every State now. Tomorrow, I will be in New Hampshire. It will be our 51st summit. We are doing summits in both the territories and in

the States. These have been rallying events. More than 20,000 public leaders from the health community, from local political leaders, from schools, from businesses have come for the purpose of being able to begin community planning.

It is part of a comprehensive plan. There is no single action that prepares a community for this kind of an event. It requires our working on vaccines, on anti-virals, developing stockpiles, on having community preparedness. At the very foundation of preparedness, however, is a prepared community. The fundamental message of our summits has been this, that any community that fails to prepare, with the expectation that the Federal Government or even the State government can get to every community and rescue them at the last moment, will be sadly and tragically, mistaken not because any of us lack a will or because we lack a sufficient wallet, but because there is no way that a government can get to 5,000 communities at the same time.

That is one of the peculiar and very important distinctions of a pandemic. It is highly local. It happens everywhere at the same time, but it is a highly local event. The truth is we are overdue for a pandemic.

The CHAIRMAN. Mike, to that point, could I ask you a question, because it really is what is on my mind? It is local. Obviously, even hurricanes are somewhat local, and 9/11 was local, but are there lessons from those response efforts that local communities are drawing lessons from that specifically related to the flu pandemic?

Secretary LEAVITT. Senator, in your statement you mentioned some of the disasters we have endured as a Nation. There are many lessons to be learned. One of the lessons is that you have to think about the unthinkable because it happens. Another important lesson in my mind is that what you do before an emergency is far more important than what happens after in terms of being able to prevent injury and damage.

But perhaps the most important will be the difference between a pandemic and any other natural disaster. Katrina was a devastating weather disaster. It covered Louisiana, Mississippi and a piece of Alabama, but at least it was constrained to that area. A pandemic would not be.

In Katrina, we had people literally come from all over the country to help. That could not occur in a pandemic because people would be in their hometowns looking after their families, their community, in a way that would prohibit it.

We also learned, I think, that most emergency events, if you will, like a hurricane or a bioterrorism event, are constrained as to time. The event occurs and then we move into recovery. That is not the case with a pandemic. It goes on for more than a year in waves. So life has to go on, so our preparation for a pandemic is different.

The CHAIRMAN. I am sorry to interrupt you.

Secretary LEAVITT. No, that is fine. I would just say that we are overdue, and we are not as well prepared as we need to be. We are better prepared today than we were yesterday. We will be better prepared tomorrow than we are today. It is a continuum of preparedness.

No one knows whether this current virus will be the spark of a pandemic. We do know that pandemics happen and that we need

to be better prepared. Everything we do on a pandemic helps us become a safer and a healthier community. Whether it is for a pandemic or whether it is a bioterrorism event, the preparation essentially is the same.

The CHAIRMAN. Does that conclude your testimony?

Secretary LEAVITT. That concludes my statement, yes.

The CHAIRMAN. Do you think local communities are taking this seriously? I know you are and I know the Department is because I have seen evidence of it everywhere on news shows and reporting that is going on. But is this just sort of, well, that is what happened in the bubonic plague era, not ours?

Secretary LEAVITT. Well, I think we are clearly moving from the buzz phase to the business phase. There are lots of communities, many companies, many schools and colleges and communities, and so forth, that are beginning to take action. Regrettably, there are those who haven't yet, and that is where we need to focus.

The thing about a pandemic and preparedness is that it requires everyone to prepare. This isn't just something we can delegate to our local government. Every business needs to have a plan. Every college needs a plan, every school needs a plan. Every day care center, every residential facility or long-term care facility for the elderly needs a plan. Every hospital needs a plan. Every family needs a plan. This is something on which there is a shared responsibility throughout society.

The CHAIRMAN. Isn't it true that where we have had these recent outbreaks in Indonesia just this week, and I believe Romania where there have been deaths, there is literally human handling of birds, specifically plucking the feathers, wringing the necks and eviscerating them in a very hand-held fashion?

Secretary LEAVITT. You are making an important point. I have said if you are a bird, it is a pandemic. If you are a human, it isn't. This is clearly a bird disease at this point. The worry is that it will mutate, and there are steps of progress that viruses make and one of those steps is to go from bird to human, and then the next step is to go from human to human, and the next step is to go from human to human in a sustained and efficient way.

We have done a very good job in this country of sensitizing people to the human-to-human worry. What we have not done as good job in is making certain that we underline the words "sustainable and efficient." We have seen human-to-human transmission in a very inefficient and highly unusual way.

We saw it in Hong Kong in 1997. We have seen it in Thailand last year, and now we have seen it, or at least there is some suspicion we may be seeing it in this case in Indonesia. In each of those cases, it can be found in an index case. The first case generally started with a bird. What we are finding in Indonesia is that there was, in fact, the index case of a woman who was, in fact, handling birds and became sick in a way very similar to that which others have.

The investigators have found that those who then later contracted it were in very close proximity to a severely ill woman, and they were sleeping in quarters that are described as essentially a closet. While it has not been demonstrated, the best hypothesis we have at this moment is that because of their intimate and close

contact with the highly sick patient, they may have, in fact, contracted it as well. There is nothing inconsistent about that over what we saw in Thailand or in Hong Kong in 1997.

We continue to watch that very closely. I am happy to report to you that we have some of the best scientists in the world on this subject who are literally on the scene and who are literally examining those people and doing the kind of investigation that needs to be done.

The CHAIRMAN. Mr. Secretary, it probably needs to be said as an assurance to the elderly who often tune in to this hearing that there is a reason why we haven't had these sporadic outbreaks in the United States, in Europe and the more Westernized parts of Asia, and that is that the eviscerating operations in this country run to very high sanitary and mechanized kinds of procedures. I suspect you have seen the turkey plants in Utah. I have seen the chicken ones in Arkansas. It is amazing. It is not a business I would want to be in, but it is very clean and sanitary.

Is it important to remind the American people what is being done to protect the fowl and the consumption of bird products in this country?

Secretary LEAVITT. It is. It is important not only to remember that, first of all, it is a bird disease, not a broadly based human disease. Second of all, we have not seen an H5N1-positive bird in the United States yet, and we have certainly not seen it in a human being.

It would not be a big surprise to us to see a wild bird with the virus on board, simply because they are wild and they fly through natural flyways all over the world. When that occurs, it will not be a crisis. It would not be a big surprise at some point to see it in a domestic flock, but your point is an important one. We manage those flocks with great care. The Department of Agriculture has seen these kinds of high-pathogenic viruses before. They know what to do.

Perhaps the final point that must be made is that poultry when properly cooked is safe. Cooking kills the virus, and there is not a reason for people to reduce, for example, their consumption of poultry out of worry because of avian influenza.

The CHAIRMAN. One of the other concerns I have, Mr. Secretary, really relates to where we are as a Nation in terms of vaccines. As you know better than anyone, we don't do many vaccines in this country anymore. We have literally litigated them abroad.

Secretary LEAVITT. Well, that may be among the most important problems that our preparedness has brought focus to. The good news is we believe there is the capacity to develop a vaccine that could provide an immune response to this virus. The bad news is we do not have the capacity domestically to produce a sufficient supply for every person in the United States to have a vaccine. That is part of what the President has put forward, an ambitious effort to change that.

Some of that is because the vaccine business has become a lousy business in our country. Over the last 25 years, most of the vaccine manufacturers have gone out of business or have discontinued that work. The Congress was, I think, insightful in appropriating \$3.3

billion. Two weeks ago, I spent \$1 billion of it on vaccine manufacturing technology research that is being done.

We have a plan that, within 3 to 5 years, we will change that. Our ambition is to have the capacity to not only isolate a virus, but then to be able to produce a sufficient supply of vaccines for every person within the United States who chooses to have one.

The CHAIRMAN. Within the United States?

Secretary LEAVITT. Within the United States.

The CHAIRMAN. That is an important thing to achieve, frankly, because if we actually had a pandemic and all the manufacturers in Europe have the same problem, they are not likely to want to send it here; they are going to use it there.

Secretary LEAVITT. That is an important insight and one that we acknowledge. Consequently, part of our criteria has been to assure that any new manufacturing capacity that we partner to develop is done domestically.

The CHAIRMAN. Senator Kohl.

Senator KOHL. Thank you.

Just to follow up a little bit more on that, Mr. Secretary, what sense of urgency is there to develop our capacity for this vaccine? You know, if it is coming on board 5 or 10 or 15 years from now, then we are just having a nice conversation today.

Secretary LEAVITT. When I first began focusing on this problem, it appeared that, first of all, there was no additional capacity coming online. Second of all, the plan to get to what is known as cell-based technology, which is the big hope in being able to manufacture it more quickly, appeared to be somewhere between 8 and 10 years away.

I have met with all of the manufacturing organizations, with NIH, with the scientists. The President has, as well, and we have asked them to help us find every way possible to accelerate the development of this technology, and for that reason we are partnering and the \$1 billion of contracts that I released on May 4 are a very good and important indication of that. The 3 to 5 years that I have spoken of is an ambitious, and I might say very aggressive approach, and will have substantially reduced the amount of time that it would have taken had we not taken that action.

Senator KOHL. If we have a pandemic this year or next year, is it fair to conclude that we will not have what we need to have by way of vaccinations?

Secretary LEAVITT. Let me go a step further than that, Senator. Pandemics, as I indicated in my opening statement, generally last about a year to a year-and-a-half, and they come in waves of between 6 and 8 weeks. It takes about 6 months from the time we have isolated the virus that caused the pandemic to create a safe vaccine and to manufacture it.

Best case: What that tells me, and I am sure you, is that during the first 6 months of a pandemic we will be without a vaccine no matter what. The business of creating vaccines is really about being able to have it for the second and the third wave.

What you have stated is correct. We would not have sufficient supply of vaccines for the first wave even after we have been able to develop this capacity because you really can't stockpile in large measure vaccines because the virus you are ultimately going to be

preparing the vaccine for may be substantially different than the one that you have been preparing for.

Now, we are stockpiling significant stockpiles of vaccines. We have 8 million doses of the best of an isolate we created in Vietnam. That would produce some level of immune response, but it would be far from perfect and we are basically working as we go. What that means is that when you start dealing with a pandemic, you have got to have a comprehensive approach, and we are working intensively right now to develop social distancing and public health tools that communities can use in order to limit or to contain viruses as they happen in their communities.

Senator KOHL. You said that local communities to a large extent will be on their own during a flu pandemic and shouldn't expect a great deal of help from the Federal Government. What assistance should State and local communities expect from the Federal Government in the event of a pandemic?

Secretary LEAVITT. Thank you, Senator. There is a very important role for the Federal Government and we are going to play it, but it is important to define it. An example of one of our roles is the international monitoring that we have just reflected with respect to Indonesia. We are building a network of laboratory capacity and having personnel on the ground all over the world so that if this begins to happen anywhere, we have a knowledge of it at the earliest possible moment.

That gives us the capacity to respond and prepare. It also would give us a head start or a jump start in the development of vaccines, for example. So international monitoring and national monitoring are a role that only the Federal Government can play, and we will play it.

Vaccine development—again, it would be unreasonable that any one community or a State, even, would develop a vaccine. Therefore, the Federal Government has taken responsibility for the development of vaccines, and we are making substantial progress and I have reported partially on that.

The third area would be in the development of stockpiles of antivirals and other matters. Now, I have been very careful and direct in telling the States that our stockpiles will be insufficient to cover every community, but at least it gives them a start on something that they can begin to build.

A fourth area in my mind is State and local preparedness. We have begun to create checklists and to hold exercises and to push hard for local communities to realize that they simply cannot ignore this and expect that the State government or the Federal Government overall will resolve it.

These checklists that I have—this is one on long-term care facilities, for example. You mentioned that in your statement. Those checklists and the exercises that we do reveal our weaknesses. We can never be afraid to see our weaknesses because that is how we get stronger, and that is one of the roles of the Federal Government.

Another role that we are playing is to work on how to communicate on this. This is a tough subject to deal with. The problem is anything you say in advance of a pandemic seems alarmist. On the other hand, everything you would do to get ready for it when

it starts is inadequate. So we are working to teach State and local governments and businesses and schools how to talk about this in ways that inform, but will not inflame, and ways that will help people to prepare, but not to panic. Those are all roles that the Federal Government can and must play, and we are doing everything possible to assure we do our responsibility well.

Senator KOHL. Earlier this week, the Washington Post reported on a study at Baylor College of Medicine that shows that people older than 65 may need as much as four times the standard level of flu vaccine for effective protection. Are you taking that into consideration as you build our stockpile of flu vaccine?

Secretary LEAVITT. That is a very important piece of information and we are taking that very seriously, and it gives me an opportunity really to talk about one of the side benefits of all of this pandemic preparedness.

We have had inadequate annual flu vaccine for many years now. Every year, we go through a period of are we going to have enough, are we not going to have enough. We have had a lot of producers offshore or out of the United States that have had problems and it is an ongoing problem that we have to solve.

One of the benefits of creating new vaccine manufacturing capacity is that we can take that annual flu vaccine problem off the table forever because we will have to keep our pandemic vaccine capacity warm, if you will, and the best way to use it will be to make annual flu vaccine. That would give us now an opportunity to say, rather than use a one-size-fits-all method of application for the annual flu, we can begin to say, well, perhaps we have got to look at seniors. Maybe they don't have a similar immune response, and if that is the case, we will now have flu vaccine that will allow us to provide it.

Senator KOHL. Thank you very much, Mr. Secretary.

The CHAIRMAN. Thank you, Mr. Secretary, for giving us insight for all the contingencies and make the preparations.

Secretary LEAVITT. Thank you, Senator.

[The prepared statement of Secretary Leavitt follows:]



**Testimony
Before the Special Committee on Aging
U.S. Senate**

Preparing for Pandemic Flu

Statement of

Michael O. Leavitt

Secretary

U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Thursday, May 25, 2006

Mr. Chairman and members of the Committee, I am honored to be here today to describe for you how the Department of Health and Human Services (HHS) is working to improve the nation's preparedness for a potential human influenza pandemic. Thank you for the invitation to testify on this issue, which is one of our highest priorities at HHS.

Strategy and Threat Assessment

On November 1, 2005, President Bush released the *National Strategy for Pandemic Influenza*, which outlines the roles of the Federal government and sets expectations for State, local, and tribal governments, private and international partners, and individual citizens in preparing for and responding to an influenza pandemic. The following day, I announced the *HHS Pandemic Influenza Plan*-a blueprint for all HHS pandemic influenza preparedness and response planning. The HHS Plan provides guidance to national, State, and local policy makers and health departments with the goal of achieving national readiness and the ability to respond quickly and effectively to a pandemic. The HHS plan also includes an outline of key HHS roles and responsibilities during a pandemic. In the event of a pandemic, under the National Response Plan, HHS will lead the public health and medical response with the Department of Homeland Security carrying out its responsibility for overall domestic incident management and Federal coordination. However, ultimately, the center of gravity for such a response will be at the state and local level.

As you know, the President requested \$7.1 billion in emergency funding for the *National Strategy for Pandemic Influenza*, of which \$6.7 billion was requested for HHS. Congress

appropriated \$3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, \$3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to becoming the first generation in history to be prepared for a possible pandemic.

We must also continue to prepare against a possible pandemic influenza outbreak. The President has proposed \$2.3 billion for the 2007 portion of the emergency funding request to fulfill the next phase of the Strategy. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including producing pandemic influenza vaccine for every American within six months of detection of sustained human-to-human transmission of bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness.

The President's FY 2007 budget also requests more than \$350 million for important ongoing pandemic influenza activities at HHS such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs, and diagnostics (NIH).

Pandemics are not new. There were three in the 20th century, the worst of which was the Spanish flu epidemic in 1918-1919 that is estimated to have killed over one half million people in the U.S. and 50 million worldwide. While we are focusing today on the impact of the H5N1 avian flu virus from a strain currently circulating in birds in many parts of Asia and Europe, many of the policy issues and preparedness measures that arise for this

strain of influenza apply as well to pandemics of other types of influenza, other emerging infectious disease outbreaks and public health emergencies. For example, pandemic preparedness offers tangible benefits in the fight against seasonal influenza which causes an average of 36,000 deaths each year in the United States.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus or the emergence of another influenza virus of pandemic potential. However, it is still useful to model possible scenarios based on analysis of past pandemics. In a report released in December 2005, the Congressional Budget Office presented the results of modeling a severe pandemic scenario similar to the 1918 Spanish flu outbreak and a more moderate outbreak resembling the flu pandemics of 1957 and 1968. In the severe scenario, roughly 90 million people become ill and 2 million die in the United States. The potential impact on the real Gross Domestic Product [GDP] is about a 5 percent reduction in the year following the outbreak. While there is substantial uncertainty associated with these estimates, they illustrate the enormous public health threat of an influenza pandemic and the need for effective access to vaccines, treatments, and a robust public health infrastructure to meet the challenge.

There are several important points to note about an influenza pandemic:

- A pandemic could occur anytime during the year and is unlikely to behave like a typical seasonal influenza. Rather, past pandemics have occurred in multiple "waves" of infection and could persist in the world for over a year.

- In the absence of effective vaccines and antivirals, the capacity to prevent or control transmission of the virus once it gains the ability to be efficiently transmitted from person to person will be limited.
- Right now, the H5N1 avian influenza strain that is circulating in Asia, the Middle East, Africa, and Europe among birds is a significant concern, but there is no way to know whether this virus will in fact lead to a human pandemic. Whether or not the H5N1 adapts itself to the human host, we know that influenza viruses are constantly evolving, and it is possible that this strain or another influenza virus, which could originate anywhere in the world, could cause the next pandemic. This uncertainty is one of the reasons why we need to maintain year-round surveillance of influenza viruses to be able to determine if there are genetic changes that may signal a potential pandemic, to develop reference viruses that can be used to develop pandemic vaccines, and to assess whether influenza viruses have developed resistance to antiviral drugs. As is the case with the H5N1 that is currently in birds around the world, pandemic influenza viruses often emerge in animals. Like other viruses, they tend to remain within a species. However, as we have seen already in the more than 200 documented cases of human infection of H5N1 confirmed by the World Health Organization, they do have the ability to infect humans who have been exposed to infected birds. Of greatest concern for human health is the question of whether the viruses will develop the ability to readily infect people and whether these viruses will be able to transmit efficiently from person to person as is the case with seasonal flu. For all of these reasons, it

is critical to maintain constant surveillance of viruses worldwide affecting animal populations and that can potentially be transmitted to humans.

- We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have been many changes in society since the "great influenza" of 1918, including dramatic changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes may have made us more vulnerable.

HHS Preparations for Pandemic Influenza

As you know, the President announced the *Implementation Plan for the National Strategy for Pandemic Influenza* on May 3, 2006. The purpose of this plan is to ensure that the efforts and resources of the Federal, State, local, and tribal governments and the private sector will be brought to bear in a coordinated manner against the pandemic threat. The *Implementation Plan for the National Strategy for Pandemic Influenza* confirms HHS' role as the lead federal agency for the public health and medical preparation and planning for and response to a pandemic.

The timing of the release of this Plan does not signal that a pandemic is imminent. The Plan is the result of much work in many Federal Departments and agencies to further prepare the government for a pandemic, whenever it might occur. It is important to note that the H5N1 avian influenza is a disease of birds, the virus has not yet appeared in the U.S., and there is no influenza pandemic in the world at this time.

HHS has already started to make progress on many of the tasks delineated in the plan.

The Department's key tasks outlined in the plan include:

- Building stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat;
- Expanding domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire U.S. population within 6 months of a pandemic declaration;
- Building stockpiles of antivirals adequate to treat 25% of the U.S. population, divided between Federal and State stockpiles;
- Building a Federal stockpile of 6 million antiviral treatment courses reserved for domestic containment efforts.
- Developing clear guidelines and decision criteria to assist State, local, and tribal governments, community service providers, and the private sector in defining groups that should receive priority access to existing limited supplies of vaccine and antiviral medications and other critical medical care, including a framework

to help maintain life-sustaining community-based services for frail and vulnerable older people in their homes.

- Working with State and tribal entities to develop and exercise influenza countermeasure distribution plans and to include the necessary logistical support of such plans, including security provisions.
- Establishing a strategy for deploying Federal medical providers from across the USG, including expanding and enhancing programs such as the Medical Reserve Corps and supporting the transformation of the Commissioned Corps of the Public Health Service.
- Creating plans to rapidly credential, organize, and incorporate volunteer health and medical providers as part of the medical response in areas that are facing workforce shortages.
- Supporting local and national efforts to:
 - establish “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories;
 - link hospital and acute care health information systems with local public health departments; and
 - advance the development of the analytical tools necessary to interpret and act upon these data streams in real time.
- Establishing a single interagency hub for infectious disease modeling efforts, and ensuring that this effort integrates related modeling efforts for transportation decisions, border interventions, economic impact, etc. HHS will also work to

ensure that this modeling can be used in real time as information about the characteristics of a pandemic virus and its impact become available.

- Providing guidance to all levels of government on a range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

Impact of a Pandemic Influenza on the Elderly

A severe 1918-like pandemic would have a profound effect on all segments of the population. Though risk groups for severe and fatal infections cannot be predicted with certainty, it is likely to include the elderly. For this reason, in 2005, two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) provided recommendations to the Department of Health and Human Services to prioritize elderly populations, particularly those with 1 or more influenza high-risk condition, for vaccine administration and antiviral drug use. As described in the National Strategy for Pandemic Influenza Implementation Plan released in May 2006, these recommendations will be reviewed and possibly revised.

HHS has advocated that states understand the needs of special populations, including the elderly, when devising and exercising their pandemic influenza plans. Through the Pandemic Influenza State Summits as well as through the CDC grant guidance to states

for pandemic flu dollars, HHS has urged states to consider and plan alternative care sites, such as home care. HHS has also asked states to take into account the special needs of the elderly when developing vaccine and antiviral distribution plans. Finally, it will be essential that local and state plans take into account how the chronic medical conditions of the elderly will be managed during a pandemic. HHS, through CMS, will work with the elderly to allow supplementary refills of medication during a pandemic, as it has done in prior health emergencies.

HHS is trying to promote individual preparedness within all segments of population, including the elderly. The Pandemic Flu Planning Checklist for Individuals and Families is relevant to the elderly in outlining how to plan for a pandemic, how to limit the spread of germs and prevent infection, and how to decide which items to have on hand for an extended stay at home.

Additionally, many older adults will be receiving home health services or long-term care. Consequently, HHS and CDC have published two checklists of particular importance to this population – a Home Health Care Services Pandemic Influenza Planning Checklist, and a Long –Term Care and Other Residential Facilities Pandemic Influenza Planning Checklist. Both checklists provide detailed suggestions on the structure for organizational planning decision making, and guidance for developing a written plan of action. Elements of a written plan of action address issues such as communication, surveillance, staff training, infection control, and planning for absences.

Current HHS Progress

In December 2005, Congress appropriated \$3.8 billion to help the Nation prepare for pandemic influenza preparedness activities. Of that total, Congress allocated \$3.3 billion to HHS for the first year of funding of the HHS Pandemic Influenza Plan. HHS will use these emergency funds to help achieve five primary objectives:

1. Monitoring disease spread to support rapid response;
2. Developing vaccines and vaccine production capacity;
3. Stockpiling antivirals and other countermeasures;
4. Coordinating Federal, State and local public health preparation and medical response; and
5. Enhancing outreach and communications planning.

HHS is working both domestically and internationally to monitor the spread of H5N1 and other possible pandemic viruses. HHS is spending \$125 million of its FY 06 allowance to promote international pandemic preparedness and planning and augment existing capabilities in areas such as international surveillance, epidemiological investigation, and diagnosis of illness. Through collaborations with the World Health Organization (WHO), the United Nations Food and Agriculture Organization, the World Organization for Animal Health, and numerous national governments, HHS is working to build capacity in other countries to detect outbreaks early and to contain the spread of the virus. Overall, HHS is supporting influenza activities in approximately 40 countries and has assigned influenza staff to the World Health Organization (WHO) Secretariat, Regional, and country offices in Europe and Southeast Asia.

On the domestic front, CDC is devoting \$50 million to strengthen local laboratory capacity and capability and \$35 million to accelerate the implementation of the national BioSense program to enhance our ability to detect an outbreak early. On January 1, 2006, BioSense RT (Real-Time) was launched in 10 select cities and 32 healthcare institutions across the country. Real-time transmission of existing clinical diagnostic and health information is being sent to CDC and analyzed. In April 2006, CDC launched a new data visualization and analysis tool for the use of all jurisdictional levels of public health (hospital, city, county, state, national). The BioSense implementation timeline is to link up to several hundred hospitals in over 30 cities by the end of 2006.

In the event of a pandemic, infection control practices and social distancing measures (such as school closures, cancellation of public gatherings, etc), and antiviral drugs will be the first line of defense before a vaccine is available and could limit and delay the spread of the pandemic. Currently, the Strategic National Stockpile (SNS) has over 5 million treatment courses of antiviral drugs on hand. On March 22, I announced the purchase of additional antiviral drugs that could be used in the event of a potential influenza pandemic. With these purchases, the SNS will have 26 million treatment courses of antiviral drugs that will be available to the States when an influenza pandemic is imminent. Our strategy is to procure an additional 24 million treatment courses of antiviral drugs through FY 07 and FY 08 funds and to offer a 25 percent federal subsidy for state purchase of another 31 million treatments courses. Thus, additional money will be needed to meet our goal to have enough antivirals for 25 percent of the population during a pandemic. Congressional support of \$2.3 billion for the second year of the President's Pandemic Influenza plan will be critical to meet this goal.

The cornerstone of the HHS Pandemic Influenza Plan is to create domestic manufacturing capacity sufficient to produce 300 million vaccine courses within 6 months of the onset of a pandemic outbreak, and to maintain a stockpile of pre-pandemic vaccine. We currently have approximately 4 million courses of pre-pandemic vaccine against a clade 1 H5N1 avian influenza strain. Plans and procedures are also underway to manufacture pre-pandemic vaccine against a clade 2 H5N1 avian influenza strain that is currently circulating the globe.

On May 4, 2006, I announced the award of \$1 billion for five contracts to support the development of advanced techniques using a new cell-based, rather than an egg-based, approach to producing influenza vaccines. We had previously awarded a five-year contract to Sanofi-Pasteur in FY 2005 for \$97 million to develop cell-based influenza vaccine technology and conduct clinical trials, so we now have six companies working under government contract to produce domestic cell-based pandemic vaccines. Using a cell culture approach to producing influenza vaccine is a promising technology and offers a number of benefits. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. In addition, cell culture-based influenza vaccines will help meet surge capacity needs in the event of a shortage or pandemic, since cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as the potential for egg supplies to be contaminated by various poultry-based diseases, including pandemic influenza strains.

Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently licensed vaccines.

A total of \$1.7 billion in FY 2006 funding is allocated for vaccine development to increase vaccine production capacity by accelerating cell-based manufacturing technology, increasing egg-based vaccine production capacity, and supporting the advanced development for antigen sparing technologies that could extend the vaccine supply by decreasing the amount of antigen needed to protect each individual.

Progress has also been made in the SNS purchase of medical supplies and equipment essential to pandemic readiness. HHS has purchased over 150 million N95 respirators and surgical masks with approximately \$50 million of FY06 funds. Other planned procurements include personal protective equipment (PPE), ventilators, IV antibiotics, and other medical supplies. Advanced development for rapid diagnostic tests also continues through the use of FY06 funds. A request for information (RFI) was issued for a point-of-care diagnostic on March 30, 2006 and a request for proposal (RFP) will be issued soon.

State and Local Preparedness

Pandemic influenza preparedness requires the active planning and participation of States and local communities. If a pandemic were to occur in the U.S., it would likely affect thousands of communities at the same time over the course of many weeks. The Federal

Government is working to provide guidance regarding how state, local, and tribal governments can develop pandemic preparedness plans and respond in the event of a pandemic. As part of the Administration's effort to enhance State and local pandemic preparedness, HHS has held pandemic influenza summits in 47 States and the District of Columbia so far. These summits have brought together State and local officials, public health, schools, businesses, and other stakeholders to discuss pandemic preparedness. With the FY 2006 emergency funding, HHS has awarded \$100 million of the \$350 million allocated for State preparedness for pandemic influenza preparedness planning activities. The remaining portion of these funds will be awarded based on benchmarks that will measure States' progress.

It is important to note that HHS funding to enhance State and local preparedness for public health emergencies, including pandemic influenza, has existed since 2001. Principally through CDC and HRSA funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting. Including the funding we have requested for FY07, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost \$8 billion.

To achieve a coordinated preparedness and response system for a pandemic, states, area agencies on aging and local administrators of aging programs will need to work together to develop plans that can help protect the safety and well-being of vulnerable older

individuals. HHS's Administration on Aging has issued a call to action to the network of national aging services organizations to seek to enhance coordination and accelerate preparedness for continuing community-based services to older adults in the event of a flu pandemic.

Communications and Outreach

Effective communications and outreach are essential to pandemic preparedness at the Federal, State and local levels. President Bush called for the development of a single, comprehensive web site to be the official Federal source of pandemic and avian influenza information. This web site, www.PandemicFlu.gov, includes a wide range of information on pandemic influenza and preparedness activities. In addition, HHS has developed a series of checklists intended to aid preparation for a pandemic in a coordinated and consistent manner across all segments of society. Thus far, ten checklists have been released and are aimed at State and local governments, the business community, the education sector, the health sector, community organizations, and individuals and families.

Conclusion

Thank you for the opportunity to share this information with you. Although much has been accomplished, continued vigilance and preparation are needed for us to be ready for a pandemic. I am happy to answer any questions at this time.

[Recess.]

The CHAIRMAN. Thank you for your patience, ladies and gentlemen.

Let me first begin with an introduction of our panel. We will first hear from Dr. Steve Cline. He is the Chief of Epidemiology for the State of North Carolina and he is overseeing the State's pandemic flu preparation efforts. He will discuss the work which States like North Carolina are beginning to undertake with the new pandemic influenza preparedness funding that Congress recently appropriated, specifically highlighting plans for outreach to the elderly community.

Then we will hear from Nancy Donegan. She is the director of Infection Control for the Washington Hospital Center. She is here today speaking on behalf of the American Hospital Association. The Washington Hospital Center was one of the primary facilities involved in the 2001 anthrax scare, so they have had firsthand experience in responding to a community-wide emergency event. Her facility has developed a communicable disease response plan and she will discuss the specific issues it addresses.

We appreciate your both being with us today. Shall we go ladies first?

STATEMENT OF NANCY DONEGAN, DIRECTOR OF INFECTION CONTROL, WASHINGTON HOSPITAL CENTER, WASHINGTON, DC; ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Ms. DONEGAN. Good morning. I am Nancy Donegan, the director of Infection Control at the Washington Hospital Center, a 900-bed, Level I trauma center which is part of the MedStar Health Corporation. On behalf of the American Hospital Association's 4,800 members, I appreciate this opportunity to appear before you today.

Pandemic influenza is one of many possible emergencies that hospitals face. Hospitals maintain all-hazards plans for responding to a range of events, from natural disasters, to terrorist attacks, to pandemic outbreaks. Today, my testimony will highlight three issues: the capacity demands of pandemic influenza, the pandemic plan at the Washington Hospital Center, and AHA's recommendations for the Federal Government's role related to hospital preparedness.

To prepare for emerging infectious diseases like avian influenza, hospitals must be ready to care for a large increase, or surge, in the numbers of acutely ill patients over a prolonged period of time. Surge capacity involves increasing hospital staffing and resources needed for patient care.

Hospitals can increase their patient care capacity for relatively short periods of time by surging in place; that is, rapidly discharging appropriate patients, canceling elective procedures and increasing the number of staff. While surging in place can temporarily increase patient capacity, most hospitals will be overwhelmed if an event involves large numbers of ill over a prolonged period of time, such as in a pandemic, as supplies and staff are depleted. At the same time, hospitals will need to continue providing routine acute care, such as treating traumatic injuries and attacks and delivering babies.

Over the last 5 years, hospitals receiving funds through the National Bioterrorism Hospital Preparedness Program have improved readiness. To date, hospitals have received about \$2 billion. However, there is still a significant gap in readiness. In a sustained disaster such as a pandemic, hospitals would rapidly face a shortage of personnel and critical supplies such as ventilators, gloves, masks, gowns and drugs. The New York Times has reported that the national supply of ventilators, which would be critical for caring for patients in an influenza pandemic, falls far short of the estimated need.

The Center for Biosecurity at the University of Pittsburgh Medical Center has estimated that the minimum cost of realistic readiness for a severe 1918-like pandemic are at least \$1 million for an average size hospital. We believe that to have adequately prepared hospitals, a portion of Federal pandemic funding should be directly applicable to hospitals.

The pandemic plan at the Washington Hospital Center follows the three pillars of the National Implementation Plan: one, preparedness and communication; two, surveillance and detection; three, response and containment. Our plan employs both high- and low-tech methods to communicate important just-in-time messages to staff and physicians. We have developed computerized and paper-based tools for reporting cases to the public health department and to hospital clinical areas.

During a pandemic, all entry points into the hospital will need to screen patients based on epidemiologic definitions provided by the CDC. Hospitals will also need to screen all workers on a regular basis during a pandemic episode. In our plan, we have detailed methods to have workers self-monitor and self-report symptoms of respiratory infection.

The best clinical response would include the use of effective vaccine or anti-viral therapy. Without effective vaccination, prophylaxis and therapy, infection control measures are the only strategies left to prevent transmission in the hospital.

Infection control measures rely on patient isolation and personal protective equipment, along with engineering controls. The hospital has designed ER One, the Nation's first all-risks-ready scalable emergency facility to handle mass-casualty events, including the ability to handle contagious patients.

The AHA supports the Federal Government's efforts to increase the stockpile of anti-viral drugs, increase research on non-egg vaccine production, and develop a prototype vaccine for avian influenza. In addition, an allocation plan for anti-viral drugs and vaccines must recognize the importance of hospital staff, physicians and emergency personnel.

In conclusion, the National Pandemic Influenza Implementation Plan states, preparation requires infrastructure and capacity, a process that can take years. Hospitals do not have the means to create infrastructure or capacity with current funding. If the Nation is to be protected, hospitals will look to the Federal Government for greater resources to meet the anticipated burden.

Mr. Chairman, thank you for the opportunity to testify. I look forward to answering any questions.

[The prepared statement of Ms. Donegan follows:]



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**Testimony
of the
American Hospital Association
before the
United States Senate
Special Committee on Aging
“Preparing for Pandemic Flu”**

May 25, 2006

Good morning. I am Nancy Donegan, director of Infection Control at the Washington Hospital Center for 22 years. I am a registered nurse with a master's degree in public health. On behalf of the American Hospital Association's 4,800 hospitals, health systems and other health care organization members, and our 33,000 individual members, we appreciate this opportunity to present our views on hospitals' preparations for a pandemic influenza.

The Washington Hospital Center is the largest hospital serving the Washington DC metropolitan area and is part of MedStar Health, a seven-hospital system in the Washington-Baltimore area. We are an acute care hospital, Level I trauma center with 900 beds and seven intensive care units.

As director of Infection Control, I oversee programs to reduce the risks of patients becoming infected as a consequence of medical treatments, personnel becoming infected with HIV and hepatitis infections while caring for patients, and preventing transmission of possible bioterrorism agents and pandemic agents such as the Coronavirus of SARS and the pandemic influenza. In addition, I have served on the District of Columbia's Bioterrorism Committee, the group that is currently writing the District's Pandemic Preparation Plan.



Public health officials across the world believe a new influenza pandemic will occur, but its timing is unknown. In other words, the question is "when" not "if" a pandemic will occur. Given the rise of avian flu in birds in numerous nations, public health leaders are rapidly preparing for a possible influenza pandemic. Pandemic influenza is but one of several possible disasters for which hospitals need an "all-hazards" preparedness plan.

America's hospitals are committed to providing quality care to the patients and communities they serve. Part of that commitment means continuing to provide every-day care for their communities as well as preparing for natural and man-made disasters and emergencies. Hospitals have long had disaster plans in place that have been carefully developed and tested. These plans are multi-purpose and flexible in nature because, as we have recently witnessed, the number of potential disaster scenarios is large. As a result, hospitals maintain "all-hazards" plans that provide the framework for responding to a range of events from conventional natural disasters to the threat of terrorist attacks to pandemic outbreaks natural and man-made disasters.

Our testimony will briefly discuss the capacity demands of a pandemic influenza; examine what's needed to make hospitals ready for a pandemic and how the lack of federal funding is hindering hospitals' preparedness. We also will discuss the pandemic plan at the Washington Hospital Center and outline the AHA's recommendations for the federal government's role.

Defining Surge Capacity – Contrasting a Pandemic with Other Emergencies

Because hospitals play a critical role in the event of a disaster, they must be able to accommodate the surge in demand for care in order to screen, stabilize and provide definitive care for affected persons. Traditional disaster planning has largely concentrated on "fixed occurrence" events, such as those created by transportation accidents or the terrorist attacks of September 11th in which there are a finite, and usually relatively small, number of victims requiring hospitalization. However, emerging infectious diseases; such as avian flu, require that hospitals be able to update their disaster plans to address prolonged periods of intense demand for services. Hospitals must plan to effectively extend their ability to deliver

uninterrupted medical care in the face of a prolonged event involving large numbers of victims, such as a pandemic disease.

Because of the dual nature of disasters – fixed versus prolonged events – hospitals and their communities must plan to create surge capacity for each of these two distinct types of events. Hospitals can increase their patient care capacity in relatively short periods of time by “surging in place.” This involves rapidly discharging existing patients, cancelling scheduled elective procedures, and taking steps to increase the number of patient care staff in the facility in order to make additional staffed hospital beds available for incoming disaster event patients. Immediately following the attack on the Pentagon, the Washington Hospital Center rapidly reduced its hospital census as we anticipated delivering care to hundreds of workers injured from that attack. And, the anthrax bioterrorism attack on the Hart Senate Office Building in 2001 caused a surge in demand for care in our institution. Many workers from the US Capitol and the Brentwood post office required screening and a large number required hospitalization and diagnostic work up to determine if they were infected with anthrax. We created an elaborate just in time clinic for patients, and educational program to reassure our worried workers.

While this type of strategy can provide a temporary ability to increase patient care capacity, most hospitals cannot sustain such a surge for extended periods of time. Individual facilities would quickly become overwhelmed if the disaster involved large numbers of victims presenting over a prolonged period of time. A pandemic is likely to impact the country for a period of several months to as long as 18 months, and to hit all parts of the country and other countries at the same time. We do not anticipate having the ability to call in health care workers and equipment from other locations as we can when a localized emergency, regardless of its size, hits.

Pandemic influenza would require the creation of “community surge capacity,” involving the development of alternative care facilities. This type of community surge capacity is complicated and costly to achieve and involves advance planning for logistical support, the development of protocols, and the determination of specific mission goals. Communities must

plan for this contingency using the advanced designation of facilities that can be used to accommodate patients, perhaps under more austere circumstances than would be faced in everyday medical care.

The U.S. National Strategy for Pandemic Influenza Implementation Plan anticipates that a pandemic will require a response that surpasses the ability of even the federal government, and that it will require responses from communities and businesses themselves. However states, localities and the private sector have limited resources and are struggling with their own financial barriers. The national plan also suggests that staffing for hospitals will be augmented by expansion of Medical Reserve Corps and the Commissioned Corps of the Public Health Service. However, it is unlikely that this effort would be adequate to meet the need faced by hospitals simultaneously in many locations. Additionally, the option is, at this point, unclear in magnitude and timing. Hospitals cannot reliably include this availability in their plans.

It is also important to note that in planning for surge demand for care due to a disaster, decision-makers must also consider the ongoing need to continue to deliver basic health care services. Hospital services will be required to maintain routine delivery of emergency care, such as delivering babies, dealing with traumatic injuries and sudden acute illness.

Are U.S. Hospitals Ready – Lack of Funding for Hospitals Is Hindering Readiness

To know where you are going you need to know where you are. Currently, federal funding for pandemic influenza preparedness has multiple streams, none of which lead directly to hospitals. Last year the President requested \$7.26 billion for pandemic influenza preparedness; however, P.L. 109-148, the *Department of Defense Appropriations Act of 2006*, provides \$3.8 billion for avian flu preparedness – \$3.46 billion below the President's request. Most of the funds, \$2.75 billion, are appropriately targeted to support core preparedness activities, such as expanding the domestic production capacity of influenza vaccine, developing and stockpiling of pandemic vaccine, stockpiling of antivirals and other supplies for the Strategic National Stockpile. These investments are critical; however, some, such as manufacturing and stockpiling antiviral agents and vaccine, come with the uncertainty of whether they will be accomplished in time for a pandemic or whether they will be effective in preventing and treating infections when needed.

Of the remaining funds, only \$350 million is intended for upgrading state and local response capacity, which encompasses pandemic response plans by state and local public health officials. **No amount is specifically targeted to improving hospital preparedness for pandemic influenza.** More recently, H.R. 4939, the *Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006*, which has been approved by the House of Representatives and Senate, includes an additional \$2.3 billion for pandemic preparedness, with \$300 million earmarked for upgrading state and local capacity. Once more, there is no direct allocation for hospitals' pandemic preparedness.

Emergency readiness requires a significant investment in hospital staff and resources. But the ability to meet these investment challenges is compromised by the significant financial pressures facing hospitals. Today, approximately a third of hospitals lose money on operations – with Medicare and Medicaid under-funding being a key driver. Another third of hospitals operate at or near the break-even point. This means that two out of three hospitals are not able to invest significantly in surge capacity. On top of under-funding by government payers, hospitals face other financial pressures: labor costs continue to rise as hospitals increase wages to attract scarce workers; the number of uninsured patients also continues to grow, contributing to greater levels of uncompensated care; and hospitals face skyrocketing costs for medical liability insurance, pharmaceuticals and clinical information systems.

A hospital's ability to deliver optimal medical care in the setting of any disaster event, regardless of its cause, is in large part contingent upon an immediate availability of key medical equipment, supplies and pharmaceuticals, as well as adequate staffing. However, due to financial pressures, hospitals have adopted just-in-time supply chains for their equipment and supplies. As a result, in sustained disaster such as a pandemic, hospitals would face an almost immediate shortage of critical supplies such as ventilators, personal protective equipment for staff, drugs and other supplies. In addition, most hospitals routinely operate at or near full capacity and have only limited ability to rapidly increase their workforce.

The funding provided to hospitals through the National Bioterrorism Hospital Preparedness Program (NBHPP), a program authorized by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, has been a good first step toward increasing the readiness of the nation's hospitals and their communities and developing improved strategies for dealing with all kinds of threats facing our communities. Preliminary estimates in 2002 suggested that hospitals would require approximately \$11 billion to obtain a basic level of "all hazard preparedness." Since then, Congress has appropriated about \$500 million per year for the program and the fiscal year 2007 request is \$487 million. This amounts to \$2.1 billion over five years, or about \$100,000 per hospital per year to fund preparedness. However, the amount that hospitals have actually received is significantly less due to dollars allotted for the federal government's administration of the program and overhead funds that the state grantees have retained.

The Center for Biosecurity at the University of Pittsburgh Medical Center, however, has estimated that the minimum costs of realistic readiness for a severe (1918-like) pandemic are at least \$1 million for the average size hospital (164 beds). The component costs to achieve minimal preparedness include:

- Develop specific pandemic plan -- \$200,000
- Staff education/training -- \$160,000
- Stockpile minimal personal protective equipment -- \$400,000
- Stockpile basic supplies -- \$240,000
- Total -- \$1 million per hospital

Using these estimates, the total for the nation's 5,000 general acute care hospitals for initial pandemic preparedness is about \$5 billion. The Center for Biosecurity estimates recurring annual costs to maintain preparedness to be approximately \$200,000 per year per hospital. These figures exclude stockpiling antivirals, since there is a separate national plan to acquire these drugs. In addition, this estimate does not include funds for the purchase of expensive equipment such as mechanical ventilators, since it is not clear that extra ventilators would be useful if there were no trained personnel to operate them.

To date, the federal hospital preparedness program has not provided the level of funding required to establish adequate "all-hazards" acute care surge capacity. As a result of the relative paucity of funding, only piecemeal solutions have been developed to address the problem of developing surge capacity. The amount of available funding for supplies and equipment has not been adequate to support the purchase and use of items of significant cost, such as ventilators, intravenous pumps, or cardiac monitoring equipment. For example, *The New York Times* recently reported that the national supply of ventilators, which would be critical for caring for patients in a pandemic influenza outbreak, falls far short of their estimated need, even considering the numbers that are being stockpiled by the federal government. The Center for Biosecurity estimates the cost to double the number of ventilators in the country, using safe but inexpensive equipment, is \$1 billion.

But again, the limiting step in surge capacity planning, namely the ability to recruit, retain and deploy staff to the bedside during any given crisis, including staff to manage a surge of patients on ventilators, has not been fully and comprehensively addressed, despite some progress in the development of systems to identify and register in advance health professionals willing to volunteer for service in a disaster. As noted above, national plans to augment hospital staffing by expansion of Medical Reserve Corps and the Public Health Service Commissioned Corps, while admirable, is unlikely to provide adequate staff to meet the need faced by many hospitals simultaneously experiencing patient surges across wide geographic areas. Additionally, since the Medical Reserve Corps and other advanced registration programs for volunteers often recruit their medical volunteers from hospital staff, it is unlikely that the volunteers' "home" hospitals would permit their staff to deploy elsewhere if there is an expectation that they would be needed in their own hospital.

Furthermore, planning and funding for medical surge capacity remain far behind the other elements of the nation's tactical response to creating a secure homeland. And given the very real concerns regarding an impending influenza pandemic, communities must focus on priorities for building such capacity that goes beyond the purchasing of beds, a metric which is too simplistic, and of little use, in creating the sort of capacity that is truly needed.

The U.S. National Strategy for Pandemic Influenza Implementation Plan states "preparedness requires infrastructure and capacity, a process that can take years." Hospitals do not have the means to create infrastructure or capacity with current funding.

The federal government must help protect the nation by providing greater resources to hospitals to meet the challenges of emergency readiness and ensuring that those resources are made available in a timely manner. In addition, given what Americans need from our nation's hospitals, today is a time for investment, not cutbacks.

Pandemic Planning at the Washington Hospital Center

At the Washington Hospital Center, we have developed a generalized plan to prepare us for any disease that can be transmitted through droplets or potentially via an airborne route and has epidemic or pandemic potential. We refer to these as Human Epidemic Respiratory Diseases, or "HERD" diseases.

The pandemic plan at the Washington Hospital Center is based on medical and scientific understanding of influenza and SARS and on logistical considerations learned from care of tuberculosis patients, and preparation for other outbreaks and possible bioterrorism-related events. It follows the three pillars of the National Implementation Plan: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment. Our plan encompasses educational programs, and pre-packaged sets of diagnostic tools and personal protective equipment.

Preparedness and Communication. The hospital has a committee of representatives from the hospital administration, emergency department, nursing, infectious diseases, infection control, pharmacy, respiratory therapy, materials management, security, public affairs, occupational health, human relations, laboratory, and others who meet regularly to assure our plan fits the most recent projections for possible outbreaks and is built on tools such as the modeling available through the Centers for Disease Control and Prevention (CDC) for likely impact.

Internally, communicating plans and disaster updates presents a challenge in a hospital. Because of round the clock coverage and staffing shortages, nurses and other personnel are seldom available for meetings. Many physicians are not employed by the hospital, have unpredictable schedules, and are not part of the hospital-based communication system. In our HERD plan, we use both high-tech methods with messages sent through various means to information groups, and low-tech messages delivered in small groups and postings such as at garage gates. A rapidly changing emergency represents a significant communication challenge.

Externally, the hospital has developed multiple reporting and communication systems with public health, and other health care providers in the region. All internal and external methods require practice drills and continued improvement methods.

Surveillance and Detection. The HERD plan uses patient screening concepts developed in the SARS preparation. During a pandemic, all entry points, including the Emergency Department, clinics, and admitting departments will need to screen patients based on epidemiologic definitions provided by the World Health Organization and CDC. Computerized and paper-based tools for reporting cases to the public health department and to the hospital clinical areas have been developed by the Washington Hospital Center, because no standardized methods for such surveillance currently exist.

Unlike other emergencies, contagious diseases put the medical workers themselves at risk. Workers and their families will be exposed and infected to the same degree as the public, and workers are likely to have increased risk of significant exposure from the care they provide to the ill.

Hospitals will need to screen all workers on a regular basis during a pandemic episode. In our HERD plan, we have detailed methods to have workers self monitor and self report symptoms of respiratory infection. As early preparation, we have used a self-assessment kit with a rapid flu test to ready our workers for this type of process during a pandemic.

In our HERD plan, we have created prepackaged laboratory kits to assure that in the early stages of a pandemic period, symptomatic patients are screened completely for likely infectious agents or for alternative causes. These kits provide instructions as pathways for emergency physicians, medical residents, respiratory therapists and laboratory workers.

Response and Containment. The hospital HERD plan establishes an incident command structure so that all responding departments know their roles and responsibilities. The best response would include the use of effective vaccine and/or therapy. Current plans address the likelihood that antiviral therapy will be available for prophylaxis and treatment. However, this assumption may prove invalid when the true nature of an influenza pandemic or pandemic from other microorganism becomes known. Especially in the absence of effective vaccination, prophylaxis and therapy, infection control measures are the only strategies left to prevent transmission in a hospital.

Patients with suspected or proven disease must be isolated to prevent transmission to other patients and personnel. The current HHS Pandemic Influenza Plan does not recommend airborne isolation because influenza viruses are primarily transmitted by droplets. However, in preparation for an unknown pandemic infectious agent or a known airborne infectious agent, we would need negative pressure isolation rooms. Such rooms require air to flow into the room. Rooms can be modified for use as temporary isolation rooms using HEPA filtered negative air machines. Isolation could require health care workers to wear, at minimum masks, gowns, gloves, and possibly a head covering.

The Washington Hospital Center's HERD plan, we have articulated exactly how to get an ample supply of the needed equipment. Equipment has been prepackaged to be rapidly delivered to areas of the hospital that will need it. From the Toronto SARS experience, we have learned that protective equipment would rapidly become contaminated and that we must set up systems to handle all aspects of equipment provision, removal, disinfection or destruction. These processes are complicated, and expensive. If, the current worst case scenario in which Avian Influenza H5N1 is the cause of a pandemic, that is, it becomes easily

transmitted from human to human, we could need to set up fail-safe systems to ensure that our workers did not become infected.

Anticipating an increase in the number of patients, the Washington Hospital Center HERD plan has used federal funding to double the number of negative pressure rooms available for patient isolation. We recognize that even with this increase in capacity, we would be unable to effectively isolate the number of patients anticipated in a pandemic involving an unknown pandemic infectious agent or a known airborne infectious agent.

ER One. The Washington Hospital Center's all-hazards planning extends beyond pandemic planning. With funding from the Office of Public Health Emergency Preparedness at the Department of Health and Human Services, we have created *ER One* – the nation's first all-risks-ready scalable emergency care facility of the future. *ER One* provides multi-fold surge capacity by building in design features to handle mass casualty events, and the *ER One* National Demonstration Project will be a national training facility providing testing, teaching, training and disseminating of surge capacity and emergency readiness best practices through the *ER One* Institute. I would be glad to provide the Committee further detail on this innovative effort.

The AHA's Recommendation for Pandemic Planning on a National Level

It is not clear at this time whether there will be treatment options for a pandemic illness and it is not clear whether a vaccine will be available. It also is not clear whether adequate supplies of antiviral medications will be available. The most optimistic scenario is that there will be adequate and effective vaccine available to vaccinate all workers and patients and adequate supplies of effective antiviral medications to care for those who are infected and exposed.

The AHA supports the federal government's efforts to increase the stockpile of antiviral drugs, increase research on non-egg vaccine production and develop a prototype vaccine for avian flu. In addition, an allocation plan for antiviral drugs and vaccines must recognize the importance of and provide priority access to these countermeasures for hospital staff, physicians, and emergency medical personnel. The government should become the sole purchaser of pandemic

influenza vaccine to assure adequate production and controlled distribution. The country also needs to increase the number and capacity of domestic vaccine manufacturers. Finally, Congress should provide liability coverage for researchers, manufacturers, providers and practitioners.

Without these assurances, we depend, as did caregivers during the SARS outbreak, on infection control behaviors. Outbreaks of influenza have been prevented or controlled through a set of well-established strategies that are clearly outlined in the Health and Human Services Pandemic Influenza Plan. These include early detection of influenza cases in a facility; isolation of infectious patients in private rooms or cohort units; use of appropriate barrier precautions during patient care, as recommended using Standard and Droplet Precautions (eye protection, masks, gowns, gloves); employing hand hygiene; and administrative measures such as restricting visitors, educating patients and staff, and cohorting health care workers assigned to an outbreak unit. In addition, supplemental precautions for health care workers, involving the use of special personal protective equipment, may be indicated during the performance of aerosol-generating procedures. Air systems need to have the capacity to provide negative airflow or filtered air, as needed.

Another difficult problem associated with the inadequate supply of vaccine, antiviral medications and other supplies and equipment necessary for treating persons with respiratory illnesses will occur if hospitals must set priorities for influenza vaccine, antiviral medications and other supplies needed for treatment. Traditionally, the elderly have been identified as the group with the greatest risk. Recent dialogue about this issue has suggested that with limited resources, there may be other approaches to resolving use of scarce resources. Hospitals will look to local, state and federal public health authorities, including the CDC, the Institute of Medicine and other groups, for guidance and consensus building to assist with these ethical complexities.

Conclusion

The recent experiences of the last several years and the information about pandemic influenza now available leads us to recognize our severe limitations in being able to assure our patients,

personnel and communities that we can provide the services needed at the time of a pandemic. We recognize that with our own resources, we will not be able to provide enough trained personnel, enough personal protective equipment, enough therapy, or enough ventilators, particularly in a pandemic involving prolonged periods of intense demand for services.

We believe that federal funding for pandemic preparation should be allocated that would be directly applicable to hospitals and would be safe guarded from being used for other worthy causes such as amplifying the public health infrastructure and amplifying short-term emergency preparedness operations.

Pandemic influenza is but one of the several possible disasters for which hospitals need an all-hazards preparedness plan. The AHA will continue to work with Congress and the Administration to forge ahead toward a shared goal of improving the overall preparedness of America's hospitals and communities.

The CHAIRMAN. Thank you, Nancy, and we will have questions. Steve, take it away.

STATEMENT OF J. STEVEN CLINE, DDS, MPH, CHIEF, EPIDEMIOLOGY SECTION, DIVISION OF PUBLIC HEALTH, NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, RALEIGH, NC

Dr. CLINE. Thank you, Mr. Chairman and distinguished members of the Senate Special Committee on Aging. I am honored to be testifying here today before you on behalf of public health and the 8.7 million citizens of North Carolina, 2.4 of whom are over the age of 50, representing 28 percent of our population. In the next couple of decades, we expect that to increase to 35 percent of the North Carolina population over the age of 50.

I am proud to be here. When I was explaining to my family that I was doing that, children have a way of keeping you humble. They said, why are you speaking to the Committee on Aging? Oh, Dad, it is because you are old. [Laughter.]

Preparing for and responding to an influenza pandemic will be a monumental task that will affect all of us, young and old. The National Influenza Response Plan and the National Influenza Implementation Plan you heard Secretary Leavitt speak of places much of the responsibility to appropriately planning, preparing, detecting and responding on our Nation's State and local health departments. Our citizens have expectations that we will get that right.

This sense of urgency is further heightened by the amount of media attention pandemic flu is getting. We see daily death counts of human cases of bird flu as they move from Southeast Asia across Europe, and certainly on its way to the U.S.

We have TV movies dramatizing fictional pandemics in this country, and newspaper stories almost daily, some saying we are not ready, some saying there is more transmission happening human-to-human, as in yesterday's article. Of course, as we have already alluded to, we all watched the devastation of Katrina on the Gulf Coast and wonder is our community ready for such a big disaster.

In my comments today, I would like to focus on three things: the progress that we have made in the area of preparedness; second, the challenges that we still face; and, third, how can Congress help keep us making progress.

First, in the area of accomplishments, let me say thank you to Congress for the substantial Federal investment you have made in public health preparedness. States like North Carolina have done much to get ready, and as Secretary Leavitt said, we are much better prepared today than we were yesterday and we hope we will be better prepared tomorrow. I will mention briefly just some of our accomplishments in North Carolina and would be happy to answer questions about them following the testimony.

As you heard, all emergencies start locally, so we have invested a substantial amount of money in our State in local public health preparedness in all 100 counties, in all 85 health departments serving those counties. We have built a health alert network system,

a secure system for notifying our key partners when an emergency occurs.

We have increased our capacity in our State Laboratory of Public Health, which will be a critical component to identifying, isolating and understanding the infection. We have built a hospital emergency department surveillance system that connects all 113 hospital emergency departments in North Carolina and reports every 12 hours to the State Health Department.

We have built public health regional strike teams and based them across the State so that they can respond wherever it emerges. We have built State medical assistance teams, which is a three-tiered system for scaling up medical surge capacity in our State. We have created public health epidemiologists in hospitals, borrowing from the concept of embedded journalists in the Iraq War, and put public health people inside hospitals, which has helped tremendously. We have also improved our interoperable communications, and training, training, training.

In the area specifically of pandemic flu response, we have a very robust plan in North Carolina, the North Carolina Pandemic Flu Response Plan, first written in October 2004 and revised substantially this year. We have a broad-based pandemic flu planning committee which makes sure we are taking into account all of the citizens of North Carolina. In particular, we have a special populations work group that can focus on the unique needs of elderly, disabled, home-bound and other minority groups, particularly those who have English as a second language. We are developing a tool kit building upon the checklists that our Federal Government has and making those specific to North Carolina.

There are challenges that are unique to being an older American and I would like to highlight just a couple of those. Older Americans, we have already acknowledged, are one of the fastest-growing segments of our population. They often have fragile health, which requires more services, not fewer. More services during a pandemic may create a problem.

We are worried about reaching the non-institutionalized older adults. How do we find them? How do we know they are safe? How do we know they are healthy? We are working closely with community-based organizations who often are best at reaching those people, but will they be available and able to help us during an emergency? We have heard some discussion this morning already about the annual flu vaccine and the importance of providing good annual flu vaccine to all Americans, particularly our elderly.

Where do we go from here? I have already mentioned the importance of funding. Sustained funding is the key component for us to continue making progress in preparedness.

The second is to improve our adult immunizations. We heard Secretary Leavitt speak about hopefully improving the vaccine production system. That is important, but it is also important to improve the demand for that vaccine. Our people need to show up for those vaccines. Only about 48 percent of adults in our State get the annual flu vaccine. Also, the infrastructure to provide those vaccines needs to be improved. Vaccine production, we have already heard about.

Communications is another important component. The communications are tricky in a normal day. In a crisis and in an emergency, they will be even trickier. We will need strong leadership and clear messages if we hope to reach the public with the important information that they are going to need.

In closing, I would like to say responding quickly and effectively to a pandemic flu will require extraordinary measures, in an atmosphere of fear, chaos and human tragedy. A strong, well-supported public health system is critical to saving lives and managing the crisis. The investments that have been made must continue if we expect to serve our citizens well.

Thank you. I would be happy to answer questions.

[The prepared statement of Dr. Cline follows:]

Testimony before the U.S. Senate Special Committee on Aging

Submitted for the Record

"North Carolina's Pandemic Influenza Response Planning With Regard to Older Americans"

J. Steven Cline, DDS, MPH
Chief, Epidemiology Section, Division of Public Health
North Carolina Department of Health and Human Services

May 25, 2006

Mr. Chairman and distinguished members of the Senate Special Committee on Aging, my name is Dr. Steve Cline. I am the Chief of the Epidemiology Section in the North Carolina Division of Public Health. I am honored to be testifying before you today on behalf of public health and the 8.7 million citizens of North Carolina, more than 2.4 million of whom are over the age of 50 representing 28% of the total population. By the year 2030 it is estimated that 35% of the state's population will be over 50 years of age.

I have devoted my career to public health, the first 13 years at the local level in North Carolina and the past 10 years at the state level. In my current job I oversee the state public health programs in communicable disease control, HIV/STD prevention and care, occupational and environmental epidemiology, the medical examiner system, the state laboratory of public health, and public health preparedness. I am the principal investigator for the federal grant programs from the Centers for Disease Control and Prevention (CDC) for bioterrorism and the Health Resources and Services Administration (HRSA) grant for hospital preparedness. Since the terrorist attacks of September 11, 2001, I have lead the state's public health efforts to build a stronger, better integrated, all-hazards emergency response system with our local, state, and federal partners.

Introduction

Preparing for and responding to an influenza pandemic is a monumental task that will touch every one of us, young and old, in some way. The National Influenza Pandemic Response Plan released in November of last year and the recently released National Implementation Plan, place the majority of the responsibility to appropriately prepare, plan, detect, and respond to a pandemic on state and local health departments. Our citizens are counting on us to get it right. The sense of urgency is only heightened by the media attention this threat is receiving. We have reports daily of the increases in the worldwide human death counts from avian flu as the disease gradually moves out of Southeast Asia into Europe and almost certainly our way. We have prime time television dramatization of a fictional pandemic flu disaster in this country. We have regular articles in our periodicals like the Associated Press story in USA Today on May 19th that quoted federal officials saying states are unprepared for bird flu. And of course we all witnessed the devastation and chaos following Hurricane Katrina in the gulf and wondered how well we would do if such a disaster struck our community. Its no surprise our public is concerned about pandemic flu. This is important work and it is important to do it now.

In my comments to you today, I'd like to focus on three things: 1) the progress we have made in preparing for emergencies like the pandemic flu, 2) the challenges we face protecting older Americans, and 3) the help we need from Congress to continue making progress.

1) Funding and Accomplishments

First let me say thank you for the substantial federal investment in public health preparedness that Congress has been making since 9/11. North Carolina, like most states, used these funds to strengthen our state and local public health system. Public health is critical to protecting health and responding to emergencies. North Carolina is no stranger to emergency response due in large part to our experience with natural disasters, hurricanes in particular. We take an all-hazards approach, which not only better prepares us for any type of emergency but helps us do better public health every day. Some of our major accomplishments since 9/11 include:

- **Local Health Department** funding for increased local public health preparedness capacity statewide.
- **Health Alert Network (HAN)**, a secure statewide system for alerting all 100 counties, 85 local health departments, law enforcement, emergency management, and other response partners.
- **State Laboratory of Public Health** expanded the main lab and built three regional labs to increase the capacity to work with select chemical and biologic agents as part of the National Laboratory Response Network.
- **NC Hospital Emergency Surveillance System (NCHESS)** – electronic reporting of clinical data from all hospital emergency departments at least daily.
- **Public Health Regional Surveillance Teams** – public health strike teams based across the state.
- **State Medical Assistance Teams** – a three-tiered system to provide medical surge capacity.
- **Public Health Epidemiologists in Hospitals** – public health epidemiologists embedded in the 10 largest hospital systems.
- **VIPER** – Interoperable communications system.
- **Training and Exercises** – developed and exercised numerous response plans.

Influenza Pandemic Response Planning

- North Carolina, again like most states, has developed and tested state and local pandemic flu response plans. The **North Carolina Pandemic Flu Response Plan** was completed in October 2004 and updated in January of this year.
- Established the **North Carolina Influenza Pandemic Planning Committee** with state and local, public and private, and multi-disciplinary representation to guide the response planning and funding priorities.
- Established the **Special Populations Workgroup** to make sure the North Carolina response plans address the unique needs of the elderly, disabled, homebound, and other minority groups including those for whom English is a second language.
- Developing a “toolkit” of educational materials and planning tools that are consistent with the federal planning checklists but customized for North Carolina to be used by

businesses, healthcare providers, educational organizations, faith communities, community based organizations, and individuals and their families.

- Created the **State Medical Asset Resource Tracking Tool (SMARTT)** which is an electronic database of all acute care hospitals in North Carolina that tracks bed availability and medical care capacity on a daily basis and more often as needed during an emergency.
- Established a registry of all licensed group homes and long term care facilities within the **North Carolina Multi-Hazard Threat Database** that maintains current contact information and geographic coordinates for each facility that can be mapped using a geographic information system.
- **Training and Exercises** - So far in 2006 alone we have conducted eight regional web-based tabletop exercises with our hospitals, health departments, and emergency management partners. We conducted two regional planning workshops. Even as I stand before you today, we are in the second day of a statewide fully functional pandemic flu field exercise.
- Established the **North Carolina Task Force on Ethics and Pandemic Influenza Planning** with broad representation from healthcare, ethicists, business, special populations, and citizens at large to discuss the tough ethical questions a pandemic will raise and make recommendations.
- North Carolina is the second largest poultry producer in the U.S. Together with public health, agriculture, and industry partners we created the **Avian Influenza/Human Health Task Force** to better understand the threat of avian flu and the impact it could have on human health.

2) Challenges for Older Americans

While much work has been done, clearly we have much more to do. Preparing for pandemic flu is not the same as preparing for a natural disaster. For example, in a hurricane we move people out of their homes and out of the path of danger into large group shelters. In a pandemic it is the opposite. We want to limit the opportunity for disease transmission between people and therefore limit mass gatherings. We will look to shelter in place. This and other aspects of a pandemic emergency pose unique challenges to older Americans.

- Older Americans is the fastest growing segment of the population.
- Elderly residents are more likely to have fragile health and often require in-home care and additional services to go about their daily lives. Due to absenteeism and/or fear of disease transmission, many of these businesses and services may not be available.
- How do we reach the non-institutionalized elderly? This population of older Americans may be living alone, are generally less mobile, and difficult to communicate with as a group.
- We work closely with local aging organizations such as the Area Agencies for the Aging (AAA), local chapters of the Red Cross, AARP, and other community groups. Can we rely on these mostly volunteer organizations to be there during an emergency?
- Less than half (48.9%) of adults 50 years and older get their annual flu vaccine. North Carolina reports more than 1000 deaths a year due to influenza. The elderly population is disproportionately affected by the annual flu due to their vulnerable health status. The immunity that results from the annual flu vaccine may offer some protection from a

pandemic flu virus. In addition, a well-vaccinated population could help us recognize the existence of a new potentially pandemic flu virus sooner. How can we increase the number of adults who get their annual flu vaccine each year?

3) Where do we go from here?

What can Congress do to assure we continue to make progress in public health preparedness and pandemic flu response planning?

- **Sustained Funding** – Public health needs a sustained and predictable stream of funding to build and maintain the systems and partnerships that are essential to an effective response. Public health preparedness funds to states have been reduced which will hinder progress. The \$100 million in the Pandemic Flu Supplemental Funding that went to state and local health departments to date is far less than adequate to protect our citizens. The current funding to states is one-time funds.
- **Improve Adult Immunizations** – The infrastructure and provider capacity is strong for childhood vaccines and therefore North Carolina, like most states, excels in getting children vaccinated. However the utilization and demand for adult vaccines is low and the capacity to provide them in our current healthcare system is lacking. We need to build strong innovative programs for adult vaccines that will improve adult vaccination rates and can be utilized during an emergency.
- **Vaccine Production** – We must continue to invest in ways to improve flu vaccine production. Both the science of vaccine manufacturing and the speed with which we can safely bring these new products to patients who need them are issues that must be resolved at the federal level.
- **Communications** – During a large scale pandemic, the availability of medications, medical supplies, and healthcare providers themselves may be severely limited. We will be forced to make hard choices about who and when patients get care. Strong leadership and clear messages will be essential to help our citizens understand how these decisions are being made and that they are being made fairly based on the best available information.

Closing

Responding quickly and effectively to a pandemic flu will require extraordinary measures in an atmosphere of fear, chaos, and human tragedy. A strong, well-supported public health system is critical to saving lives and managing the crisis. The investments that have been made in public health preparedness are clearly moving us in the right direction but they must continue and expand if we are to be as strong as we must be and as strong as our citizens deserve.

Thank you.

The CHAIRMAN. Thank you, Steve. Forty percent of adults or seniors show up for flu shots in North Carolina?

Dr. CLINE. No. Forty-eight percent in North Carolina get the annual flu vaccine.

The CHAIRMAN. What if the other 52 percent showed up? Would you have it?

Dr. CLINE. It is often an issue of timing and mal-distribution, not that we haven't had enough vaccine. We have had seasons when we did not have enough vaccine, but most recently the vaccine arrived late. People think about getting their vaccine in October, November, December. January and February, which is still part of the annual season—often, that is not on their mind anymore and they don't show up for those vaccines.

The CHAIRMAN. Is it for want of information, or is part of it some choose not to have it?

Dr. CLINE. I think some choose not to have it. I bet we have all heard of people who say I am worried the flu vaccine is going to give me the flu, which is false. Let me go on the record saying that.

The CHAIRMAN. That is why I asked the question. I want to get that out. It is false.

Dr. CLINE. But also I think people think if it is a vaccine toward the end of the season, it is not going to help them that season. That is also false. Flu can occur all year. In fact, we have flu all year, and whatever immunity you develop to that virus that year may help you, in fact, in any other flu virus attack.

The CHAIRMAN. Steve, since this is the Committee on Aging, what is your State, and what should other States be doing to have some coordination with nursing homes and assisted living or people living independently, but who are still needy?

Dr. CLINE. We have built something in our State called—the acronym is SMART, but it is the State Medical Assets Tracking System. What it does is allow us to know exactly how to contact every long-term facility, hospital, group home in our State that is licensed. We are able to put that in a geographic information system so we can map it. They are part of an electronic communications system so that we can easily communicate with them. Hopefully, working with them to develop their own facility plans, there will be a way for us to get good information to those residents.

The CHAIRMAN. You are getting information to them to have a plan in case of an epidemic?

Dr. CLINE. Yes. I would say probably the most important thing we are doing now, and I would suggest we should all be about, is engaging that group, that population, the facility employees, directors, staff, as well as the public.

Dr. CLINE. Do you also have a relationship with area agencies on aging and with faith-based organizations that have their own networks?

Dr. CLINE. We do. We work with them at the State level and their State representatives, but our real work is getting our local public health departments to work, and know those and build those relationships locally.

The CHAIRMAN. Well, that is very commendable.

Nancy, I wonder if Washington Hospital Center and other MedStar facilities have staff vaccination policies; in other words,

getting the people who are working there and taking them coming in—how do you keep them healthy?

Ms. DONEGAN. We do have a policy and we encourage flu vaccine very actively. It is not adequate that some of these biases and feelings that people have about flu vaccine have continued through time, despite, I would say, increasing campaigns to reach our health care workers to get a better vaccinated staff.

Recently, the guidelines for influenza for next year introduced a new issue that encourages us to have declination statements from health care workers who refuse the vaccine. Although it hasn't been implemented yet, I think it is a very good strategy as the bridge to probably some time when we will have mandatory vaccine for our workers.

We hope that when there is a face-to-face decision with some face-to-face counseling rather than posters and education campaigns that people will make that choice. We approach the campaign with a little bit of information focused on protecting the employee, but I think we focus more and have our greater success when we focus on the patients they are talking of and their obligation to not be a conduit to expose their most vulnerable patients, and probably most effectively that, being in the public exposure, we want them to protect their babies at home and their elderly at home. That seems to be our greatest take right now, now that it is voluntary.

The other thing that we are doing with that in preparation for pandemic flu is that we are trying to increase the dedication to vaccine that everyone in the hospital recognizes is their obligation, so that as we sometimes fall on a bad year, whether it is avian influenza or just a very bad non-avian influenza, we already will have the infrastructure; that this is a hospital where our workers get vaccinated. So the last couple of years, we are really trying to promote that with a much more aggressive stance.

The CHAIRMAN. You mentioned in your testimony the need for Federal dollars coming directly to hospitals for these preparations. That is not happening now?

Ms. DONEGAN. No. It seems as though most of the funding goes to public health and that we appeal to public health for distribution to hospitals, so that hospitals are really quite independent in their problem-solving, although they look to public health for reinforcement.

The CHAIRMAN. Are public health agencies not sympathetic to hospitals?

Dr. CLINE. I would like to answer that. She is correct. The HRSA funding for hospital preparedness comes to public health, and we think at least in our State that is a very good way to do it because we are actually able to work at a State level and coordinate all of the needs—hospitals, emergency medical services, homeland security grant dollars and public health dollars—and then apply it where it is appropriate.

The CHAIRMAN. But if you see the need, you are going to be there. She is saying the need is there, or at least it could be. Are you sensitive to that, Steve?

Dr. CLINE. Well, all of that money is going out to hospitals, correct, yes.

The CHAIRMAN. I know we are spending a lot of money. It just seems like there is never enough, but that is true in almost any category of the appropriations that goes on here. Senator Kohl is in charge of appropriations, so we will look to him to figure out how to get the right amounts.

The question I have, Nancy, is as to partnerships that Washington Hospital may have with other medical facilities in the area. Are there regulatory issues that are an impediment to using one another's backups or anything you need us to be aware of that we should—

Ms. DONEGAN. No. I think that the hospital community has worked together one institution with the other quite well through time. We refer to each other, we refer to each other's services, and many of our workers work in multiple institutions.

Clearly, after September 11 and after the anthrax attacks, that communication linkage became much more formalized. There are networks that are very formalized, and even some of the smallest threats that—you know, in this area, sometimes we have worries that will come up and we quickly go into a network kind of methodology where we have communication and reinforce that communication.

Our hospital, the Washington Hospital Center, is part of a corporation, so we have a linkage with the corporation that is very formalized, and then one that is somewhat formalized with other hospitals in the region so that we have sharing.

Our biggest problem, despite our sharing—our sharing is really more on the communication level, but in our area, and I think in many areas, we really have all of our beds full everyday. We have patients in our hallways. So the idea that we could take more patients from another location—we aren't able to do it, nor are we able to send our patients to another facility. They are full, too.

So the idea of surge capacity, I think, is limited. We have limited success in that, in that we can do sort of an immediate response. But once we have filled those beds and once we need to maintain an ever-increasing population of patients, we really max out and we run out of structure, and there isn't a sister institution that can pick up our burden. We really sort of max out through the system.

The CHAIRMAN. Just one last question. Are there any protocols existing between post-9/11 and Katrina from lessons learned there that would help all the medical facilities in this area? If there were actually someone who came down with avian flu here, is there a facility identified as the best one to take that individual, someone with a contagion of that nature?

Ms. DONEGAN. I don't know everyone's readiness. Our hospital does work very much to be able to stand behind the statement that we are all-risk-ready. Clearly, we have quite elaborate plans for a pandemic, and we had those plans beginning before 9/11. We clearly ramped them up after anthrax and the idea of bioterrorism, and I think our greatest educator so far has been SARS, especially what happened with Toronto and their experience. We really used that as our model for readiness.

So we would say we are very ready, but I suspect from talking to people in other hospitals that each hospital has amplified their readiness significantly. I don't know if it is to the same degree as

we have. Partly because of our location and partly because of our sort of unique make-up, I think we are really dedicated to this issue. But I think most hospitals have changed their point of view on this and have much more accelerated degrees of readiness than they had.

The CHAIRMAN. Well, I am not even suggesting that the policy implicit in my question is a good one. I don't know.

Steve, should there be a facility designated or not, or should each one be prepared to deal with it on their own?

Dr. CLINE. I think each one has to be prepared to deal with it on their own, and I think if we look at the smallpox experience when we were planning how we would deal with smallpox, no hospital wanted to stand up and say, OK, I will be the smallpox hospital. It really didn't make sense until you knew more about where it was emerging and how it was happening.

I think the best readiness is going to be to make sure each hospital has a plan and that all hospitals are talking to each other and public health, and we will make a good decision when that happens.

The CHAIRMAN. Senator Kohl.

Senator KOHL. It seems as though it would be a reasonable conclusion that, depending upon individuals such as yourselves all across this country, some communities are far more advanced in making preparations. Would it be reasonable to assume that other communities of equal size would be far less advanced? Because it is apparently being handled as a situation that needs to be dealt with on a State-to-State and local-to-local basis, would you estimate that to be the case?

Ms. DONEGAN. I would suspect there is some variability. For the most part, the efforts that you take in preparing for these, there are not special teams; no one gets hired to be the pandemic coordinator. The efforts come from taking busy people in busy jobs and sort of peeling off a new layer of responsibility. So I would imagine there is significant variability in the amount that different institutions have been able to do and that it is quite a task, but I don't know the measurement of that variability.

Dr. CLINE. I would agree there is not really a good measurement of it. North Carolina is an urban and rural State, so we have small communities that we know are not as well prepared as some other parts of the State. What we are doing to compensate for that is to build some regional capacity that we hope can move into that area if it happens and while we are still working trying to get every community ready.

Senator KOHL. In the event of a flu pandemic, isn't it essential that we have sufficient quantities of vaccination, without which most other preparations are going to be totally inadequate? Is that a fair conclusion?

Dr. CLINE. Well, I think we are preparing for the reality that for the first wave of the flu there will not be a vaccine that is highly effective. But after that, we are hoping that there will be a vaccine and there will be some control measures that our citizens have gotten used to. Vaccination is one of the marvels of modern medicine in terms of preventing disease. We certainly want to get there as fast as we can, but with the flu virus, which changes regularly, we

are going to have to wait until it emerges and then develop the vaccine.

Senator KOHL. How long does that take? In your judgment, how long will that take?

Dr. CLINE. Well, I think Secretary Leavitt said 6 months. I think the annual cycle is closer to 9 months for when they develop and can manufacture enough to get it out to all the providers. As you heard, they are making efforts to reduce that cycle to where it is a shorter time, and if we can move to the newer cellular technology—right now, they use eggs for developing that vaccine—we hope that will shorten that time.

Senator KOHL. Well, does this mean that if a flu pandemic breaks out, we are defenseless for several months?

Dr. CLINE. I will let you answer, but it does mean that infection control is going to be the important factor.

Senator KOHL. Is that right, Ms. Donegan?

Ms. DONEGAN. That is exactly right. The SARS experience really is our best model for teaching us not only that hospitals can put in good practices without therapy and without vaccine, but that infection control can work. However, infection control efforts are very difficult to maintain because they are behavior-based and they are barrier-based. In a complicated hospital setting where the technology and the acuity of the patients demands sort of a focus on patient care, some of the burden of using masks and goggles and gowns—it is very hard to have personnel do that with the reliability that they need to do to make this a fail-safe plan.

So with a vaccine, you can really protect the employee while they are doing their typical activities. Otherwise, you are left with this infection control behavior that is difficult and has an element to fatigue to it. The workers in Toronto needed quite a bit of reinforcement because of the fatigue factor from really doing infection control strategies completely. Clearly, as they do more work on a respiratory track—when they sort of do a more high-risk procedure, then we need to provide even more barrier for them to protect them during those procedures.

So those elements work, but they need reinforcement, they need a lot of equipment. They really need us to protect our employees for issues like the fatigue factor and that we have a good stream of material for them.

Dr. CLINE. I do think SARS was a success story for containment without treatments and vaccines in this country, but it was much smaller scale. North Carolina had one of only eight laboratory-confirmed cases of SARS in the United States. It involved three of our hospitals. At the time, we thought it was only being transmitted in the health care setting. So it was not in the community. Pandemic flu will be very different because it will be in the community and our public will be asking how do I protect myself and my family. Some of the extreme measures of mask and gown and barrier protection are not going to be available, or maybe not even effective in the community.

Senator KOHL. What do you imagine will happen if the flu pandemic breaks out and communities all across our country know that it is here and about, but we don't have a vaccine? What is

going to be the individual reactions of families and entire communities? You have probably thought about that. What do you think?

Dr. CLINE. We have thought about that and we have also asked our public what is their likely response. What we get is they will self-isolate. They will figure out how to take care of themselves and their family in their homes as much as possible for as long as possible to try to avoid being in a place that they are worried could transmit the flu.

Senator KOHL. Does that mean they won't go to work and won't send their kids to school, just go out maybe to buy essentials at the store and go back home?

Dr. CLINE. Exactly, exactly.

Senator KOHL. Is that what is likely to happen across our country?

Ms. DONEGAN. I think that is the view that we share, yes.

Senator KOHL. You can imagine a situation where the entire country virtually shuts down if it is a truly national pandemic, a flu pandemic, because there is no vaccination available and the hope is isolation so that you are not contaminated. The only way you can do that is by staying isolated, meaning you don't go to work and the kids don't go to school. All the meetings that are scheduled are called off. Is that right?

Ms. DONEGAN. I think so. I think the dim view is how much economic and social impact this will have by behaviors like you are talking about. Then the more rosy view I think we also learned from SARS is that we saw this adaptability of a population where they met many of their responsibilities in life. They put on masks and they kept their social distancing. Humans in large degree are adaptive, and so I don't know to what extent—clearly, I would think there would be the extent that we are talking about with this enormous impact and dysfunction. Then I would imagine that we would also see examples of resiliency and some return with adaptation that comes on a personal level, is my view on that.

Dr. CLINE. Yes, I agree with her. Obviously, though, if we all self-isolated, there are some things about our way of life that would stop and that we not really prepared to do. There is some critical infrastructure and critical business that gets done in this country that we really can't afford for all of them to stay home.

So we are beginning that dialog in North Carolina to say where do you draw that line. Has every business taken a look at what they need to do to maintain just the bare minimum of their work going and develop a plan for that? We are trying to help them with that and coordinate that so that those critical needs of food and power and shelter can continue.

Senator KOHL. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kohl.

Nancy and Steve, we are grateful for your presence here today and your patience with the interruption of the roll call vote. You have contributed greatly to our understanding and we salute your preparations.

With that, we are adjourned.

[Whereupon, at 11:33 a.m., the Committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR HILLARY RODHAM CLINTON

Thank you, Chairman Smith and Senator Kohl, for calling this hearing today, and bringing attention to the issues of the elderly population in pandemic situations.

In many of our discussions around pandemic influenza, we have been looking back at the events of 1918, when young, healthy individuals bore the brunt of illness and death.

But when you consider the other pandemics of the 20th century—those that occurred in 1957 and 1969—the elderly were among those that were hardest hit by the virus.

The pattern in the 1957 and 1969 pandemics mirrored those that we see every year during our seasonal flu epidemic, when we have over 36,000 deaths and more than 200,000 hospitalizations that are concentrated among elderly individuals, who are at greater risk of complications from the flu.

As such, I think that we need to increase our preparedness for the special needs of senior citizens to ensure that they will be able to continue to access necessary medical and support services without interruption.

But what is particularly worrisome to me, when thinking about our nation's ability to help seniors get the vaccines and antivirals that will help them survive a pandemic, is the fact that we aren't even prepared to deal with the seasonal influenza epidemic that we face—that we know with certainty that we will face every single year.

Since 2000, we have had multiple shortages of seasonal flu vaccine. We all recall senior citizens lining up for hours to obtain flu vaccine, unscrupulous distributors attempting to sell scarce vaccine to the highest bidder, and millions of Americans delaying or deferring necessary flu shots.

Because we don't have a system through which to track vaccine, we can't ensure the supplies that we do have reach the highest priority populations—including seniors and the chronically ill—who should get vaccinated as early as possible in any given flu season.

I've introduced legislation with Senator Pat Roberts, the *Influenza Vaccine Security Act*, that would help us make some positive changes in our nation's system for distributing, tracking and delivering seasonal flu vaccine.

Our legislation would establish a tracking system through which we could better trace the distribution of vaccine from the factory to the provider and identify counties with high numbers of priority populations, including senior citizens.

With such a system in place, we could easily determine in times of shortage where vaccine was most needed and facilitate distribution to those areas to help our elderly get the shots that they need. All of this could take place in a matter of hours, rather than days or weeks.

It simply makes sense to establish an operational tracking system for vaccine distribution that can be used in both seasonal and pandemic events, rather than rely on untried mechanisms in an emergency situation where we will already be facing multiple obstacles to delivery of health care—in particular, life saving care for elderly populations.

I look forward to working my colleagues on this committee to continue to raise awareness of the needs of senior citizens in pandemic and other emergency situations. Thank you.



American Health Care Association

**Statement of the
American Health Care Association
to the
United States Senate
Special Committee on Aging

Hearing on
Pandemic Influenza Preparedness**

May 25, 2006

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) thank Chairman Gordon Smith and Ranking Member Herb Kohl for addressing the important topic of pandemic flu preparedness, and we appreciate the opportunity to offer comments to the Special Committee on Aging on a matter of great concern and interest to the long term care community and the 1.5 million frail, elderly, and disabled Americans our members care for each day.

For years, government, academic and other health experts have warned that it is not a matter of "if" but "when" another pandemic will occur. Because we care for America's most vulnerable citizens, we must be certain that they are a top priority when it comes to being included in the National Disaster Medical System (NDMS), and better integrated and represented in the national response plan under development.

The 2005 Hurricane season taught us many things. Perhaps the most important lesson was that ensuring the safety of our frail, elderly, and disabled must be a higher priority for our state, local, and federal governments.

America's hospitals are seen as the key community, health care, and societal focal point when it comes to handling medical crises, and indeed, our nation's hospitals have the expertise and capacity to play a central, vital role. However, as a 2005 study by the Research Triangle Institute indicated, skilled nursing facilities could also play a key role in time of public disaster and public health emergencies. According to this study, skilled nursing facilities provide not only highly trained medical staff, but available beds – both of which are at a premium during times of crisis.

The message we want to stress today, Mr. Chairman, is that long term care should and must be included in the NDMS, and better integrated into the overall national response plan. AHCA/NCAL are pleased to be working with the Department of Health and Human Services' (HHS') Office of Emergency Operations to rectify this matter, and we thank Secretary Leavitt, who is here today, and the Administration, for their responsiveness and assistance in addressing our ongoing concerns.

We also note for the record we are pleased that HHS and the Centers for Disease Control and Prevention (CDC) just released a pandemic influenza planning checklist, which was developed with substantial input from AHCA/NCAL, the Alzheimer's Association, the American Medical Directors Association (AMDA), the National Association of Directors of Nursing Administration in Long Term Care (NADONNA), and the American Association of Homes and Services for the Aging (AAHSA). This new checklist is a valuable tool for long term care facilities when crafting a comprehensive pandemic influenza plan, and is an excellent first step toward better integrating the long term care community into disaster preparedness planning.

In order to prevent the problems we saw with Hurricanes Katrina, Rita, and Wilma, long term care association representatives of the Gulf States recently convened a "hurricane summit," which included representatives of both state and federal governments, and where we began an open dialogue about what worked and what didn't

work during the hurricanes and immediate aftermath As is the case today, our summit presented an opportunity to partner with the federal government to ensure that the needs of our seniors and disabled are addressed in their time of greatest need.

Moving forward to what has been in the media spotlight most recently is the question of not only what are we all doing to respond to crises, but what are we doing to proactively prepare for pandemic flu. Under any situation, nursing facilities – particularly those with hospital surge patients – will need increased supplies and medical assistance, in addition to help in paying for these items.

Mr. Chairman, in order to properly care for both long term care and hospital surge patients, we recommend a relaxation of many federal rules, similar to what was done in the aftermath of Hurricane Katrina:

- Waive the 3-day hospital stay requirement for reimbursement under Medicare Part A;
- Temporarily relax the survey process in order to first meet critical emergency needs;
- Allow for changes to Medicare “spell of illness” requirements; and
- Provide for Medicaid coverage across state lines.

On a broader basis, the National Response Plan (NRP) Emergency Support Function (ESF) #8 Public Health and Medical Services, which provides the mechanism for coordinated federal assistance to supplement state and local resources in response to public health and medical care needs in disasters, does not appropriately acknowledge the needs of long term care facilities.

While the federal government has indeed been receptive to our suggestions, and we are pleased nursing facility residents will be included in the upcoming exercise, we are still precluded from participating in the NDMS – where only hospitals can volunteer to be pre-identified as treatment sites, and guaranteed payment under the program.

We urge the Centers for Medicare and Medicaid Services (CMS) to develop a disaster protocol specifically clarifying that when a disaster does occur, regulatory flexibilities are instituted in a manner that helps us to prioritize our response activities in conjunction with the available resources at hand. Flexibility and the ability to respond agilely to rapidly unfolding developments are essential. We need, for example, to prepare to deal with emergencies with a much smaller staff structure – and temporary relief from the *Fair Labor Standards Act* must be considered.

Currently, providers are not certain what CMS will do – Katrina flexibilities, for example, were extended during Hurricane Rita, but not when Hurricane Wilma hit and knocked out electricity to much of Florida for several weeks. To best care for residents in dangerous, uncertain conditions, providers need, and deserve, more certainty and regulatory clarity. Lives will depend on it.

Yet another aspect of boosting our disaster preparedness is our technological readiness. In long term care, we are lacking in the development of our information

technologies. As an example, in some circumstances, when facilities were evacuated after Hurricane Katrina, the ability to track all patients was simply not available. We need electronic health records.

Because of the lessons learned from the recent hurricanes, we hope that the national advisory commission, the American Health Information Community, and others pay attention to long term care providers as they go forward with incentives to motivate implementation of information technology. For nursing homes, because we are primarily under-funded through Medicaid, finding the dollars to invest in information technology is difficult, but necessary.

Finally, in creating the pandemic plan, there are issues specific to long term care that need to be addressed – again with regulatory clarity and specificity. What, for example, would a mandated quarantine mean to staff, family members, and patients? How would frail patients – in nursing homes or at home – receive the care and support services they require?

The plan must also take into account the distribution of vaccines – particularly if they are only available in limited quantities. In 2004, during the flu vaccine shortage we were successful in our work with CDC to establish that nursing facility patients and staff as one of the highest priority groups. But in the event of pandemic, would these vaccines go to the frail and elderly or would they be redirected to persons required to keep the country running?

These are enormously difficult questions, Mr. Chairman, but they must be addressed as part of any comprehensive plan. We at AHCA/NCAL have been moving ahead in our disaster planning efforts – many aspects of which will bring long term care facilities one step closer to preparing for a pandemic. The bottom line is that in order to best protect the nation's most vulnerable, as well as to ensure we maximize our capacity to protect every American as best we can, long term care must be included and integrated into all emergency preparedness planning, and at every level of government.

AHCA/NCAL looks forward to continuing our work with this Committee, this Congress, and this Administration to make certain we are prepared to handle any disasters or public health emergencies that may arise. While we may not know which disaster we must prepare for – natural or otherwise – we must do our best to ensure long term care providers don't skip a beat in the delivery of care during our nation's critical time of need.

