

PREPARING FOR THE 2009 PANDEMIC FLU

HEARING
BEFORE THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS
FIRST SESSION

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PREPARING FOR THE 2009 PANDEMIC FLU

TUESDAY, SEPTEMBER 15, 2009

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The committee met, pursuant to call, at 1:10 p.m., in Room 2123, Rayburn House Office Building, Hon. Henry A. Waxman [chairman of the committee] presiding.

Present: Representatives Waxman, Dingell, Markey, Pallone, Eshoo, Stupak, Green, DeGette, Capps, Harman, Schakowsky, Inslee, Baldwin, Butterfield, Melancon, Barrow, Hill, Matsui, Christensen, Castor, Sarbanes, Murphy of Connecticut, Space, McNerney, Braley, Barton, Hall, Upton, Deal, Whitfield, Shimkus, Pitts, Walden, Murphy of Pennsylvania, Burgess, Blackburn, Gingrey, and Scalise.

Staff Present: Karen Nelson, Deputy Committee Staff Director for Health; Ruth Katz, Chief Public Health Counsel; Sarah Despres, Counsel; Elana Leventhal, Policy Advisor; Stephen Cha, Professional Staff Member; Alvin Banks, Special Assistant; Jen Berenholz, Deputy Clerk; Mitchell, Smiley, Special Assistant; Ryan Long, Minority Chief Health Counsel; Chad Grant, Minority Legislative Analyst; and Aarti Shah, Minority Health Counsel.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. The meeting will please come to order.

Today's hearing on the 2009 pandemic H1N1 flu is a continuation of this committee's ongoing interest in learning more about and staying on top of this developing and continuing situation. The hearing builds on the work of Chairman Pallone's Health Subcommittee, which held an initial hearing on the issue earlier this year.

From then until now, one thing has become crystal clear, even as events continue to evolve. As a Nation, we must be prepared for whatever the H1N1 virus brings in its path, to fight it as best we can, and to ensure adequate and appropriate resources to treat those who fall seriously ill.

We are especially pleased to have as our witness today the Secretary of Health and Human Services Kathleen Sebelius. Secretary Sebelius will share with us the government's plan for addressing this enormous challenge.

When the Health Subcommittee first met 6 months ago, there was much we did not know about H1N1 virus. We didn't know how

dangerous the virus was. We didn't know if there would be a vaccine available. We didn't even know if the virus would return in the fall. Many of those questions have now been answered.

We know this outbreak won't be the false alarm of 1976, when the surge of swine flu cases never materialized. Indeed, we are already seeing a large increase in cases, a pattern that is likely to continue. The epidemic will undoubtedly lead to hospitalizations. Schools may close. Health care facilities may become overwhelmed. And almost certainly there will be some who will die.

But there is also good news. This administration has carried on the efforts begun several years ago to prepare the country for the very situation we must now tackle. The plans developed appear to be unfolding appropriately, and experts tell us that, so far, the 2009 H1N1 epidemic will not be anything like that which occurred in 1918, when an unusually dangerous flu virus devastated our Nation.

More good news was reported just last week. We not only will have an effective vaccine in place; studies now indicate that the vaccine will probably require only a single dose rather than the two doses many had predicted. As a result, I hope Secretary Sebelius will report today that across the country we will have a good supply of vaccine, allowing us to avoid both the additional cost and the additional needle stick that a second dose would mean.

I expect that we will hear more about this as well as other H1N1 flu activities from Secretary Sebelius. I know all of us are also particularly interested in getting the Secretary's perspective on not only the progress we are making in taking on this virus but also the difficulties we surely will face along the way.

But as we make preparations and carry out detailed plans for dealing with this new virus, we must also take heed of the battle we confront annually against the seasonal flu. Each and every year, some 36,000 Americans, mostly among the elderly, die from this preventable disease. We can and should do much better than that, and I hope that Secretary Sebelius can also share with us the administration's thinking on addressing this concern and, in particular, how that approach relates to its H1N1 strategy.

With that, on behalf of the entire committee, I want to thank the Secretary for appearing before us today. We all look forward to hearing from you and to learning more about the H1N1 challenges that lie ahead. But before the Secretary will be recognized to make her statement, I want to call on several of the members of the committee to make opening statements.

And we will start with Mr. Deal.

[The prepared statement of Mr. Waxman follows:]

**Opening Statement for Chairman Henry A. Waxman
Committee on Energy and Commerce
Hearing on “Preparing for the 2009 Pandemic Flu”
September 15, 2009**

Today’s hearing on the 2009 pandemic H1N1 flu is a continuation of this Committee’s ongoing interest in learning more about -- and staying on top of -- this developing and concerning situation. The hearing builds on the work of Chairman Pallone’s health subcommittee which held an initial hearing on the issue earlier in the year.

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With that, on behalf of the entire Committee, I want to thank the Secretary for appearing before us today. We all look forward to hearing from her and to learning more about the H1N1 challenges that lie ahead.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman.

I want to thank you for holding this hearing on the examination of our Nation's preparedness for the H1N1 flu virus as we approach the flu season.

And I look forward to Secretary Sebelius's testimony and welcome her to the hearing today.

As I mentioned during the subcommittee hearing last April, the threat of a global influenza pandemic is one of the greatest public health threats that we face today. When speaking to scientists, researchers, health care providers, and other experts in the field, I truly believe that it is not a matter of if a flu pandemic hits but when. And I believe we have the responsibility to ensure the greatest public protection possible when the situation arises. We all recognize that is not a simple matter.

Since the first reports of this novel strain of the influenza virus began to surface earlier this year, U.S. and international authorities have taken aggressive steps to mitigate the spread of the illness. This has taken the dedication and cooperation of all those involved, both public and private sectors, particularly as the infection rates have increased.

As my home State of Georgia and other areas in the South have witnessed the easily transmittable H1N1 strain as it continues to spread, particularly as we have now begun school somewhat earlier than other parts of the country, we all recognize that this is a real threat. I have been in contact with my State's agencies, and they are also coordinating, of course, with your offices at the Federal level, and also as you are coordinating with international groups during these months that will lie ahead as we try to deal with this problem.

The current response to the H1N1 strain was coordinated in large part with plans which were developed to respond to a similar situation, the H5N1 avian flu. In 2006, Congress provided approximately \$6 billion for pandemic planning and cross-agency collaboration. These earlier efforts and others focused on preparedness for emergencies have streamlined the response to this situation. While our efforts to combat H1N1 have been aggressive, we must continue to monitor the situation closely and be proactive, as we hopefully will be able to avoid this but regrettably know that it will probably increase in severity.

Again, thank you, Secretary Sebelius, for being with us today. I look forward to your testimony.

I yield back, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Deal.

Mr. Pallone.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

And thank you, Secretary, for being here today to give us an update on the H1N1 situation.

When the virus first hit, it was devastating. It caused sickness. It generated fear. It caused panic. And it caused many deaths, and there were many unknowns about the virus. We did not know how the disease would present itself over time, how well it would respond to the antiviral medications on the market today, or how quickly it would develop resistance to those drugs. And we didn't know if and how quickly we would be able to develop and manufacture a vaccine.

While we have learned more about the virus, and we have made progress on the vaccine, it has spread worldwide across continents and hemisphere. And now as a level six pandemic, the highest warning level there is, it has continued to spread in the U.S. during the summer months, which is unusual for the influenza, and that adds to the unknowns and reinforces the fact that we still have to take it seriously.

In my State alone, 17 people have died since the beginning of the outbreak and over 570 have been hospitalized, and we have yet to see the disease at its strongest. In addition, the peak of this flu coincides with the normal flue season, which on its own can be extremely taxing on the health care delivery system.

I am curious to hear how the Federal Government is tackling the fact that this flu tends to affect individuals under 50 years of age, unlike the seasonal flu that hits the elderly the hardest. The younger population does not deal with disease often and tends not to seek medical care as readily.

There have been many questions about our Nation's ability to respond to medical emergencies. Unfortunately, it is hard to justify spending money on programs that are in place in case something bad happens, especially since so many programs that are needed on a daily basis have been chronically underfunded, but as history has taught us, grand-scale disease outbreaks can be devastating.

At a time when our economy is just beginning to mend and the number of uninsured is rising, we must now, more than ever, be prepared for such a situation, and we don't want to add to the health insurance crisis, and we certainly don't want to hinder the economic recovery.

So I want to commend you and your team, Secretary, for the excellent work you have done on this issue. During the first wave of the virus, I know you and your staff were working around the clock to provide tests and test results States, to develop a vaccine, to educate State and local governments, and keep the public informed of the latest information on the virus and how best to protect themselves from becoming sick. So I want to thank you for that, and look forward to hearing more today about how the Federal Government is prepared for this next wave of H1N1. Thank you.

Mr. WAXMAN. Thank you, Mr. Pallone.

Mr. Barton.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman. Thank you for holding this hearing.

And thank you, Madam Secretary, for being here.

I want to say that this is a very important issue. Obviously, America and the world is worried about the pandemic flu. We had begun to discuss this this year back in April when we had a hearing on the H1N1 virus. I would like to review some of the recent history.

Department of HHS has responded by declaring a public health emergency which has allowed the Food and Drug Administration to approve the use of approved antivirals and other measures. The Centers For Disease Control has responded by releasing antiviral drugs from the Strategic National Stockpile. To date, all 50 States have received their portion of that stockpile, which has been replenished through purchases. HHS is working with the Department of Homeland Security and is coordinating response efforts.

Much of this work has been successful because we aren't breaking new ground. This committee and the Federal Government had begun serious work back in 2004, so, in 2009, while we are not totally prepared, we are better prepared than we ever have been.

There are still some issues that should be addressed, as outlined in the President's Advisory Council on Science and Technology. It is my understanding that the administration is actively working to address these concerns, and I look forward to hearing from you, Madam Secretary, on those issues.

I guess that is it, Mr. Chairman. I have another part of my statement, but it is on the overall health care reform, and I understand that you limited your statement to the pandemic flu. So, in the spirit of this hearing, I am going to do that.

I want to take a point of personal privilege and say I appreciate all the good wishes that many of you have given me about my birthday. Today is my 60th birthday. And 30 didn't bother me. Forty didn't bother me. Fifty didn't bother me, but 60 bothers me. But I am glad to be having it, and I am blessed to have a great family, great friends and I think to be on the greatest committee on the House of Representatives.

So, with that, Mr. Chairman, I yield back.

Mr. WAXMAN. Thank you, Mr. Barton.

I, too, want to wish you a happy birthday, and tell you, you don't look a day over 59.

Mr. Dingell.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Thank you, Mr. Chairman. The gentleman from Texas has spoiled my opening remarks. It was my intention to congratulate him as a fine young man who has performed well in his responsibilities, and to congratulate him on his 60th anniversary and hope that he reaches many more. I am sure that at the least I am the first on this committee to have the privilege and the pleasure to doing that.

So, Mr. Barton, all of us on the committee do wish you a very, very happy birthday and many, many happy returns.

Now, Mr. Chairman, I want to thank you for holding this important hearing.

And I want to welcome Secretary Sebelius and thank her for joining us this afternoon.

Madam Secretary, you recall that your father was a member of this subcommittee, a very distinguished one, and I am sure that gives you good memories when you appear in this room.

You have taken a proactive role in preparing our country for the upcoming H1N1 pandemic by implementing surveillance procedures to track an outbreak, mitigation measures to keep Americans healthy, a proper vaccination plan, and a communications strategy to disseminate information of importance. I want to commend you and look forward to hearing your update on the administration's progress in planning for a potential outbreak.

At the same time, I want to recall that on an earlier occasion, we made some fine mistakes in dealing with a health problem of this kind on a related virus which led to some splendid costs and some fine earnings for the legal profession. And I want to tell you, Madam Secretary, I am pleased that you have not fallen into any of the holes that your predecessors did on that one.

In any event, we have held, as all know, a hearing earlier on H1N1 when there were only the first few people who were infected with the virus. It appears that the spread of the influenza virus that we are discussing did not let up during the summer as some had hoped, and experts predict an increased number of cases in the upcoming months.

As of September 5, 2009, my own State of Michigan has already seen 3,419 confirmed or probable cases of H1N1. Further, 11 people, most with underlying health conditions, have died after contracting the virus. All 50 States have reported now that there are cases of the virus within their borders, and Nationwide about 600 persons have died and 9,000 have been hospitalized. These figures highlight the need for the Congress and the administration to work together to prepare for the months ahead.

Preventing the spread of H1N1 will require collective action not only from Federal, State, and local governments, but also from individuals as well. To address this, it is imperative that we prepare evidence-based programs for parents, children, and businesses, and also public health professionals, on what to expect as the Nation prepares for more flu cases than seen in the past few years. I want to applaud the administration and the Federal Government for stockpiling vaccines, masks, antiviral medications, ventilators, and other things necessary to address the potential upcoming problems. Influenza is unpredictable, and we must indeed be prepared for a wide variety of surprises.

Today, Federal, State, and local officers are planning and executing multimedia outreach campaigns to arm Americans with the information they need to best keep themselves healthy or to address their problems once they become ill. This is imperative, because while we wait for H1N1 vaccine to become available, we must each play a part in slowing or reducing the spread of the virus with simple steps like handwashing and staying home when sick.

Additionally, it is important for families and businesses to prepare their strategies for dealing with H1N1. I have created an H1N1 agenda for my own office, and urge other businesses here

and elsewhere to do the same. I look forward to working with you, Mr. Chairman, and the committee, and also with you, Madam Secretary, as we seek to mitigate the outbreak of H1N1.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Dingell.

Mr. Stupak.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Thank you, Mr. Chairman, for holding this important hearing on the pandemic flu preparedness.

Secretary Sebelius, welcome to the committee, and I look forward to hearing your testimony on the Department of Health and Human Services' efforts to ensure Federal, State, and local public health officials are ready to prevent or respond to the spread of the H1N1 flu.

When the H1N1 outbreak began in late April, Federal and State health officials acted quickly to deal with the outbreak. Among other things, antiviral drugs were released from the National Stockpile, and efforts were immediately undertaken to develop, manufacture, and to test a vaccine. Congress provided an emergency appropriation of \$1.9 billion for a full response. An additional \$5.8 billion was authorized contingent upon a Presidential request documenting the need for and the proposed use of the additional funds. I am interested in learning how much of this money is actually going to public health agencies.

In our communities, particularly rural districts like the one I represent, our local public health agencies, hospitals, and clinics, shouldered the responsibility for responding to a public health crisis. It is vital they receive financial support from the Federal Government.

H1N1 is unique from flu season. Unlike the seasonal flu, H1N1 affects a different population; in particular, young people with children, younger adults, and pregnant women. From all indications I have read, the vaccines for H1N1 will not be ready until mid October. I am looking forward to hearing from you on what types of infrastructure HHS and CDC will have in place to distribute the vaccines in a timely fashion to pregnant women, people who live with or care for young children, health care and emergency services personnel, persons between the ages of six months and 24 years of age, and people between 25 and 64 who are at a higher risk from the H1N1 because of chronic health disorders like asthma.

As chairman on the Subcommittee on Oversight and Investigations, this is an issue I will continue to monitor following today's hearing. I look forward to your testimony and learning how well the Federal Government is coordinating with State and particularly local officials and as a Nation will respond and hopefully prevent widespread outbreak.

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

Mr. WAXMAN. Thank you, Mr. Stupak.

By previous understanding with the minority, we said that the only ones who would be recognized for opening statements would be the chairman, the ranking member, Mr. Dingell, and then the

Chair and the ranking member of the Health and the Oversight Subcommittees.

But, without objection, the record will be held open for any opening statements from any member that wishes to include them. I want to do this and move on because—Mr. Walden, are you ready for your opening statement?

Mr. WALDEN. Mr. Chairman, I will submit it for the record, because I don't want to take too much time away from the Secretary. I appreciate the opportunity to do that. I look forward to your comments on this, and I do hope you will be able to come back at some point because I am sure we have questions on the overarching health care bill.

But I would just say that the flu is something we are all concerned about. I have a son who is a sophomore at Wake Forest University, which got swept pretty early on with the flu outbreak. He got it. I don't know if it was the H1N1 and neither does he, but he has recovered, thankfully. But it is an issue all families are worried about. So I look forward to your testimony.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Walden appears at the conclusion of the hearing.]

Mr. WAXMAN. Madam Secretary, we are delighted to have you with us. Your full testimony has been submitted in advance and will be made part of the record, and we want to recognize you for your oral presentation to us.

STATEMENT OF THE HONORABLE KATHLEEN SEBELIUS, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY REAR ADMIRAL ANNE SCHUCHAT, MD, ASSISTANT SURGEON GENERAL, UNITED STATES PUBLIC HEALTH SERVICE, DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES

Secretary SEBELIUS. Thank you very much, chairman Waxman, Ranking Member Barton, Mr. Deal, Mr. Pallone, Chairman Emeritus Dingell, Mr. Stupak, Mr. Walden, members of the committee. It is very good to be back before the Energy and Commerce Committee. And I appreciate the opportunity to give you an update on the public health challenges of the H1N1 influenza.

Let me just start by saying the administration is taking these challenges very seriously. In fact, the night I was sworn in on April 28, I went immediately to the situation room because this virus was just breaking out, and from day one, this has been very high on my radar screen.

We are working in close partnership with virtually every part of the Federal Government, but also with Governors, mayors, tribal leaders, State and local health departments, emergency personnel, working with the medical community, the private sector, to actively prepare for the virus outbreaks that may develop over the next few months and to have some mitigation strategies in place in the meantime.

Since the initial outbreak of the 2009 influenza, not only has a worldwide pandemic been declared, it has also presented itself as the dominant flu strain in the southern hemisphere during the winter flu season. Here in the U.S., we continued to see H1N1 flu

activity over the summer, which is unusual, and as a number of you have already noted, it has increased now that the fall is under way. We are anticipating further increases in flu cases as seasonal flu begins circulating among us.

We have provided, Mr. Chairman, each of the members with an update that is at your seats with some more details on the current situation, including a situational update that is on, I think, the third page of your handout. Dr. Anne Schuchat from the Centers for Disease Control is with me today, and CDC gives us the these situational updates on a daily basis, and we wanted you to have the newest information.

Although evidence to date shows that the virus has, fortunately, not changed to become more deadly, what we know is this influenza is unpredictable, and we need to monitor both the impact of the 2009 H1N1 and seasonal flu throughout the next several months.

The virus is in fact in more people than we typically see with seasonal flu, including children, younger adults, and pregnant women, and slowing this spread of the virus is a responsibility shared by all of us.

Chairman Emeritus Dingell already referenced there are some simple steps; handwashing, covering coughs and sneezes, and staying home when you are sick are important steps. The government-wide web site, www.flu.gov, does have comprehensive information about what to do to avoid getting the flu.

And I would suggest, Mr. Chairman, I know we have communicated this to the offices, but on that Web site, flu.gov, are widgets. If any Members of Congress want to put a widget on your own Web site so that your own constituents can monitor on a regular basis, see the latest basis CDC guidance, get regular information, we would strongly encourage you to do that. If I am speaking in techno speak, a 12-year-old can be hired easily and tell you what to do with a widget. My recommendation.

Oh, I apologize, Ranking Member Barton, I should have started with a happy birthday. And you will find the 60s will treat you well. It is a good place to be.

To date, the CDC has issued recommendations on how individuals, schools, child care settings, colleges and universities, large and small businesses can guard against the flu, as well as a recent guidance on the appropriate use of antiviral drugs. Again, all of those are on the Web site and can be downloaded and shared with constituency groups if you are going to have some meetings at home. Guidance on infection control and worker safety in health care settings is forthcoming in the next few days.

As I announced this weekend, we plan to initiate our H1N1 vaccination program in October. Mid October is still the target for the large-scale campaign to get under way, but we anticipate having limited amounts of vaccine available a week or 10 days earlier.

I am pleased to report that today the Food and Drug Administration has approved applications for vaccines for the 2009 H1N1 virus from four of the manufacturers of the U.S.-licensed seasonal influenza vaccines. The vaccines for this virus are being produced under careful FDA oversight using the same licensed manufac-

turing processes and facilities used for seasonal flu vaccines that are provided every year to protect millions against the flu.

And in response, Mr. Chairman, to your point, seasonal flu vaccine is now available widely in cities around the country, and again, we are urging people strongly, particularly if they are in the target population for seasonal flu, to go ahead and get the seasonal flu vaccine right now.

We recently, just last week, had good news from studies being done both by NIH and manufacturers that a single dose of the vaccine rapidly introduces a strong immune response in healthy adults. We think that age group could go down as low as age nine, but the clinical studies in children and pregnant women are still under way, so we don't have the full data about whether children will need two doses or not. They do in seasonal flu, younger children. We are still waiting for those results to be back.

And, Mr. Chairman, originally we thought that it would take up to 21 days for the immune response to be robust, and it is showing up in 8 to 10 days. That is very good news. So one dose, 8 to 10 days for most of the population above age nine we think is a very positive step forward. The trials in pregnant women are under way, as I said, and in children, and our expectation is that the vaccine will be a good match in protecting against these populations as well.

Once ready, the vaccine will be shipped through a central distribution system and available in up to 90,000 sites around the country. Every State was asked to develop a plan and identify the appropriate vaccination sites. Our contractor is shipping directly to those sites so there is not a glitch along the way.

Two types of vaccine, a flu shot made from inactive aided virus and a nasal spray made from live weakened virus, will be available, free of charge, though some providers may charge an administration fee. And, again, Congress did authorize funds at the time of the supplemental bill to cover some of the costs, and the Department of Health and Human Services has expended on top of that about \$1 billion in our funds to get that process started before the supplemental funding was available.

CDC's Advisory Committee on Immunization Practices, ACIP, recommended that initial doses of the H1N1 vaccine go to people at greatest risks of complications from the flu as well as those who have frequent contact with people at risk, and we are working with States, territories, tribes, local communities, as well as the private sector to help distribute and administer the new H1N1 vaccine. Thanks to Congress, we have allocated \$1.44 billion for States and hospitals for planning and preparation.

The Nation's current preparedness is a direct result of the investments and support of the Congress and the hard work of the HHS agencies and States and local officials across the country, both recently, but certainly over the last several years. So we look forward to continuing to work with Congress in the weeks and months ahead.

Again, Mr. Chairman, I thank you for the opportunity to participate in the conversation, and I look forward to taking your questions.

[The prepared statement of Ms. Sebelius follows:]

	<p>Testimony before the Committee on Energy and Commerce United States House of Representatives</p>
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**Preparing for the 2009-2010 Influenza
Season**

Kathleen Sebelius
Secretary,
U.S. Department of Health and Human Services

For Release upon Delivery
Expected at 1:00 p.m.
September 15, 2009

Chairman Waxman, Ranking Member Barton, Chairman Emeritus Dingell, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. I want to assure the Committee that the Administration is taking these challenges seriously, and has mounted an aggressive plan to address H1N1 throughout this fall and winter. HHS has a leading role because this is a health event, and we are working in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, the federal government has been actively preparing for possible H1N1 virus outbreak scenarios that may develop over the next few months.

Since the initial spring outbreak of 2009 H1N1 influenza, the virus has triggered a worldwide pandemic, and has been the dominant flu strain in the southern hemisphere during its winter flu season. The evidence to date shows that the virus has not changed to become more deadly. Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably in summer camps. More recently, we have seen an increase in 2009 H1N1 influenza activity in several states and expect this to continue across the United States during the coming months. As fall begins, we anticipate that even more communities may be affected than those that saw cases this past spring and summer. In addition, communities may be more severely affected, reflecting wider transmission and causing potentially greater impact. Seasonal influenza viruses may cause illness concurrently with 2009 H1N1 this fall and winter and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal

influenza, or other respiratory conditions based on symptoms alone. It is also difficult to predict the severity of the disease that we will see in the coming months from either 2009 H1N1 or seasonal influenza. Influenza is an unpredictable disease and we know that things will change and we will learn more throughout the fall.

Shared Responsibility and Science-Based Guidance

Slowing the spread and reducing the impact of H1N1 and seasonal flu is a shared responsibility, and we all need to plan for what would need to be done when the flu impacts our community, school, business or home this fall. Given that flu already is circulating in the United States this fall, it's important for every American family and business to prepare their own household and business plans and think through the steps they will have to take if a family member or co-worker contracts the flu.

CDC has provided specific recommendations for what individuals, communities, clinicians, and other professionals can do. Individuals can take actions to prevent respiratory infections. We emphasize frequent hand-washing as an effective way to reduce transmission of disease. It is very important for sick individuals to stay at home, and for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, or other places children gather. Similarly, sick individuals should not get on an airplane or any public transport. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory illnesses.

We have issued new guidance from the CDC on flu.gov for schools, child care settings, colleges and universities, and large and small businesses that also includes strategies for preventing the spread of flu, especially in the early fall when the 2009 H1N1 vaccine will not yet be ready. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. The CDC also has issued guidance for healthcare providers about appropriate use of anti-viral drugs to treat patients who are at highest risk from complications from the seasonal and 2009 H1N1 flu. Additional work is being done on critical guidelines to address infection control and worker safety in healthcare settings.

Our recommendations and action plans are based on the best scientific information available to help our nation respond aggressively and effectively to the 2009 H1N1 virus. We are working to ensure that Americans are informed and consistently updated with information in clear language. This is a dynamic situation, but it is essential that the American people are fully engaged so they can be part of the response. The federal government, particularly the CDC, will be conducting weekly and, when necessary, daily briefings that will be available at flu.gov to get critical information out to the American people.

Vaccination Campaign

The federal government is also preparing for a voluntary national vaccination campaign for the 2009 H1N1 virus starting in October. With unprecedented speed, we have completed key steps in the vaccine development process -- we have characterized the virus, identified a candidate strain, expedited manufacturing, and performed clinical trials. The speed of this vaccine development was possible due to the investments made through ASPR/BARDA over the past six

years in advanced research and development and infrastructure building. One-hundred ninety-five (195) million doses of H1N1 vaccine have been purchased from five manufacturers by the U.S. government. Two types of vaccine will be available: vaccine made from killed virus for injection (flu shot) and vaccine with live, weakened virus administered by nasal spray.

The vaccines are being manufactured by the same methods used for the production of the seasonal flu vaccines administered every year. NIH is conducting a series of clinical trials on the vaccine to determine the safety and number of doses needed to induce a protective immune response. Trials in healthy adults and the elderly began in the first week of August. Complete immune response data from the first trials—those studying two doses in healthy adults—are expected in late October. Preliminary data indicate that the vaccines are safe and that a single 15-microgram dose induces what is likely to be a protective immune response in healthy adults between the ages of 18 and 64. For adults aged 65 and over, the preliminary data indicate that the immune response to the 2009 H1N1 influenza vaccine is somewhat less robust, as is the case with seasonal influenza vaccine. Trials in children began in mid-August, and trials in pregnant women have just begun. Our expectation is that vaccine will be a good match for the virus currently circulating in the United States based on intensive monitoring of the virus.

We are coordinating this 2009 H1N1 vaccination campaign with the seasonal influenza vaccination campaign, and are working hard with state and local authorities and the clinical community to address the challenges this presents.

From what we know as of today, 2009 H1N1 virus preferentially affects a population different from that affected by seasonal flu. In particular, this virus is infecting more young people including children, younger adults and pregnant women. Typically these groups, particularly young children and pregnant women, are at greater risk of serious complications from any influenza, including the 2009 H1N1. CDC's Advisory Committee on Immunization Practices (ACIP) recommended on July 29 providing initial doses of the new H1N1 vaccine to five groups—approximately 159 million people. CDC endorsed these recommendations. These groups are:

- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel,
- persons between the ages of 6 months through 24 years of age, and
- people from ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders like asthma and diabetes or compromised immune systems.

The H1N1 virus is particularly dangerous to healthy women who are pregnant. Not only has this virus caused greater numbers of pregnant women to be hospitalized, it has also been fatal in a higher percentage of this population than in other affected groups.

The federal government will be working in partnership with states, territories, tribes, and local communities as well as the private sector to help distribute and administer the new H1N1

vaccine. Thanks to support from Congress, the federal government has allocated \$1.444 billion for states and hospitals to support planning and preparation efforts.

The large scale 2009 H1N1 vaccine program will begin mid-October with small amounts of vaccine becoming available the first full week in October. The vaccine itself will be available free of charge to the American people, but some public and private providers may charge an administration fee. It will be distributed to providers and state health departments in a manner similar to how federally purchased vaccines are distributed in the Vaccines For Children program. The CDC and states will work with a contractor to get vaccine to where it needs to go. The number of doses shipped will be reported to the CDC daily, and the number of doses administered will be reported to the CDC weekly.

The fact that vaccine won't begin distribution until October makes preventing the spread of flu even more critical. Again, we need to remind all Americans about the things they should be doing right now: washing hands, staying home if you're sick, and taking the necessary precautions to stay healthy and avoid getting sick. Flu.gov has good tips for what you need to do to avoid getting the flu.

While the 2009 H1N1 flu virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by the seasonal flu viruses. More than 36,000 people die each year from complications associated with the flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all infants, children, and people at greater risk for influenza complications. Seasonal flu vaccine already is becoming available in many places.

It is not too early to get a seasonal flu shot as soon as it is available. The protection you get from the vaccine will not wear off before the flu season is over.

Closing Remarks

At HHS, we are simultaneously working hard to understand and control this outbreak while also keeping the public and the Congress fully informed about the situation and our response. We are working in close collaboration with our federal partners as well as with other organizations with unique expertise that helps us provide guidance for multiple sectors of our economy and society. It is important to recognize that there have been enormous efforts in the United States and abroad to prepare for this kind of an outbreak and a pandemic. Our nation's current preparedness is a direct result of the investments and support of the Congress and the hard work of state and local officials across the country. While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our nation's history have we been more prepared to face this kind of challenge.

But the government cannot solve this alone and, as I have noted, all of us must take constructive steps. Taking all of those reasonable measures will help us mitigate how many people actually get sick in our country.

We look forward to working closely with the Congress to best address the situation as it evolves in the weeks and months ahead. Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to taking your questions.



Flu.gov Fact Sheet *from the*
Department of Health & Human Services

The repurposed and redesigned Flu.gov Web site (formerly PandemicFlu.gov) will:

- Update and aggregate flu content from HHS Agencies, including CDC, NIH, FDA and SAMHSA and other federal Departments, including Agriculture, Ed, Defense, Commerce, State and others.
- Consolidate, compare and contrast information about seasonal, H1N1 (Swine) and H5N1 (Bird) flus.
- Appropriately present information for the general public, health practitioners and those charged with emergency planning in a balanced and intuitive architecture.
- Publish this information in Spanish and (selected portions) in multiple other languages including Chinese, Vietnamese and Hmong, with same-day translation of critical information.
- Eliminate redundant Web-based flu content, conserving resources and avoiding the confusion (and potential risk) created by conflicting content.
- Provide for immediate emergency communication via Web video streaming, video on demand, social media and mobile outreach
- Be managed and maintained by HHS with oversight and advice from a collaborative cross-federal Content Coordination Committee.
- Incorporate geo-spatial mapping tools capable of supporting critical location-specific information including local vaccine distribution points.
- Link to primary state flu content and flu planning Web sites.
- Be supported by virtually unlimited surge protection to ensure that download demand will be met at all times under all circumstances.
- Raise, through social media and other means, public awareness of the flu and need for flu prevention.
- Be heavily promoted utilizing traditional and new media outreach methods.



STAY INFORMED ABOUT H1N1 ADD the www.FLU.gov WIDGET TO YOUR HOMEPAGE

What Is a Widget?

A widget is something that can be embedded on any web page, linking to more information on another website.

What Does It Do?

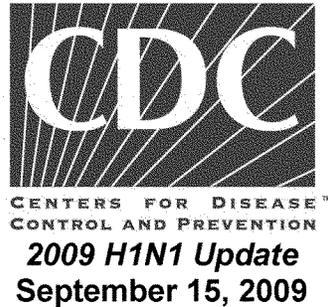
Adding the 'Know What To Do About the Flu' widget to your Congressional homepage will allow your constituents to get the most up-to-date information about H1N1 flu.

How Do I Add the Widget?

Follow these simple steps:

- 1) The widgets are live on <http://www.hhs.gov/web/library/hhsfluwidgets.html>.
- 2) To add the "Know What to Do About the Flu" widget, this code should be used:

```
<script type="text/javascript"
src="http://transparency.cit.nih.gov/widgets/flugovlinks.cfm?javascript"></script>
<noscript> <iframe src="http://transparency.cit.nih.gov/widgets/flugovlinks.cfm"
name="flugovframe" frameborder=0 id="flugovframe" scrolling="no" height="160"
width="198" marginheight="0" title="Flu.gov widget" marginwidth="0"
>Flu.gov</iframe> </noscript>
```



United States Update

- Increased disease from the 2009 H1N1 influenza already has started in several states and is expected to become evident across the United States during the coming months.
- Influenza like illness is already well above baseline for this time of year in several Southeastern states. This early increase in the southeastern states may relate to earlier school openings in some of these areas, compared with northern parts of the country.
- So far we are continuing to see that children and young adults are disproportionately affected, and elderly persons are less likely to come down with illness from the H1N1 virus.
- The severity of the virus has not changed at this point and clinical disease we are seeing continues to be a range, with most people getting better with a few days of rest at home, but some people having severe illness leading to difficult hospitalizations and unfortunately, death.
- CDC expects that as fall begins, even more communities may be affected, and communities may be more severely affected than during spring 2009, reflecting wider transmission and potentially greater impact.
- Seasonal influenza viruses may cause illness concurrently with 2009 H1N1 viruses this fall and winter.
- CDC has updated its recommendations to assist businesses and other employers of all sizes.
- During an influenza pandemic, all sick people should stay home and away from the workplace. Handwashing and covering coughs and sneezes should

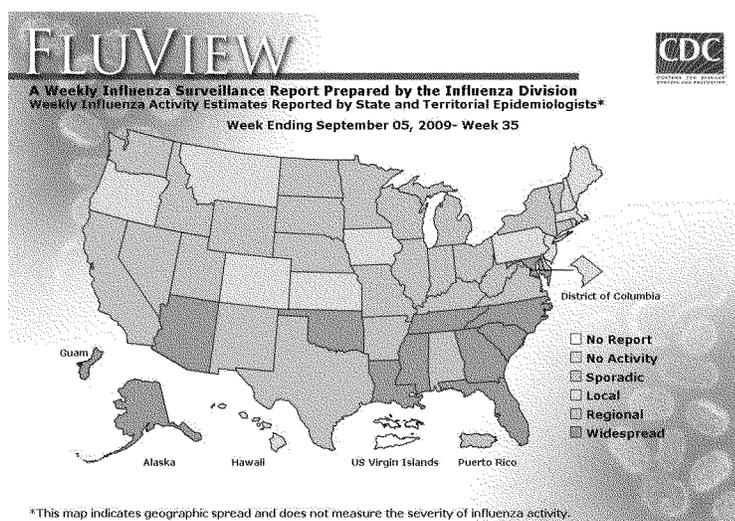
be encouraged; routine cleaning of commonly touched surfaces should be performed regularly.

Geographic Spread in the United States

The influenza activity reported by state and territorial epidemiologists indicates geographic spread of both seasonal influenza and 2009 influenza A (H1N1) viruses and does not measure the severity of influenza activity.

During week 35, the following influenza activity was reported:

- Widespread influenza activity was reported by Guam and 11 states (Alaska, Arizona, Florida, Georgia, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, and Tennessee).
- Regional influenza activity was reported by Puerto Rico and 13 states (Alabama, Arkansas, California, Illinois, Kentucky, Minnesota, Nebraska, Nevada, New Mexico, Ohio, Texas, Virginia, and Washington).
- Local influenza activity was reported by the District of Columbia and 10 states (Colorado, Hawaii, Iowa, Kansas, Maine, Massachusetts, Montana, New Jersey, Oregon, and Pennsylvania).
- Sporadic activity was reported by 14 states (Connecticut, Delaware, Idaho, Indiana, Michigan, Missouri, New York, North Dakota, South Dakota, Utah, Vermont, West Virginia, Wisconsin, and Wyoming).
- No influenza activity was reported by two states (New Hampshire and Rhode Island).
- The U.S. Virgin Islands did not report.

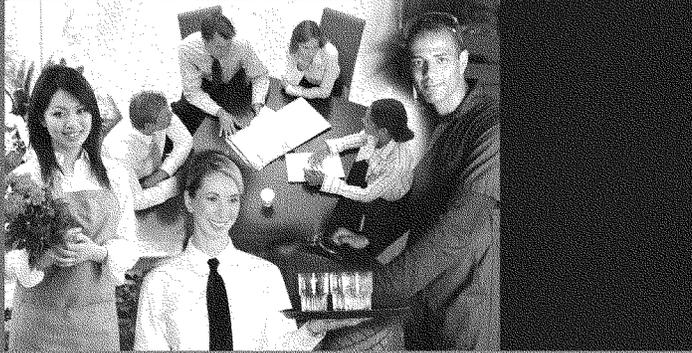


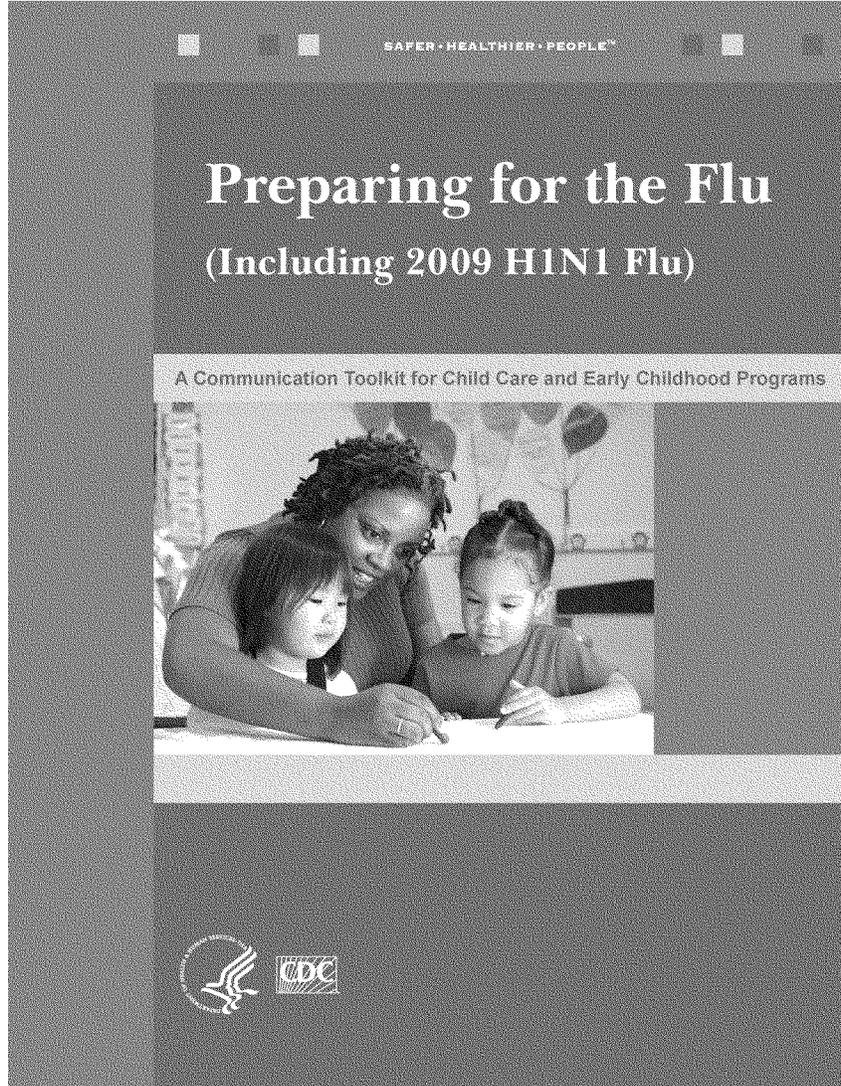
SAFER • HEALTHIER • PEOPLE™

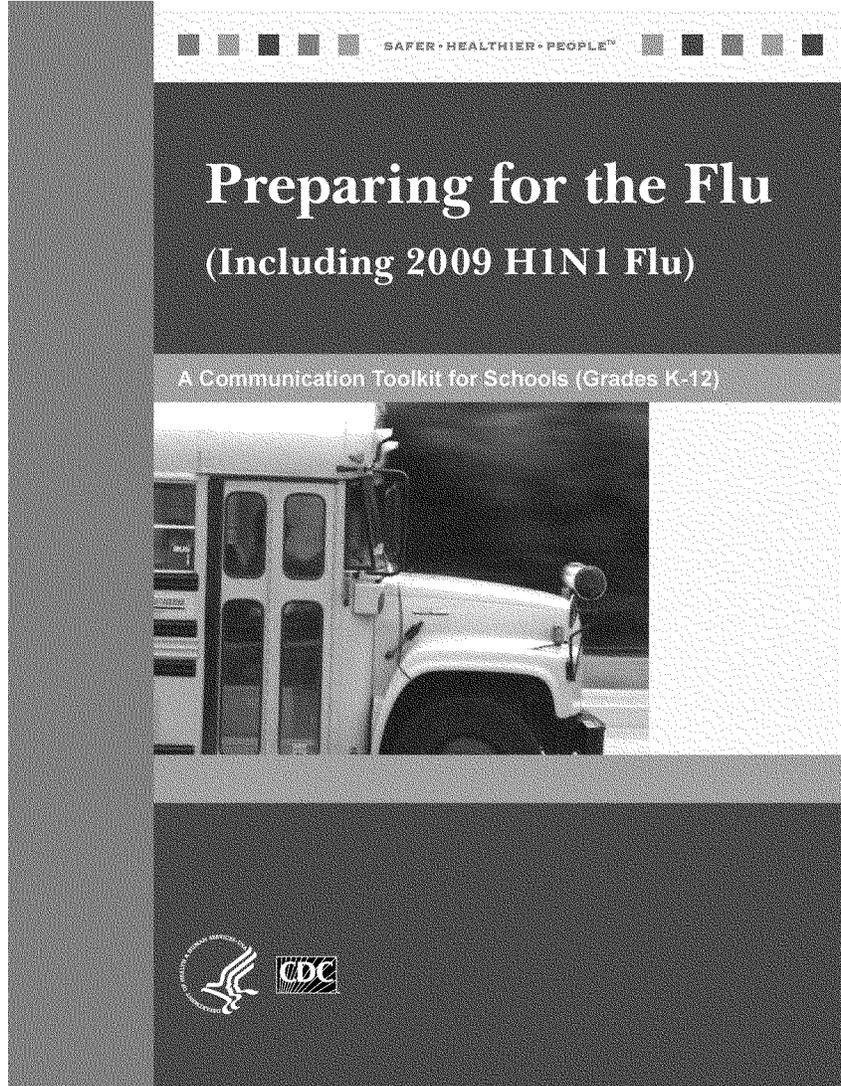
Preparing for the Flu

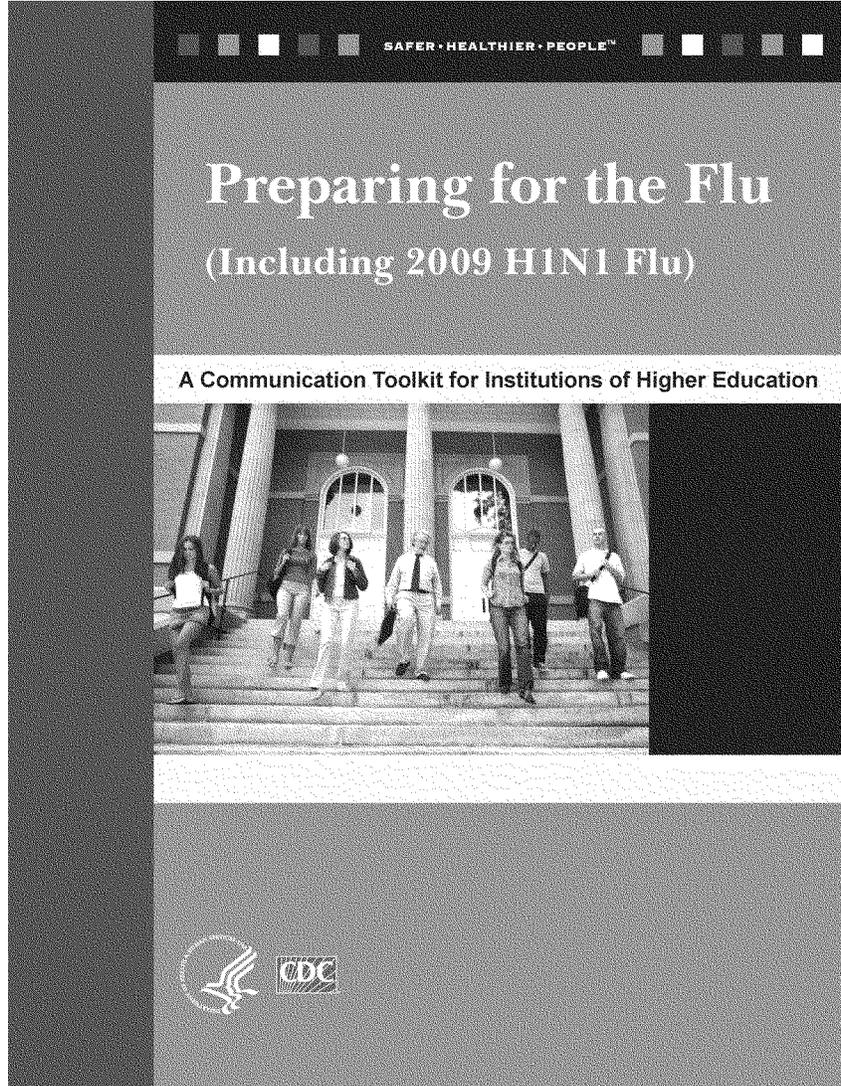
(Including 2009 H1N1 Flu)

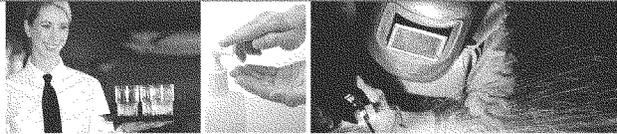
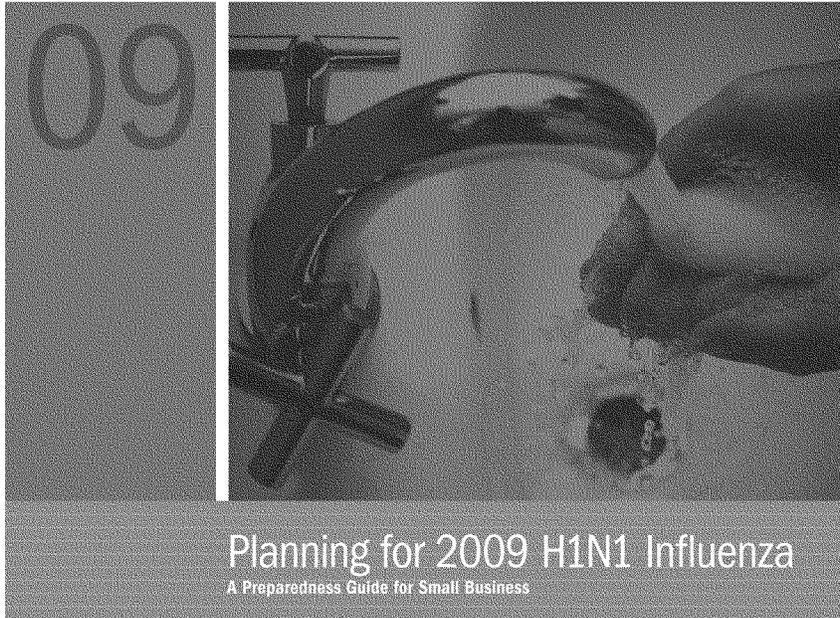
A Communication Toolkit for Businesses and Employers













***5 Things Employers Need to Know
About H1N1 Flu***
Department of Health & Human Services

Until the 2009 – 2010 flu season actually hits this fall, we will not know whether H1N1 flu will remain at the same levels we've seen over the spring and summer, or mutate into a more severe form of flu. But even a moderate outbreak can cause serious illness and deaths. As an employer, you need to be aware of 5 basic steps to keep flu from spreading in your workplace and your community.

1. **Keep your sick employees home.**
If they're already sick, let them stay home. If they get sick at work, send them home. And if your employees have kids who are sick, or can't go to school or child care because they've been exposed to flu, your workers should stay home as well.
2. **Plan now so you can continue to operate with a reduced workforce.**
Promote teleworking, cross-train your staff, and use staggered shifts to have fewer workers in the workplace at the same time.
3. **Encourage employees to get vaccinated.**
Vaccines will be available for seasonal 2009 H1N1 influenza and seasonal flu. Encourage your employees to get both of them.
4. **Keep the workplace clean.**
Encourage your employees to wash their hands often. Remind them to use a tissue or their sleeves when they have to cough or sneeze. Make sure that surfaces likely to have frequent contact with hands get cleaned with cleaning agents.
5. **Go to flu.gov for the latest information on H1N1 and seasonal flu.**
Flu.gov is a one-stop government wide resource with planning tools for employers to get a jump start on the 2009 flu season.



5 Things Schools Need to Know About H1N1 Flu

Department of Health & Human Services

The flu season coincides with the school season. This year schools and communities are not only facing the regular seasonal flu, but also the H1N1 virus, a potentially more dangerous strain. However, good planning now can allow schools to stay open, and protect students and staff, particularly those at high-risk of complications. Here are the 5 most important steps:

1. **Make prevention the first line of defense.**
Everyone—students, teachers, administrators and other staff—need to make it a routine to wash their hands often with soap and water. Remind them to cough or sneeze into their sleeves or into a tissue, not in their hands. These steps are easy, but they only work if students, teachers, and every member of the staff participate.
2. **Make sure you know who's at increased risk in your school.**
H1N1 flu spreads rapidly among kids between the ages of 6 months through 24 years of age. The people who work with and care for them need to be careful as well. But this flu is especially risky for pregnant women and anyone between the ages of 25 through 64 who have chronic health conditions, for example, asthma, diabetes, or neuromuscular disorders. If children have underlying health conditions, encourage their families to contact a doctor at the first sign of symptoms.
3. **Make sure sick people—children or adults—stay home.**
If conditions in your community become severe, you might even consider preemptive school dismissal. Actively watch for signs of illness—similar to seasonal flu—in students and staff: Fever, cough, sore throat, stuffy nose; achiness, headache, chills and fatigue. Sometimes H1N1 causes diarrhea and vomiting. Both H1N1 and seasonal flu can be severe and occasionally deadly.
4. **Make sure staff and families get vaccinated.**
Vaccines are the best means we have to protect communities from flu. Vaccines for both H1N1 and seasonal flu will be available this fall. Scientists at the National Institutes of Health, the CDC, and the Food and Drug Administration are working around the clock with vaccine manufacturers to make sure that flu vaccines are safe and effective.
5. **Go to flu.gov for the latest information on H1N1 and seasonal flu.**
Flu.gov is a one-stop government-wide resource with planning tools for schools and families to get a jump start on the 2009 flu season.



5 Things Parents Need to Know About H1N1 Flu

Department of Health & Human Services

Right now, parents everywhere are preparing for a new school year. But if you're a parent, you need to add one more item to that back-to-school checklist: what to do if someone in your family gets the flu.

This fall we're not only facing the regular seasonal flu, but also the H1N1 virus, a potentially more dangerous strain. As a parent, you need to be aware of 5 basic steps to keep your family healthy and keep flu from spreading in your community.

1. **Make prevention the first line of defense.**
Everyone needs to make it a routine to wash their hands often with soap and water. Remind your family to cough or sneeze into their sleeves or into a tissue, not in their hands. These steps are easy, but they only work if every member of the family participates.
2. **Make sure you and your entire family get vaccinated.**
Vaccines are the best means we have to make sure that families and communities are protected from flu. Vaccines for both H1N1 and seasonal flu will be available this fall. Scientists at the National Institutes of Health, the CDC, and the Food and Drug Administration are working around the clock with vaccine manufacturers to make sure that flu vaccines are safe and effective.
3. **Keep your children home if they're sick.**
If you're sick, stay home as well. H1N1 spreads rapidly among kids and young adults; it's especially risky if you're pregnant. Look for these symptoms: Similar to seasonal flu, with H1N1 you'll get a fever, cough, sore throat, stuffy nose; achiness, headache, chills and fatigue. Sometimes H1N1 causes diarrhea and vomiting. Both H1N1 and seasonal flu can be severe and occasionally deadly.
4. **Start planning now in the event that one of your kids gets the flu.**
Ask yourself these questions: If you work, have you made arrangements for child care? Have you talked with your employer about what to do in case you need to be out?
5. **Go to flu.gov for the latest information on H1N1 and seasonal flu.**
Flu.gov is a one-stop government wide resource with planning tools for parents to get a jump start on the 2009 flu season.

What should I use for hand cleaning?

Washing hands with soap and running water (for as long as it takes to sing the "Happy Birthday" song twice) will help protect against many germs. When soap and running water are not available, wipes or gels with alcohol in them can be used (the gels should be rubbed into your hands until they are dry).

If your child is sick

What can I do if my child gets sick?

If your child is 5 years or older and otherwise healthy and gets flu-like symptoms, including a fever and/or cough, consult your doctor as needed and make sure your child gets plenty of rest and drinks enough fluids.

If your child is younger than 5, or of any age and has a medical condition like asthma, diabetes, or a neurologic problem and develops flu-like symptoms, including a fever and/or cough, call your doctor or get medical attention. This is because younger children and children who have chronic medical conditions (like asthma or diabetes) may be at higher risk of serious complications from influenza infection, including the new H1N1. Talk to your doctor early if you are worried about your child's illness.

What if my child seems very sick?

Even children who have always been healthy before or had the flu before can get a severe case of flu.

Call on take your child to a doctor right away if your child of any age has:

- Fast breathing or trouble breathing
- Bluish or gray skin color
- Not drinking enough fluids
- Severe or persistent vomiting
- Not waking up or not interacting
- Being so irritable that the child does not want to be held
- Flu-like symptoms improve but then return with fever and worse cough
- Has other conditions (like heart or lung disease, diabetes, or asthma) and develops flu-like symptoms, including a fever and/or cough.

Can my child go to school, day care or camp if he or she is sick?

No. Your child should stay home to rest and to avoid giving the flu to other children.

When can my child go back to school after having the flu?

Keep your child home from school, day care or camp for at least 24 hours after their fever is gone. (Their fever should be gone without them having taken a fever-reducing medicine.) A fever is defined as 100°F or 37.8°C.

*Though the scientific evidence is not as extensive as that on hand washing and alcohol-based sanitizers, other hand sanitizers that do not contain alcohol may be useful for killing flu germs on hands in settings where alcohol-based products are prohibited.



Seasonal and Novel H1N1 Flu:

A Guide for Parents



For more information, visit
www.cdc.gov or www.flu.gov
or call
1-800-CDC-INFO

Flu Information

What is the flu?

The flu (influenza) is an infection of the nose, throat, and lungs caused by influenza viruses. Flu viruses cause illness, hospital stays and deaths in the United States each year. There are many different flu viruses and sometimes a new flu virus emerges to make people sick.

What is novel H1N1 flu?

Novel H1N1 flu is a new and very different influenza virus that is spreading worldwide among people. This new virus was called "swine flu" at first because it has pieces of flu viruses found in pigs in the past. However, novel H1N1 virus has not been detected in U.S. pigs.

Influenza is unpredictable, but scientists believe that the new H1N1 virus will cause illness, hospital stays and deaths in the United States over the coming months. This flu season, the new virus may cause a lot more people to get sick than during a regular flu season. It also may cause more hospital stays and deaths than seasonal flu.

How serious is the flu?

The flu can be very serious, especially for younger children and children of any age who have one or more chronic medical conditions. These conditions include asthma or other lung problems, diabetes, weakened immune systems, kidney disease, heart problems and neurological and neuromuscular disorders. These conditions can result in more severe illness from influenza, including the new H1N1 virus.

How does flu spread?

Both novel H1N1 flu and seasonal flu are thought to spread mostly from person to person through the coughs and sneezes of people who are sick with influenza. People also may get sick by touching something with flu viruses on it and then touching their mouth or nose.

What are the symptoms of the flu?

Symptoms of seasonal flu and novel H1N1 flu include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people also may have vomiting and diarrhea.

How long can a sick person spread the flu to others?

People infected with seasonal and novel H1N1 flu shed virus and may be able to infect others from 1 day before getting sick to 5 to 7 days after. This can be longer in some people, especially children and people with weakened immune systems and in people infected with novel H1N1 flu.

Protect your child

How can I protect my child against flu?

Get a seasonal flu vaccine for yourself and your child to protect against seasonal flu viruses.

Take everyday steps to prevent the spread of all flu viruses. This includes:

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water, especially after you cough or sneeze. If soap and water are not available, alcohol-based hand cleaners are also effective.*



- Avoid touching your eyes, nose and mouth. Germs spread this way.
- Teach your child to take these actions too.
- Try to keep your child from having close contact (about 6 feet) with sick people, including anyone in the household who is sick.
- Keep surfaces like bedside tables, surfaces in the bathroom, kitchen counters and toys for children clean by wiping them down with a household disinfectant according to directions on the product label.
- Throw away tissues and other disposable items used by sick persons in your household in the trash.

Is there a vaccine to protect my child from H1N1 flu?

A vaccine against novel H1N1 flu is being produced and will be available in the coming months as an option for the prevention of the new H1N1 flu. A vaccine against seasonal flu is available each fall and winter. More information about the new H1N1 flu vaccine and the seasonal flu vaccine is available on the CDC Web site.



Is there medicine to treat the flu?

Antiviral drugs can treat both seasonal flu and the new H1N1 flu. These drugs can make people feel better and get better sooner. But they need to be prescribed by a doctor and they work best when started during the first 2 days of illness. These drugs can be given to children. The priority use for these drugs is to treat people who are seriously ill or who have a medical condition that puts them at high risk of serious flu complications.

Mr. WAXMAN. Thank you very much, Madam Secretary, for that update.

There are many members here, because this is an important hearing, and I know you have to leave in a couple hours. In order to accommodate the members, what I am going to do, with Mr. Barton's assent to ask each member to ask one question. We will put the timer on at 3 minutes. But we would appreciate it if members could ask just one question, but no more than 3 minutes.

Mr. Barton, is that correct?

Mr. BARTON. Yes. And I want to let the minority members know that I support this; in fact, it is my recommendation. There is a precedent for this. Other Cabinet Secretaries that have been before the panel, we have adopted this practice. I think it is fair, so that the junior members have an opportunity to ask a question as well as the senior members.

Mr. WAXMAN. Thank you, Mr. Barton.

I am going to start off the questions with a more junior member to me, Mr. Markey.

Mr. MARKEY. I thank the chairman very much. We have been sitting next to each other for 33 years.

And the 60s are great, too, Madam Secretary.

You know, one of the real questions that people have is the safety of this drug, and there was a real concern going back to 1976 and that swine flu epidemic and the diseases later associated with the distribution of that drug. So just so I can understand this, this drug has not yet been FDA approved; is that correct?

Secretary SEBELIUS. It just was licensed today.

Mr. MARKEY. It was licensed today. That is great news. And could you talk a little bit about what is different, what the difference is between this drug and the drug back in 1976 in terms of what the FDA and the agency believe will be the impact on Americans?

Secretary SEBELIUS. Well, Mr. Markey, one of the first steps that the President took was to actually gather the experts from 1976 together and ask for advice about what went right and what went wrong. And we had an opportunity to meet with everybody from the then Secretary of Health Environment to the Surgeon General to some of the scientists who were involved, and they gave some very good advice.

The principle difference may not have been in the manufacturing of the drug but the fact that the flu never spread, so that the outbreak that was initially identified among about 200 soldiers in Fort Dix never went anywhere. So a massive vaccination campaign was launched. About 40 million Americans were vaccinated, and yet there was no flu. Not in America, not anywhere.

So we are in a very different situation today, where we know this virus is spreading. And this vaccination, vaccine, is actually being manufactured exactly like the seasonal flu vaccine. It is showing up in the same way, and it is using the same processes and procedures.

So, in terms of the safety and efficacy, while there are clinical trials under way to determine the right dosage and really the efficacy of the vaccine, is it hitting the right target, there have been years of clinical trials and lots of data gathered on seasonal flu vac-

cines. So we are assured by the scientists that lots of steps have been taken along the way to make sure that this will be a safe procedure.

There has been more oversight than in 1976, better made somewhat differently, more oversight in testing and in quality. So we do not anticipate the same problem. And, as I say, if it were a different process than seasonal flu, we would have more concerns, but it has been similar.

Mr. WAXMAN. Thank you, Mr. Markey.

Mr. Barton.

Mr. BARTON. Madam Secretary, I may have questions for the record, but my one question is something you may not be aware. I was briefed this morning by officials at Texas A&M, which is not in my district, but it is the school that I went to. They have developed, if I understood them correctly, a vaccine that is made from hydroponic tobacco that they can produce up to 100 million doses very quickly, if necessary. Are you familiar with that, by any chance?

Secretary SEBELIUS. Mr. Barton, I don't know about that vaccine. I do know that tobacco is one of the growing agents looked at as an alternative to the egg-based vaccines. But I don't—

Mr. BARTON. If I were to get the researchers to touch base with your staff, would you all be willing to be briefed about that program?

Secretary SEBELIUS. Sure.

Mr. BARTON. Thank you, Madam Secretary. Thank you.

Mr. WAXMAN. Mr. Dingell had to leave.

Mr. Pallone.

Mr. PALLONE. Thank you.

Madam Secretary, I am concerned about emergency room hospital capacity, that type of thing. There was this report that was issued last month by the President's Council of Advisers on Science and Technology that said there could be as many as 1.8 million hospitalizations in the United States during the epidemic. And of this 1.8 million, up to 300,000 could require intensive care units. And those patients could occupy 50 to 100 percent of all ICU beds in affected areas at the peak of the epidemic.

Even without the epidemic, those ICUs nearly operate close to capacity in my district. So what, with regard to the Nation's hospitals, I mean, do we have the surge capacity to meet this potential demand? And can you tell us what steps the Department is taking to help hospitals prepare for this surge in cases?

Secretary SEBELIUS. Mr. Pallone, I think it is a very important question.

Part of the planning effort that was launched well before this virus was identified was in building surge capacity for hospitals. And billions of dollars have been invested over the last number of years. In fact, I had a chance here in D.C. To visit their five regional center sites that have been developed to get even increased capacity, and one is here in Washington, D.C., and get a sense of what they are doing. So there have been recent dollars put forward, but also dollars over the years to have that planning go on for surge capacity.

We are concerned that we also try and get information to the public as rapidly and as clearly as possible. The worst of all worlds is to have everybody show up at the hospital or come through an emergency room door. The vast majority of individuals who get H1N1 so far are not terribly ill, do not require additional treatment, and certainly don't require testing to see what kind of flu they have, so that we are trying to assure people the flu is the flu is the flu right now. CDC will continue to test through hospitals and other areas those who are getting seriously ill so we can monitor the cases. But the testing isn't required.

So we have resources to hospitals. We are helping with systems that will put in place additional medical capacity, everybody from the Medical Reserve Corps to additional personnel who we can help with assistance. So we don't think at this point that the PCAST, the Presidential Advisors scenario, is the most likely scenario to happen. We have watched the southern hemisphere very closely and what they have done for surge capacity, and, again, we will learn a lot from them. But they had no critical emergencies that weren't able to happen with shifting some space.

So I think, at this point, we are doing everything we can to get people ready and provide for some alternative, but part of it is to diminish, hopefully, the strain on hospitals by encouraging people to go to the Web site, to learn more, to call the primary care provider and urge them to just take steps that they would with regular flu.

Mr. WAXMAN. Thank you, Mr. Pallone.

Mr. Deal.

Mr. DEAL. Thank you.

I would like to ask about the distribution of the vaccine when it becomes available. Will the distribution be sent to the States and the States determine where it will go to within their States? And will there be a determination of how much goes to each State, and what will be the factors that will be looked at in determining how many doses the State would be allocated?

Secretary SEBELIUS. The distribution is based on a per-capita basis, and States absolutely develop their plans working with their emergency personnel, their local health departments, and others to determine the vaccination sites.

So, again, the distribution contract is not going to go to one central site in a State as the traditional vaccine. It is going directly to the sites that have already been predetermined. States were asked to send plans to the CDC. Part of the resources provided by Congress helped with that planning effort. And the contract will be up to 90,000 sites that have already been determined. So it will be some traditional providers offices and health clinics and hospitals, but also a number of nontraditional sites.

Mr. DEAL. Could I ask one brief question on that? That per-capita amount, is that determined by who the CDC thinks should be eligible for getting the vaccination, or just a general per-capita?

Secretary SEBELIUS. No. It is a general per-capita amount in terms of how it rolls out. We will have enough vaccine available for everyone. There is enough on order. We are looking now at the re-orders for the one dose versus two. There will be enough vaccine.

What we are concerned about is getting it to the priority populations as quickly as possible, and that is what we have asked the States to focus on, how to get pregnant women, children under the age of 24, caregivers of infants, health care workers, how to make sure that those folks get to the front of the line, if you will.

Mr. WAXMAN. Thank you, Mr. Deal.

Mr. Green.

Mr. GREEN. Thank you, Madam Secretary.

And I have read several articles in the media indicating the administration supports voluntary school-based vaccination to protect our children from the H1N1. And I am a cosponsor along with my colleague from Pennsylvania, Mr. Murphy, with a pilot program, H.R. 2596, which would allow HHS to perform a voluntary multi-State demonstration project to test the feasibility of using the Nation's elementary schools and secondary schools as influenza vaccination centers, in coordination with school nurses, school health programs and local health departments, community health providers, insurance companies, private and State insurance agencies and private insurance, and I am pleased that bill is part of H.R. 3200.

Would the administration support a voluntary, multi-State school-based seasonal influenza and H1N1 vaccination program such as was created in H.R. 2596? And let me say that that version, I know Senator Reid in the Senate is looking to do a national version of that particular provision.

Secretary SEBELIUS. Well, Mr. Green, what we are going to have is a demonstration, national demonstration project of the bill you just suggested going on in the next couple of months. And certainly our leadership at the Centers for Disease Control feel strongly that if we are successful in using schools as partners in vaccination, that that may be a great way to enhance the vaccination take-up rate going forward for seasonal flu and other issues. I am old enough that I was part of the group with the early polio vaccine, and we got that vaccine at school. That was always a partner.

And this effort, we have school districts who are very eager to be vaccination sites and are standing by to do that. So we will know a lot about your voluntary program, and we think it probably will be a very good idea.

Mr. GREEN. And being part of the sugar cube generation also, that I think this important; again, it needs to be voluntary, but we can have a great deal of more coverage by dealing with our schools, our centers in our community. And we are talking about our children.

Secretary SEBELIUS. Given the age group that this virus is targeting, we thought schools and actually daycare centers and others are very appropriate outreach sites to reach the population who we need to reach. And so, working closely with the Secretary of Education and his counterparts, superintendents, the Governors. And I think most Governors are very enthusiastic of having the schools be voluntary vaccination sites.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Green.

Mr. Murphy.

Mr. MURPHY of Pennsylvania. Thank you, Mr. Chairman. It is a pleasure to have you here, Madam Secretary. And thank you for all the work you are doing on health care, too.

As part of this, I am assuming that part of the analysis you give with regard to this virus, if it was unchecked and unabated, the impact it would have overall on America's health care system, including the cost. One of the issues this committee is trying to grapple with, as you are, is the cost of health care in America.

We have an impossible time getting information from the Congressional Budget Office on anything that has to do with prevention. Therefore, I am wondering if your office has gathered some information, analyzed that as this, for example, as these vaccinations are advanced out there earlier, what we are saving, and what is this overall savings that comes from, yes, the government is spending money to move these out there, but what is the impact on saving money and saving health care costs, and wondering if you have that information? If not, could you get it to us?

Because this committee really would like to have some of that, if I could say so, Mr. Chairman.

Secretary SEBELIUS. Mr. Murphy, I will certainly look to see what kind of cost effectiveness or strategies we have put together. I am not sure. I think we can tell you probably and gather it for you the cost of what happens with seasonal flu every year, the 200,000 hospitalizations, the 36,000 deaths, you know, what the impact is.

I would suggest, though, what we don't have is then a huge sort of social cost. One of the projections, absent a vaccine, of this virus spreading even in a relatively mild case, which would be 200,000 hospitalizations, 36,000 deaths, that is what seasonal flu looks like every year. But if you have a widespread part of the population who misses work, what the impact is then on businesses and trade, whether you can even do continuity of businesses if you have essential workers missing.

Part of the issue about schools is what happens if half the teachers are sick, or how do people go to work if half the kids are sick. So I don't know that we have added those costs, but we can try to put together some information for you about that.

Mr. MURPHY of Pennsylvania. I would appreciate it, because it is a type of modeling which we just don't have, not only in terms of scenarios of analysis, but now we have something very real that we anticipate could have an impact on workforce, education, as well as direct and indirect medical costs. And I would appreciate if you would get that to us.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Murphy.

I would call on Ms. Harman.

Ms. HARMAN. Thank you, Mr. Chairman. Thank you for holding this hearing. And thanks to a very capable former governor and a very capable team for putting in place a plan to prepare, not scare, the public. I do want to commend you on the tone of this plan, which has I think overcome a lot of the original hysteria that met the early stories about the effect of this illness. So thank you very much.

My question, really, is taking this to the next level or perhaps to the next problem. Is this basic set of protocols we now have in place and the public pitch that we are making quite effectively about this strain of flu, will this be—could this be applicable to perhaps a pandemic that is more severe, a possible biological attack in our country, or other huge health challenges that might arise? And if this set of procedures and protocols and tone that we are using is not applicable, what steps can you take now to be sure it does—we are able to adapt it to future problems we don't presently anticipate?

Secretary SEBELIUS. Well, I think that is a great question. And no question about the fact that Congress, working with the prior administration, put in place steps really that have been executed over the last 6 or 7 years of not only resources that have amplified efforts within the Department of Health and Human Services, including in our own vaccine development, operation, enhancements to NIH and Centers for Disease Control and FDA, but certainly resources at the State and local level and a lot of planning. As a former Governor, we went through pandemic planning. I never dreamed I would be sort of here with a pandemic, but we called together efforts over the years.

So I think, at a minimum, what is happening over the next several months will enhance our entire public health infrastructure. Having hospitals look at the spring where the gaps were, redouble efforts to get ready for the fall is enormously helpful how they direct resources. Looking at workforce issues, how to get vaccinations to people. A huge challenge, and it is an ongoing challenge, is just information, how to make sure folks can access timely, accurate information in a very transparent fashion, and walk that balance between complacency and panic but get people prepared and ready.

So I don't think there is any question that what we do over the next several months will significantly prepare us for whatever challenge is next. We know, whether that is a natural disaster or a manmade disaster, that that infrastructure strength, the communication strategies, working with the partnerships not only throughout government but in the private sector is enormously helpful and is exactly what you go through region by region. We just haven't done it nationally really in 40 years.

Mr. WAXMAN. Thank you, Ms. Harman. Mrs. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And, Madam Secretary, thank you for taking the time to come and talk with us today. I am pleased that you are here, and I don't envy the task in front of you. I know it is going to be a rough flu season from what we are seeing and hearing already, and I do think the free flow of information is going to be an imperative as we try to handle this with our districts, with schools, with our public events that are taking place.

You have testified before our committee twice. And the first time that you came, we were working on the health care reform bill, and now we are looking at what could end up being one of the, significant to our constituents, as the impact of that health care reform bill. This is a public health situation that we know is going to be in front of us to deal with this event.

Now, when you were here before and we talked about the issues dealing with health care, we talked a little bit about the TennCare situation. I asked you about some of the issues that were there. Your responses took a while to get to me. They were a single sentence, and that prompted another question, and I just received the response to those today. So I do thank you for getting those. But I do ask that, as we move forward, that knowing that this is going to be critical, that we have timely and accurate information, that we do have that free flow of exchange as this public health issue affects our districts, and maybe a little bit more timely than the response to the questions which was a little bit curt and inadequate and bordering on disrespectful.

I do want to say thank you for the widgets. I appreciate that those are on your Web site and that we can link to those. And I do want to ask you, as we are talking about the supplies and the supplies being let to the States, and you mentioned those that are most vulnerable to the flu, are those that—the physicians and the caregivers that are going to administer the flu shots, do they have a ranking or a priority system, or will the States work that out? Are they going to take seniors and pregnant women first? Or do you have—can you give us any guidance on what that protocol is going to be for who gets to go at the front of the line?

Secretary SEBELIUS. Well, Congresswoman, we have not tried to determine for States the most proper way to get to their target populations. We thought that was a local and regional decision. We have done a lot of work with the provider community outreach directly to OB/GYNs, outreach to primary care docs, to health clinics with the health infrastructure. But States are submitting plans based on their own determination, region by region, area by area, how best to target their vulnerable populations, and that is where the vaccine will be distributed.

Mrs. BLACKBURN. So our best response to those populations when they call our offices is, consult your local physician?

Secretary SEBELIUS. In terms of where to get the vaccine?

Mrs. BLACKBURN. And who gets priority?

Secretary SEBELIUS. Well, their local physician won't be determining who gets the priority. Again, the State health department has determined that, and that information should be available right now. There will be vaccine for everyone. It won't roll off the production line simultaneously. So the State really has predetermined where the priorities areas are and what sites should get it.

Mrs. BLACKBURN. Thank you, ma'am.

Yield back.

Mr. PALLONE [presiding]. The gentlewoman from Wisconsin, Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

Thank you, Secretary Sebelius, for your testimony. There were several very encouraging items of news in terms of the hope that one dose will be sufficient, that it will be getting the desired immune impacts within 8 to 10 days, and that you think you will have sufficient dosage for everyone starting with priority targets.

I have a few questions, very short questions related to that vaccine issue, and then in follow-up will submit some written questions on strengthening our public health system, addressing work-

force shortage issues, and technology issues. But on the vaccine, three quick questions.

Of the 195 million doses ordered, is the hope that you can reach everyone through use of the adjuvant that you have also ordered? And so tell me a little bit about the use of adjuvant during this season.

Second, I know that we had shortage of seasonal flu vaccine I think back in 2004 when there was a closure of a production facility in the U.K. We did not have a lot of domestic manufacturing capacity at that point. I believe that has changed, but I wonder if you can tell me, of the five manufacturers that we are working with for these dosages, where their facilities are located domestically versus foreign.

And then, I believe you announced in your testimony that four out of the five manufacturers have been approved today by the FDA. What is the status of the fifth? Is there any reason we should be worried?

Secretary SEBELIUS. No adjuvant is currently anticipated to be used in the United States at all. There are some backup plans if things took a terrible turn for the worse. We have never used in any widespread area an adjuvative vaccine, so the scientists strongly recommended that we not head down that path. And this time, the current purchases are likely to be enhanced to get to the point. What you have reported is the initial purchases. But as we see the take-up rate as we get the rest of the clinical trials, we will make the purchases based on what is anticipated the take-up rate is for 300 million potential users. As you know, 100 percent of the people will never get vaccinated for anything, unfortunately. We currently have five facilities. In the year that we ran out of vaccine there was one. I'm sorry. We were down to one. There were two but one was debilitated.

I can't tell you off the top of my head unfortunately exactly where they are. We will get you that information back. But what I was told yesterday by the vaccine committee is that we fully anticipate that all five will be licensed. There were some final steps needed to be taken in the final contract.

Ms. BALDWIN. Just on the domestic production and vaccines being made in America, I remember a particularly telling hearing during the last administration where if we were having a particularly virulent pandemic, the presumption was that if we weren't manufacturing it here in the U.S. it would not be available to us in the U.S., and I certainly hope that we are bolstering our domestic production of vaccine.

Secretary SEBELIUS. What I am told is it is greatly enhanced and most of it is domestic.

Ms. DEGETTE [presiding]. The gentleman from Georgia, Mr. Gingrey.

Mr. GINGREY. Madam Chairman, thank you. Madam Secretary, thank you very much for being with us again. And let me just say at the outset that your efforts, along with those of Secretary Janet Napolitano when, way back, I guess, in June, July when you were getting confirmed I think you have done a great job. No question about it. I don't think anybody could ever accuse you of being "Katrina'd" on this issue. You have gotten a lot of money appro-

priated toward this effort. And my only concern, back then, a little bit lesser now, was the issue of creating a pandemic of fear. And I mentioned that to you, and you have already addressed that in your testimony. But I want to ask you about, particularly about pregnant women because that was what I did in my previous life as an OB-GYN physician, and I have three adult daughters and a daughter-in-law and nine grandchildren, the daughter-in-law just had a baby 3 weeks ago.

Secretary SEBELIUS. Congratulations.

Mr. GINGREY. Thank you, Madam Secretary. Very concerned was she, though, about this issue of the swine flu and what should she do and that sort of thing, questions about what if she got it, what would be the risk to her, especially in the third trimester, as she was then. And what was the risk to the fetus. And I think that we need to get more information. I noticed on WebMD a recent print-out from WebMD. July 29, 2009. It says pregnant women, even if they are healthy, are at high risk of hospitalization and death from H1N1, swine flu, the CDC reports. Now, I would like for you to answer that question. Are they, I mean, I know they are at increased risk over the general population and there are certain issues with decreased lung capacity and not as vigorous immune response because of their pregnancy.

It does put them at higher risk than the general population of women. But are they at high risk of hospitalization and death? And I think the answer to that is probably no, but comment on that if you will.

Secretary SEBELIUS. Congressman, what we saw in the spring is that pregnant women constitute about 1 percent of the population. They were 6 percent of the hospitalizations and deaths that occurred, a significantly out-of-kilter population, and with no underlying health condition other than the pregnancy. So we are not talking about somebody who had diabetes going into pregnancy or someone with chronic lung condition.

Mr. GINGREY. They are definitely at higher risk than the general population, maybe as much as five times, a factor of five.

Secretary SEBELIUS. Six would be the—so, in terms of the outreach, we have tried to be—and that was not only the U.S. data, that is showing up around the world. That, again, pregnancy seems to be, in and of itself, an underlying health condition that significantly enhances the risks. So, I know that for a lot of pregnant women, I certainly did this myself, was reluctant to take anything during the term of the pregnancy. But talking to a number of OB-GYNs, looking at the data, talking to the scientists, there is a great belief that the risk of any sort of event occurring because of the vaccine far is outweighed by the risk that occurs without being vaccinated. And in your daughter's case, a new mom, babies under 6 months old are not recommended for the vaccine, so another of the target population is caregivers of infants 6 months and younger, to try and protect the infant. So you sort of have—

Mr. GINGREY. Madam Chair, I realize that my time—can I do a real quickie question? Maybe we can do a second round. I yield back. And thank you, Madam Secretary.

Ms. DEGETTE. The gentlelady from California, Ms. Matsui is recognized.

Ms. MATSUI. Thank you, Madam Chair. And thank you, Madam Secretary, for being with us today again. In States and in cities across our country, local public health departments are really getting decimated by budget cuts. In my hometown of Sacramento, the public health department has already had to cut 17 percent of its budget this year alone. These cuts mean that in my district alone, the public health department will be losing three communicable disease specialists and two microbiologists from a public health lab. This is on top of losses in field nursing staff, bioterrorism preparedness workers and other people who work behind the scenes every day testing samples for H1N1 virus and other communicable diseases. Madam Secretary, the one bright spot in these statistics I just mentioned is that my local public Health Department will be able to retain at least some positions thanks to a one-time infusion of recovery package dollars. What other plans do we have at CDC or in the department at large, to help local public health departments cope with the huge responsibilities they are going to have soon? And also too, what is the plan if the virus mutates some time soon so we have a greater pandemic emergency?

Secretary SEBELIUS. Well, Congresswoman, part of the planning effort has certainly been to recognize that the situation you are describing in California is nationwide, that public health agencies have been severely hampered by the budget cuts, so that the resources, the \$1.4 billion which was pushed out, hopefully, will help enhance that. We have also reactivated the Commissioned Corps, the emergency group of retired medical providers and volunteers who came together after 9/11. They are now about 200,000 strong throughout the country, registered in every State and kind of put them on notice to help with the vaccination efforts and have them able to be called upon. We do have our Commissioned Corps of health workers who, again, can be brought in to supplement some of the State-based efforts. But every State, as they submitted plans to the CDC, recognizes that part of the challenge in dealing with this is a restricted core of personnel, of trained personnel.

Again, we are not urging folks to continue with the testing protocol. That was important early on to determine, but right now we are just moving more to the vaccination and mitigation phases to try and just diminish the circulation of the flu. So some of the earlier activities hopefully will be shifted into the vaccination effort.

Ms. MATSUI. Thank you

Ms. DEGETTE. The gentleman from Louisiana, Mr. Scalise.

Mr. SCALISE. Thank you Madam Chair. And Secretary Sebelius, appreciate you coming before us. And since all my colleagues asked the questions that I had regarding the H1N1 situation, concerning last week's testimony, the President's address to the joint session of Congress, there were some things that he had said regarding I guess the new developments on the health care debate. Since the bill that passed out of this committee, the Congressional Budget Office testified that it would add \$239 billion to the debt, and that 8 million illegal aliens would have access to the government plan. Since the President in his statements last week said that he wouldn't sign a bill that would add to the deficit and wouldn't allow illegals, would you support changes that would be necessary to make H.R. 3200, which passed out of this committee, comply with

those two initiatives that President Obama stated before the joint session to make sure that the bill doesn't add to the deficit which, right now it would add, and then to make sure illegal aliens wouldn't have access to the government plan, which CBO testified 8 million would.

Secretary SEBELIUS. Congressman, I am pleased to have any number of discussions on health reform. And you know it is a top priority of the administration, and I would be pleased to come back and do that. The chairman asked that this hearing be on H1N1, and I would like to defer to that. I don't know—

Mr. SCALISE. We have never had the opportunity to ask you, because your only testimony to us was at a time when you had acknowledged that you hadn't looked at the details of the bill. So really, we are not going to have another opportunity that I know of to talk to you personally about the concerns we have that are in H.R. 3200.

Ms. DEGETTE. Would the gentleman yield?

Mr. SCALISE. I would yield, yes.

Ms. DEGETTE. I would advise the gentleman on behalf of the chairman that he does intend to have further discussions and meetings and hearings, and the chairman really has asked the Secretary to come and be prepared today to talk about the H1N1 situation. And I think, you know, obviously, Members are allowed to ask any questions they like, but I think the Secretary's really prepared on that topic today. And I can communicate to the chairman that he should have the Secretary back, and I know she is willing to come.

Mr. SCALISE. And I appreciate that. The problem we have is that these discussions are ongoing every day. There could be a bill on the House floor. We don't have any assurance that we are going to have a hearing before a vote occurs, and I would imagine that the Secretary is well-versed in these issues because I know you were in the joint session with us last week in the House Chamber when the President made those firm commitments. He said he would not sign a bill that added to the deficit by a dime. He said that he would not support illegals getting access to health care. And yet in the CBO testimony, the CBO sat here in the chair you are sitting in and said 8 million illegal aliens would have access to the government tape. And he said that it would add \$239 billion to the deficit, so I am sure you understand those issues.

You were there at the speech last week. I am sure you have some ideas of how we can fix that. We have got ideas of how we can fix those problems. But would you support the fixes that would be necessary to make the bill conform with what the President said before Congress.

Secretary SEBELIUS. Congressman, as a recovering legislator, I am reluctant to sign off on any legislative language. I would happy to take a look at it to see if I could support it. I certainly support what the President stated going forward, that he, I mean, he will sign or not sign a bill. I think you can actually count on him.

Mr. SCALISE. And you weren't here, I know, but we presented some of those amendments here in committee.

Secretary SEBELIUS. I have not heard the CBO's testimony

Mr. SCALISE. To specifically fix those two problems. They were voted down by this committee.

Secretary SEBELIUS. If you could send me that language I would be delighted to take a look at it.

Mr. SCALISE. I would like to get the commitment from the acting Chair that we would be able to get the Secretary back before any vote is taken on the House floor. I think that is very important that we get these questions answered.

Ms. DEGETTE. The gentleman's time has expired. I did give him extra time because of the colloquy. And I know the Chairman will work with the Secretary to make sure we can get her back here to answer any questions people may have. And with that, I will recognize the gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Ms. DeGette. As far as the last gentleman, section 246 of the bill makes it very clear illegal aliens are not available to get health care underneath H.R. 3200. And if you remember, since you sat through the markup with us, the Space amendment that SCHIP and Medicaid also made it illegal. That was unanimously adopted by the committee. But so be it. Let's move on to H1N1. Currently, States are expected to purchase a portion of the needed vaccine to protect their citizens. But it includes a 25 percent subsidy from the Federal Government. And my concern is, a lot of our States are suffering right now because of the economic downturn and may not be able to meet their obligation because of limited resources or operational constraints.

Is there some kind of a plan available under DHS to help some of these States like Michigan, California, others that are struggling? I don't want anyone not to get it because of States budget concerns.

Secretary SEBELIUS. Congressman, through the resources that Congress has provided and through the resources from the Department of Health and Human Services, the vaccine will be free, distributed to the States free. They are not expected to have a cost share. I think there has been a cost share associated with their purchases of anti virals which are in the stockpile but not with the vaccine. The vaccine is free, going to be distributed. There may be an administration fee by the provider, but there is no fee to get the vaccine.

Mr. STUPAK. What about the anti viral then?

Secretary SEBELIUS. States have purchased anti virals over the years in a stockpile. Those are being pushed out as we speak, and the department is continuing to replenish that stockpile and, if needed, will supply those to States.

Mr. STUPAK. Okay. So no State should have to worry about not being able to afford or obtain the anti viral.

Secretary SEBELIUS. That is correct. That is what we are trying to do with the resources.

Mr. STUPAK. Let me ask you right now. It is flu season now, traditional flu season and people are getting their shots. Is there some kind of waiting period they should have before they get their seasonal flu and the H1N1 flu shot?

Secretary SEBELIUS. Well, again, since we don't anticipate the real supply of H1N1 until October 15, we are saying to people get it now. It is my understanding that the clinical trials underway

right now are looking at whether or not there is any harm to simultaneously getting the flu shot, and as we get closer to October we will have that data available.

Mr. STUPAK. Let me ask you this: I am from Northern Michigan and we share a border with Canada. We go back and forth daily and we are doing a lot of preparation on this side. Is there any special considerations being given to border communities on the southern border, northern border, and what are they doing in those countries, especially as we are moving back. It seems like we have got a much more robust program here in this country. I haven't seen the same in Canada or especially Canada.

Secretary SEBELIUS. The Department of Homeland Security looked carefully at that issue and the scientific advice during the spring, and it was determined that since there was already a robust outbreaking of H1N1 already within our borders, that border closings really would harm commerce potentially, but not really help with the disease outbreak. So there is no anticipation at this point to do anything with our northern and southern borders.

Mr. STUPAK. Well, I don't want to see a border closing, but are you coordinating with our countries like Canada in particular to make sure that we are doing basically the same things, same education programs?

Secretary SEBELIUS. There definitely has been a lot of national and international discussions and particularly with Canada and Mexico. That has been underway since the early spring and will continue.

Ms. DEGETTE. The gentleman from Oregon, Mr. Walden.

Mr. WALDEN. Thank you, Madam Chair. And I appreciate the Chair's commitment to have the Secretary come back before the committee before we have a vote on the health care overhaul bill on the House floor.

Ms. DEGETTE. I don't have that power. But I am going to talk to the chairman who does have that power.

Mr. WALDEN. But if you had that power you would give us that commitment I know. I appreciate that because a lot of us share that concern. I also wanted to draw attention of the Secretary to a letter, a bipartisan letter Mr. Rogers, Mr. Gonzalez and I and others sent to you recently regarding the 2010 fee schedule on Medicare as it relates to cardiologists and oncologists and proposed cuts that could be as high as 40 percent in some codes.

If you haven't gotten that, I don't expect you to be on top of every letter that comes your direction, but if you could flag that one we would appreciate your response. I was reading a story in the paper, one of the papers coming out here yesterday from Oregon about the problem in the southern hemisphere related to H1N1 as it related to folks in the hospital trying to deal with those who were sick. And they raised the issue, in the story at least, that the hospital workers, the nurses. The doctors, others did not have a sufficient and early supply of masks and other protective equipment to prevent the spread within the hospital setting.

Are you and your folks confident that in these environments where all of us who get sick are going to rush, that there is adequate whatever we call it, the materials, the masks, the protective equipment, the whatever, so that those we rely upon for our health

care will, in and of themselves, be healthy in the process and not at unnecessary risk?

Secretary SEBELIUS. Congressman, that discussion is actively underway. And as I say, the guidance from the CDC is about to be issued. We—the scientists have not been in complete agreement about the right protocol, particularly with the use of respirators going forward, so the request went to the Institute of Medicine to do a sort of rapid response study. They came back with a protocol which I would suggest is the ideal case scenario, a respirator per provider for every patient seen. There are not adequate supplies to follow that protocol.

Mr. WALDEN. So one new respirator for every patient? Every time you see a patient the doctor or nurse would have to put on a new respirator?

Secretary SEBELIUS. That is what the IOM suggested. And the stockpiles in the country in the manufacturing capacity would not allow us to follow that protocol, so right now, we are working actively with OSHA and CDC and the health care providers to develop a protocol that actually is more in fitting with what the supply looks like, because IOM was told not to take into account what is available or what could be available over the next 6 months. Unfortunately, the reality is we have got to look at what is available. So that discussion is actively underway as we speak.

Mr. WALDEN. And on that point, the Vice President had said at one point, and I think he probably regretted it, that he wouldn't put his family on an airplane, et cetera. I was on an airplane yesterday and the person behind me was coughing, and I am convinced was taking no precautions about the emissions. I directed the air filter to flow backwards. What advice and counsel do you have for all of us about—I realize we ought to cover our mouths and all. But if you are on the other side of that, should we be wearing those kinds of protective face masks when the outbreak comes? Is it going to be helpful or is that just overboard?

Secretary SEBELIUS. What I have been told by the scientists is that probably not; masks are really not—if you are in a caregiver capacity in a home situation, coming in close contact, it may provide some protection. But basically, no. And if this continues to present much like seasonal flu, you know, a number of people get hospitalized with seasonal flu every year, we don't have that kind of rigid fitted mask protocol underway. So we are trying to balance safety and security. What is most alarming, and I think all of you would be great to help with, health care workers right now don't get vaccinated. Less than 50 percent of health care workers ever get vaccinated for seasonal flu, even though they are a priority group for H1N1 we are afraid that take up rate may be the same.

So I would say that is step one is to take advantage of the protection that is there with the vaccination, both with seasonal flu and then with the H1N1 vaccine because they are at the front of the line and we would hope that they would do that.

Ms. DEGETTE. The gentlelady from the Virgin Islands, Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you, Madam Chair, and thank you, Madam Secretary, for being here with us again today. Individuals 25 to 64, with underlying medical conditions such as asthma, dia-

betes and compromised immune systems are one of the target groups for the forthcoming vaccine. As you know, racial and ethnic minorities are disproportionately affected by all of these chronic diseases and more. Are your clinical trials, are the people in the clinical trials diverse? And what outreach is being, has been done that is culturally and linguistically appropriate to reach these sometimes hard to reach populations, often with poor public health infrastructure, to ensure that they get the adequate prevention treatment and so forth?

Secretary SEBELIUS. The clinical trials, it is my understanding, are diverse, and we are aware of the concerns that have been raised in the past. Again, a lot of the trials underway are specifically about dosage because the clinical trials have been done for years on seasonal flu, which deal a lot with outcomes. The challenge of communication and outreach strategies is one that we are taking very seriously. So traditional media is being used, non traditional media, ethnic specific media, so translating everything on the Web site into Spanish, into Vietnamese automatically, and then other languages can be requested as needed, looking at a variety of media outreach that reach non traditional community, working with the faith-based and community outreach programs.

Mrs. CHRISTENSEN. Okay, because a lot of these communities also are not connected.

Secretary SEBELIUS. Right. So we are using the faith-based groups to connect. For the younger population it is an equal challenge. So Facebook and Twitter and ESPN has agreed to become a partner for the scrolls they put across college dorms. We have a PSA contest on YouTube in terms of trying to get to people. So we are really trying to maximize. And special outreach to minority providers and health clinics, knowing that they are likely to see a lot of folks with underlying health conditions who need to understand how serious the risk is for this virus where nobody has an immunity.

Mrs. CHRISTENSEN. Thank you, Madam Chair.

Ms. DEGETTE. Dr. Burgess.

Mr. BURGESS. Thank you, Madam Chairman. Secretary Sebelius, I guess I should point out, for health care providers of my age, we were, most of us, in the midst of our training during the last swine flu outbreak during the Ford administration, and remember very vividly some of the problems encountered. So as information is gathered as to the safety of this vaccine, I think it is extremely important to get that out and get it disseminated. We had a big problem in Fort Worth, Texas, with the first round of this in the spring. The school district closed, and I would say, I think appropriately so, but they received a great deal of criticism. The school district across the Trinity River in Dallas did not close and obviously there were a lot of comparisons made between the decisions of the two school districts.

Still, I think Superintendent Johnson did exactly as she should have when she was confronted with a large number of suspected cases, and could not get information back in a timely fashion from the CDC as far as recommendations. To prevent that type of difficulty from occurring again in the fall, I asked, and your department was kind to respond and we did a seminar on H1N1 in Fort

Worth this past August, and we had representatives not just from HHS but from DHS and CDC as well as the State and county health departments. The impression I got from that day's discussion was that the decisions about closure or non closure of schools would be left up to the local authorities.

But then seems like less than 48 hours later, the guidelines coming down that your Department would decide when schools should close. So I would just simply ask the question, who is going to be making these decisions? Is it the local folks? Is it you? Is it Secretary Duncan from the Education Department? Who is going to be making these decisions? Because it obviously impacts not just the school year of the kids, the learning curricula of the children, but in Texas, of course, we have, like many other States, we have a testing protocol under No Child Left Behind, and we don't want to see our school districts unnecessarily penalized, but we don't want to see our school districts take unnecessary risks with the children's safety.

Secretary SEBELIUS. School closure both in the spring and now, moving forward, are always a local decision. That is made at the local level. Having said that, the Centers for Disease Control has issued school guidance, and it is just that, guidance, what they are seeing from the science and what they would recommend. And at this point, the guidance is different than what was being discussed this spring, in part because we didn't know how lethal the disease would be, and it was very unclear whether or not sending your child to school could, indeed, cause much more serious harm. Now, we have learned a lot over the spring and summer. I have learned a lot from the southern hemisphere, and so the guidance issued by the Centers for Disease Control and put forward by Secretary Duncan and others in outreach to schools across this country is really leaning towards keeping schools open, having protocols available in the school to deal with outbreaks, isolating kids, sending them home, trying to make sure that teachers and students are vaccinated, but keeping schools open. That could change. The flu could change. We are watching it very closely. But the school decision will continue to be made at the local level.

Ms. DEGETTE. The gentlelady from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Madam Chair. And thank you, Madam Secretary, for all of your efforts in educating the country on H1N1. I am not unlike the millions of parents across the country that have been, we have been teaching our kids, you know, wash your hands all the time, cover your cough. We haven't altered substantially the way we live our lives. So this Saturday we had a dozen 9- and 10-year olds over for my 10-year old daughter's birthday party. And they did not protest when I had them wash their hands before snacks, wash their hands again before cake, wash their hands again towards the end of the evening. But wouldn't you know it, that one of my daughter's friends got sick at the party. And her mother called me yesterday and, sure enough, it is H1N1.

Now, of course she is staying home from school, and there are a number of kids out this week. But parents want to know, and your guidance is very good. The CDC guidance is very good. But the question I hear a lot from neighbors and other parents, you know, how long does the child have to stay out of school? And this

guidance, it says that a person who has it can infect others up to 5 to 7 days after getting sick. But it also says that it is okay to go back to school 24 hours after the fever is gone. So what is the most consistent answer I can give to parents of a child that has just come down with H1N1?

Secretary SEBELIUS. I think the scientists are saying 24 hours after the fever is gone, without any medication to lessen the fever. And the problem is that for the kind of average, maybe five to 7 days, a lot of kids it may be two to 3 days and then 24 hours later they are ready to go. So it is hard to give you a date specific. I think it is a child-to-child situation. Some have more serious cases. Some have lesser cases. But 24 hours without any medication since the time you have had a fever they say is safe to go back.

Ms. CASTOR. Even though they could still infect other kids a few days after that?

Secretary SEBELIUS. The doctor is telling me what they are seeing is that the vast majority can't infect at that point, and that is why they have arrived at this 24 hours after the fever.

Ms. CASTOR. Terrific. Okay. Thank you very much.

Ms. DEGETTE. The gentleman from Iowa, Mr. Braley.

Mr. BRALEY. Thank you Madam Secretary for joining us. And I think everyone is concerned about the public health implications, but there are some unintended consequences of the public health campaign that I think we also need to be conscious of. And one of the concerns that I expressed at an earlier hearing when we had representatives of the CDC here, was the decision to refer to this virus generically as swine flu, despite its origins, and the enormous negative impact it has had on our pork industry because of a lot of myths and misconceptions.

And yet I know that public health officials have determined that it is easier to get college students' attention about the need for getting prepared and exercising precaution when you refer to it by the name swine flu, as opposed to H1N1. So we have got these conflicting things going on. And one of the things that I am very concerned about is how we balance those interests, given the enormous economic implications to states like mine, when people have half truths and misinformation and yet the reports that I have seen as recently as this weekend in The Washington Post, "Sebelius encouraging news regarding swine flu vaccine, their choice, not yours." New York Times, "One vaccine shot seen as protective for swine flu." So how can we address the enormous public health challenge that we are all legitimately concerned about, and still address this enormous negative economic impact that it has had on our pork industry.

Secretary SEBELIUS. Congressman, that is a great question, and I can tell you it is one that we are wrestling with a lot. I hope never out of my mouth have you ever heard that other term, or out of CDC or NIH or the FDA. And I have taken it on as a bit of a personal mission when I am with media, reporters and being interviewed to correct them and ask that they please use the terminology that is accurate, because there is a lot of misinformation and we have, on several occasions, and I join with Secretary Vilsack and again the other side of this, assuring people that noth-

ing at all in this flu is related to eating pork. You can't get it from pork. There is no crossover.

But you are absolutely right. I know there has been over a billion dollars, if I understand it, and that may be very underestimated at this point. And we would welcome any suggestions. I think it is easier to do so they do it. But I would agree it is a huge, and it has an enormous economic impact. I have even suggested, and maybe you want to conduct your own media campaign, that maybe we should challenge people to use the right terminology. You could send them a pork chop every time they use the right term, but take it away.

Mr. BRALEY. Or they could come to the Congressional rack of pork reception tomorrow night in the Longworth.

Ms. DEGETTE. The Chair now recognizes the gentlelady from California, Mrs. Capps.

Mrs. CAPPS. Thank you, Madam Chairman. Secretary Sebelius, you have been very patient this afternoon and I hope that this won't take the full 5 minutes. But I want to thank you and I want the record to note that you really did hit the ground running. After your confirmation you had a lot of issues on our plate. I have seen you everywhere on both health care reform in very positive ways and also on this topic. And I am referring to a bicameral briefing that you and several Secretaries presented to Members of Congress. It was midsummer, if I am not mistaken, in between, sort of like the spring outbreak. And my question then was to acknowledge the role that a school nurse played in the first case in the Bronx that resulted in massive school closures. And as a former school nurse, I sort of emphasized, I know why districts close their schools, but it is chaotic when it happens. Parents have to—parents don't have back up plans a lot of times and they miss work and all the things that ensue and you find kids in the mall and all kinds of places when that happens.

So now I am pleased to follow the chain of questions that have been asked. And I will, since this topic has come up, I am interested in the nuances now that have occurred watching the epidemic as it has proceeded, and now as this school season hit, and many of the campuses, a little older teenagers, young adults and that captive environment which can be dealt with somewhat differently because they are not so dependent on parents and jobs and things.

But still, I would like to have you address just for a minute for the record, because the relationship between your department and CDC and the local communities is very specific and I think, unlike many other departments, with very direct communication, and outline for us a few of the ways that you have been working with local health departments as they then are partners with local school districts to formulate and get the right kind of advice tailored to different parts of the country, so that we behave in the proper way as this comes out, both in terms of immunizations, vaccination plan, and also what to do when, like my colleague, Kathy Castor's own child's daughter's friend, you know, what, how do you respond?

Secretary SEBELIUS. Well, I think that is a great question. Since the spring I would say the three cabinet secretaries who have been sort of at the forefront of this effort are Secretary Napolitano with the Homeland Security and government coordination work, but

Secretary Duncan from the Department of Education, because, given the age group of the target population, that has been a real effort. And he has regular calls, regular outreach with superintendents and principals and teachers all throughout. The CDC has specific guidance that is on the flu.gov Web site at which we have asked schools to download and take a look at.

And what happened to really change the school advice, the guidance that was out, from leaning toward closing schools to leaning toward keeping them open, was first realizing that it would not present itself as a more lethal disease. Secondly, recognizing that there are a whole series of other health impacts for children who are sent home, missing often school breakfast and lunch which has a nutritional impact, being in an unsafe environment, which has a significant impact if there is nobody home to take care of them. And on balance, given the way the disease was presenting, it seemed wiser that the guidance be toward keeping schools open, but trying to isolate and send home sick children, urging parents to keep them home in the first place, but if they show up at school, send them back home, isolate them until you can find a parent. I think that this may change as we go along.

And what we know is that what we saw this spring there are going to be some areas of the country, some cities that have lots of cases like New York did in the spring. There have going to be others relatively close by that may have very few cases, so it is impossible to have a national protocol, and school decisions will continue to be very local. But that outreach, we do an every 2-week call; we have had a big flu summit and asked governors to send in their education secretaries, their homeland security, their emergency planner, their health, so the school folks have been part of this conversation in a very robust way from day one.

Mrs. CAPPS. Thank you very much.

Ms. DEGETTE. The gentleman from Georgia, Mr. Barrow.

Mr. BARROW. Madam Secretary, thank you for your service, and thank you for coming here today and sharing with us on this. My name is John Barrow. I represent Savannah, Georgia, Augusta, Georgia and all points in between. Our prior response to seasonal flu might not be the best guide for what we should do, but it is probably a pretty good guide as to what we will do unless we do something different. And I am given to understand that less than half the targeted populations we reach out to on a regular seasonal basis get the vaccine that is suited for that situation. And so we have got to anticipate, unless we do something different we are going to have a similar success rate in response to this new threat. I understand that one of the targeted populations we are trying to reach in response to the H1N1 is the population of children and young adults 6 months to 24 years of age.

Kind of sets it apart a little bit perhaps from the seasonal flu. I am having a telephone conference call this afternoon with a pretty influential bunch of folks with respect to that targeted population. My public health expert, Ms. Betty Dixon, is with me today, and she is going to be participating in this conference. We are going to be talking with every superintendent, every assistant superintendent, the principals from every elementary, middle and

high school in the district, and the deans of students at many of the 18 institutions of higher learning that we have in my district.

So my question to you is sort of a general one. What can we do, what can we say in the course of that conversation, for that captive and very influential audience to help them get a higher success rate in reaching the targeted population they have some influence over than we have been able to do so far with respect to seasonal flu? What can we tell them that we are not already telling them?

Secretary SEBELIUS. Well, I think that you can tell them that we know that they have the target population, and that if it is nothing more than just lots of folks getting the flu, that has a huge disruptive factor, so having, minimizing the spread right now, and then vaccinating we know is the best defense against the flu spread. We do have some great information on the Web site. I would suggest that maybe if you put the widget on your Web site and urge them to come and download, you know, we have got parent tool kits and information for teachers.

Mr. BARROW. This is how to. What can we tell them as to why to? What can we tell them to motivate them to make a greater effort than has been made in the past?

Secretary SEBELIUS. Well, they can keep people from being hospitalized and dying. If 36,000 children in this country die from this flu, I would suggest it will have a huge impact on communities around the country. And that is the average death rate for seasonal flu. So even if it is just like regular flu, given the population that, basically, they are responsible for, that is what it looks like. And so I think you need to convince them even the regular flu is particularly, is different because it is kids and it is young adults. They have no immunity to this whatsoever.

So anybody with underlying health conditions is really at far higher risk. And I think just getting their hands around 200,000 hospitalizations year in, year out with seasonal flu, 36,000 deaths, that is what the profile looks like, but typically, because of the age of the population who is typically affected and because of their frail condition I am not sure it has the kind of societal impact, community impact. There is, Dr. Schuchat tells me, a new tool kit for school immunization that will be on-line, well, that went online on the 13th.

Mr. BARROW. Available at?

Secretary SEBELIUS. But I just think, you know, getting their attention about how even mild flu is very serious. People die, people get very sick. And anything we can do to prevent that, really, we need them to do.

Mr. BARROW. Thank you.

Ms. DEGETTE. Mr. Pitts is now recognized for 3 minutes.

Mr. PITTS. Thank you, Madam Chairman. Madam Secretary, what geographic regions of the country does HHS expect to be hit the hardest by the H1N1 strain during the winter flu season? Is there any projections that your Department has made? It seems like the south has reported an increase in cases. That might be just because they start school earlier in the south. I don't know. Do you have any ideas on that?

Secretary SEBELIUS. We really, Congressman, saw very scattered cases throughout the country over the spring, during the outbreak.

There was no one region, one area isolated. We think that the rise in cases in the southeast, which showed up first, is because of the fact that they did start school earlier and kids came together earlier. We are starting to see cases though, spread, Oregon, Kansas, I mean so it is beginning to spread out as people come back to school, as colleges re-engage. So we don't have any information that gives us kind of a regional or local look at what is likely to be more of an outbreak, which is why it is so important that we keep watching it very closely and monitoring what is happening on the local level.

Mr. PITTS. Have all of the States implemented what you would consider adequate stay preparedness plans for this?

Secretary SEBELIUS. Well, Congressman, all States were required in order to access the funding available to help them implement, they were all required to submit plans. I think that the assessment was that many States are ready in a very robust way. Others were in okay shape, and some really needed a lot of help. We have provided technical assistant, support, on the ground surveillance. We also had teams that did site visits to try and verify that what was coming in in the written plan was actually accurate in terms of what was available. So we are trying to provide resources, help, support, and get States ready to go, because a lot of this will have to be, the shots in the arm are really going to be a State and local effort.

Mr. PITTS. Will there be enough vaccine for all of the States to have?

Secretary SEBELIUS. Yes.

Mr. PITTS. And are they adequately stockpiled now?

Secretary SEBELIUS. Well, the vaccine isn't stockpiled because it hasn't been produced, so that the vaccine, we hope, will begin to be widely available on the 15th of October, which is the target date. We anticipate having some early supplies as early as 10 days before that and it will be distributed as soon as it comes off the production lines.

Mr. PITTS. Okay. My time is up. Thank you.

Ms. DEGETTE. The gentlelady from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Madam Secretary. It is wonderful to see you. And I want to salute you for your very steady, strong, sensible leadership. Whether you are testifying here or I see and hear you on whatever TV program, I think that you speak very clearly to the American people, and I think that we all appreciate that. There are, what, five companies that are making the—responsible for the—

Secretary SEBELIUS. Five manufacturers.

Ms. ESHOO. Making the vaccine. One of them is MedImmune, and they are in my Congressional district. Theirs is a nasal spray, while the others are the traditional injections. What I would like to know is, is this something that would be better used for children? Are you going to make a choice relative to that? Does it really matter? Is it good for adults? Is it as good for children? And how do you think that it might affect the voluntary compliance rate for those opting to get the H1N1 vaccine? And what I am going to do, since we only can have one question, is to follow up on some fund-

ing questions relative to this whole thing. But I will just stick with that for now.

Secretary SEBELIUS. What Dr. Schuchat tells me is that it isn't, the nasal mist is not recommended for the youngest children.

Ms. ESHOO. Oh, it is not?

Secretary SEBELIUS. Two to 49 seems to be the target population, as long as they don't have underlying health conditions. So, again, some of the highest risk children would not be recommended to get the nasal mist instead. But it certainly is a viable alternative for a lot of population.

Ms. ESHOO. Good. Well, thank you again for what I think is really special and highly needed leadership. We are proud of you. Thank you.

Ms. DEGETTE. The gentleman from—Mr. Shimkus for questions.

Mr. SHIMKUS. Yes, I just want to—again, I was here for some of the opening statements. Welcome, Madam Secretary here. Education, education, education is the key, especially for a couple of things. Obviously, just you know, passing of the food and the germs and all this other stuff. But also, we already have a run on hospitals, emergency rooms with people who are, in essence, just having the everyday flu-like concerns. And I know that we have to do a good job calming the public so that they use the services when they are needed but don't over-utilize them when they are not. And I don't know how you—I am not a health practitioner so I don't know how you gauge that, but I do think that education is the key.

And I would agree with my friend, Anna Eshoo, the calming presence that your position is going to be required to hold especially as we come into this season of the year. I have three small—well, they are not small. I have a junior, a freshman and a fourth grader, so we are all concerned when they start closing down schools and maybe before they should and so I just want to encourage you. I don't have any answers. I would like to yield the rest of my time to Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Shimkus. I just had a follow-up question that came up. One of the questions down here was on the funding issue. And there was a little over \$7.5 billion for the H1N1 flu in the stimulus bill; is that correct?

Secretary SEBELIUS. That is correct.

Mr. BURGESS. So have these funds been disbursed? Are they readily available to you? Are they still being held somewhere in the stimulus pot? Or do you have all of the money you need? Do you have the funding that you need at this point?

Secretary SEBELIUS. At this point, Congressman, we do. We are drawing that money down. We have made a couple of draw downs to buy vaccine and get ready to distribute it. Now that we have a little more clinical data, we are likely to have a more accurate picture of how much vaccine we are going to need. We have used some of it to replenish the stock piles of anti virals that we sent to the States to help, as I say, about a billion four so far has gone out to States and hospitals for surge capacity. We are buying protective equipment. So we are trying to do a step at a time. And at this point, the funding provided is extraordinary helpful, and we—

Mr. BURGESS. So at the present time you don't anticipate having additional funding requirements that we will be asked to deal with?

Secretary SEBELIUS. At this point I don't have them. Again, we are watching this very closely. If this turns more lethal, if it begins to present itself in a different way, if, you know, things change and the surge capacity wrong, at this point I think we are on target, but it is a day-by-day operation.

Mr. BURGESS. Let me just ask you one other follow up for Mr. Walden. He, of course, alluded to the fact that we have got, and this is off the subject of the avian flu, but it is so important because in 3 months' time, cardiologists, oncologists and, indeed, all physicians who practice under the Medicare system are going to receive a 21 percent reduction if Congress doesn't do something. Now, we still have a vacancy at the head of the Center for Medicaid and Medicare Services, is that not correct?

Secretary SEBELIUS. That is correct currently.

Mr. BURGESS. How close are we to filling that position?

Secretary SEBELIUS. We hope very close.

Mr. BURGESS. This is a critical issue, and I would encourage you to get that done. And again, Congress has an obligation to its provider community to step up and do the right thing as far as the sustainable growth rate formula, but it is very, very difficult to even get an answer out of the Center for Medicare and Medicaid Services right now without anyone at the helm.

Secretary SEBELIUS. We do have, as you probably know, Congressman, a new leader for the Medicare and a new leader for Medicaid who are in place, John Blum and Cindy Mann, and they are doing a spectacular job. But I share your concern about the leadership, and we are very close.

Ms. DEGETTE. Thank you. The Chair now recognizes Mr. Sarbanes from Maryland for 3 minutes.

Mr. SARBANES. Thank you, Madam Chair. Thanks so much for spending all this time with us. You are close to the end here. I know we are all very grateful that you are in this position at this time because you have handled things so superbly, and I think with a sense of calm that is contagious in a good way. So just don't get the flu.

Secretary SEBELIUS. Well, maybe I can walk people through it a step at a time.

Mr. SARBANES. Right, exactly. I think you answered the first question I was going to ask, which is the lethality, the judgment about how lethal this thing can be could change. I know that initially there was concern that it be more lethal than it has turned out to be but you just alluded to the fact that it could turn back in the other direction; is that right?

Secretary SEBELIUS. That is correct.

Mr. SARBANES. Okay. And I was just curious. I imagine you have ways of judging the success of our overall effort to contain this pandemic as we go forward, which would include clearly looking at the number of lives lost in the process. I would imagine how well we are doing addressing these high risk groups out of the gate, what is happening in particular communities in terms of the modeling that that suggests. I wonder if you could just point to any other

sort of prime indicators you are going to be looking at, and also comment on whether you anticipate that there will be kind of pivot points along the way, where we may need to regroup and move in a kind of different direction than we are anticipating right now.

Secretary SEBELIUS. Great questions. I think that one of the lessons learned from the '76 experts was that there do need to be points along the way that you make sure we are still on track because, as people keep telling me, the predictable fact about the flu is it is unpredictable. It could change. So monitoring very closely what we are seeing and part of the lethality is really watching what happens when H1N1 begins to mix with the seasonal flu viruses. What we saw in the southern hemisphere is still encouraging, that it did not mutate into a significantly more dangerous virus. That is good news. But can that happen next month, the following month? You bet.

So there will be continued monitoring and testing, particularly the more serious cases when they come to the hospital, and making sure that we know we are on target. The vaccine seems to be exactly what it should be to target H1N1. The robust response is great. The limited time that it is taking is very good. And the fact that one dose seems to actually produce a good immunity response. All of that is very good news. But I think watching the outbreak, certainly monitoring very carefully hospital capacity, how to deal with the more seriously ill folks, we really worry about, right now, anti viral treatments. We are, unfortunately, seeing many providers give anti virals prophylactically, so suggesting that people would fill a prescription and take it to prevent the flu.

What our scientists tell us is exactly that is the wrong direction because it actually lowers people's immune response. It could make them far sicker in the long run, and it will draw down our anti viral stockpile. So that is a particular concern that we put out new anti viral guidance. We are doing some aggressive outreach to the provider communities trying to remind them that that really is a strategy which is very counter productive in the long run. So I don't know what is the next challenge like that. But we will have them.

Ms. DEGETTE. Thank you. The gentleman from Washington, Mr. Inslee.

Mr. INSLEE. Thank you. Do you have any issues as far as prioritization, geographically or otherwise, when we have a vaccine become available? Could you identify those issues that the public may be interested in or we may be interested?

Secretary SEBELIUS. Well, there is certainly no geographic priority. We have asked the States to present plans, which they have. And the community on immunizations, I mean, the Committee on Immunizations has developed a priority list based on the science, basically five categories of people who total about 160 million Americans, pregnant women, caregivers of infants under the age of 6 months, children 6 months to 24, particularly those with underlying health conditions, adults 24 and up with underlying health conditions and health care workers.

And that is about 160 million people. We said to States, figure out how to get those folks to the front of the line. What are the best outreach opportunities, and that is where the vaccine will

flow. There will be about 90,000 sites that will receive vaccine based on the State plans that we have. So we are not targeting folk. We are not making, we are just trying to use our bully pulpit in the communication to say to those target populations, you really need to think about this. And one of the challenges, as you all know, will be to get parents ready to sign consent forms for kids, so information is going home in schools to say to parents, this will be available we think by the middle of October. But here is what the concept form is going to look like. Think about it. Get ready to sign it. So if we have a vaccination effort at your school, your child actually can be vaccinated.

Mr. INSLEE. I heard a, to me, sort of surprising comment by an ER room doc last week when I was home suggesting that one of the problems may be overutilization of our ER room services associated with this, that they are concerned about people coming in.

Secretary SEBELIUS. The worried well.

Mr. INSLEE. The worried well. And we understand worry and we would all like to be well. You know, just to the extent we disseminate information, what would you tell us all? And you may have already talked about this, but it bears repeating, I think, in that regard. When should people really feel compelled to go into the ER room as opposed to calling your physician first or nurse?

Secretary SEBELIUS. Well, I would even back it up a step; that if someone comes down with the flu, either an adult or a child, and there are no serious consequences more than a fever and aches and pains, go to bed, chicken soup, stay away from other folks. I am not sure you need to take additional steps. Anyone with underlying health conditions, asthma, diabetes, neuromuscular disorders, should contact a physician on presentation of flu-like symptoms. That is the population for anti virals. That is who needs Tamiflu fairly quickly, or Relenza. And then certainly anybody who then is more seriously ill or a child who becomes lethargic or, you know, there are a series of again, tips on the Web site. You take the next step. But it is really a triage. People who just come down with the flu probably don't need to call a doctor or have an anti viral or certainly not go to the hospital.

Mr. INSLEE. Thank you. Thanks for your work.

Ms. DEGETTE. Thank you very much. The Chair will now recognize herself for, I think, the last questioning. And I want to thank you Madam Secretary and also the CDC staff again, for the remarkable job all of you have done in getting the information out, in tamping down panic. I think that the public health effort is going really well here. Several times in your testimony, you referred to the concern that we have that this virus could mutate. We hope that it won't. It didn't in the southern hemisphere. But we have had a number of hearings in this committee over the years about various flu strains. And, of course, the avian flu has been a big concern in this committee over the years. I am wondering, first of all, how are we coming in developing a cell-based vaccine, rather than the traditional egg-based vaccine that we are still using for development of the H1N1 vaccine?

Secretary SEBELIUS. My understanding, Congresswoman, is we are still a couple of years away from the different technology. Cell-based, I think, is the sort of high tech version. Actually tobacco

growing is also regarded by folks as sort of promising, but we are not close to, I mean the last time I talked to folks it is probably still a couple of years away.

Ms. DEGETTE. But are we making a real effort towards these other vaccines? Because part of the problem we have, and part of our concern last spring with H1N1, was that we might not be able to identify the strain quickly enough to make a vaccination because we do have to produce the eggs.

Secretary SEBELIUS. Well, that, investing in developing a faster newer technology is still very much underway. It is part of what we are doing on an ongoing basis. So we are trying to accelerate the work. But it is not imminent that we will have another methodology for developing a vaccine than the egg-based methodology.

Ms. DEGETTE. I think you can expect more hearings on this topic, and we are going to also ask some of the experts for the NIH and CDC because what could happen is if we have an avian flu or some other kind of epidemic that is as fast moving as this H1N1 then we would have really been in trouble.

Secretary SEBELIUS. Well, I think you are absolutely right. And I think this is a, hopefully it won't be more than this, but a sort of wake up call that up till now it has been hypothetical. It is now very real and we are watching a disease spread enormously quickly, not only in this country but it has now presented in about 120 countries around the world. So we know this is real.

Ms. DEGETTE. Right. And with great rapidity. What are we doing for people who are allergic to the egg-based vaccines with the H1N1 vaccine? Can they just not get it?

Secretary SEBELIUS. I was just told that they can not get it. But vaccinating those around them is the best way to help to protect.

Ms. DEGETTE. Now, what is its status right now of H1N1, the avian flu virus? Is it still lurking out there in parts of the world.

Secretary SEBELIUS. It is still there. It is continuing to cause disease, but it isn't being transmitted very easily.

Ms. DEGETTE. I have a last question. Ms. Castor has the 9 and 10-year-olds at home. I have the college student. And the college students now, this was like when our kids were little and we had the chicken pox parties, the college students are now having flu parties where they are trying to purposefully get—I don't want to know exactly how they are trying to share the virus, but they are.

Secretary SEBELIUS. Sneezing on each other.

Ms. DEGETTE. And so she and her friends asked me to ask you, what is your advice about this practice of these flu parties?

Secretary SEBELIUS. I would say it is a pretty bad idea.

Ms. DEGETTE. That was my motherly advice, too. So I just want to know from the expert.

Secretary SEBELIUS. And I am sure they won't listen any more to me than to you. But, again, this is a serious disease. Most people, getting the flu is a problem. You miss work, you miss—but for a lot of people, this is deadly. And so doing anything to transmit the disease, and particularly I would say to our young and people who think they are invincible, a number of the younger folks may have health conditions that they are not even aware of and they really could be in serious trouble by voluntarily getting this flu.

Ms. DEGETTE. So, I mean, in all seriousness, the advice of the CDC and everybody else is that, for everyone, they should be taking hand-washing protocols, doing their best if they feel sick to isolate themselves to others and to keep this from spreading.

Secretary SEBELIUS. Absolutely. And 6- to 24-year-olds, including the college age group, are in the first priority to get vaccinated. That is the best way on a college campus and a dorm to keep kids safe. We have done a lot of outreach to college presidents to say, find a dorm or find an isolation room. You can't often send kids who are away from school home, but isolating them from one another. Don't have them go to the school cafeteria to get meals. Figure out a way to get the meals. Keep them away from roommates. Because what we know is this spreads very, very rapidly.

Ms. DEGETTE. And when the vaccine does come out, the college students should all go get vaccinated.

Secretary SEBELIUS. Exactly.

Ms. DEGETTE. Thank you so much. We have ended under time, and we are very appreciative of your testimony today. We look forward to seeing you again.

Secretary SEBELIUS. Glad to be here.

Ms. DEGETTE. Before I adjourn the hearing, let me say the record will stay open for 7 days for members to submit additional questions.

[Whereupon, at 3:16 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement
Congressman Greg Walden
Full Committee Hearing on H1N1 Flu
September 15, 2009

Welcome today to the Energy and Commerce Committee, Secretary Sebelius. H1N1 flu and seasonal flu is a topic that is on the minds of everyone's constituents. I'm eager to hear your assessment of our nation's preparedness to address the myriad challenges a widespread outbreak of either or both of these flu strains will present.

I'm also coming at the as a parent whose son came down with the flu -- not sure which strain -- a few weeks ago shortly after returning to college for the falls semester. His small campus of a few thousand

students has seen approximately 100 cases of H1N1. The University has planned for several years for pandemic influenza and they've activated their response plan.

I'm encouraged by how much medical researchers have learned about H1N1, how it behaves and how it reacts to antiviral drugs. Additionally, HHS's declaration of a public health emergency with respect to H1N1 in the Spring of this year triggered important protections that have allowed vaccine manufacturers to do what they do best and ramp up production of antiviral drugs. Without these protections, I question

if we would be even close to having the antiviral drugs and diagnostic tests needed to address the President's Council (of Advisors on Science and Technology) estimates that 30 percent to 50 percent of the U.S. population could be infected by a fall resurgence of H1N1.

Local, state, and federal health officials along with we here in Congress have our work cut out for us in helping Americans differentiate between at-risk populations for seasonal vs. H1N1 flu, helping them understand that a flu shot for one strain doesn't help protect you against the other.

and that old-fashioned soap and water is among the best forms of protection against catching the flu.

We've also got our work cut out for us in the realm of health reform. There is great unrest among my constituents about how Congress will reform our nation's health care system.

Secretary Sebelius, it's my hope that you will come back to the full Committee in the near future to give all of us an opportunity to ask questions, share ideas and flesh out concepts as they relate to health care reform.

The principles laid out by the President—most specifically that he would not sign a bill that adds a dime to the deficit—are in direct contradiction with the legislation passed out of this committee at the end of July, which CBO said would increase the deficit by \$239. So I hope that at some point the majority leadership would invite everyone to the table to hammer out a serious, bipartisan measure that lives up to the President’s vision in that regard, and doesn’t jeopardize the private coverage that 67 percent of Americans have.

Thank you and I yield back the balance of
my time but not before I extend Happy
Birthday wishes to Ranking Member Barton.

STATEMENT OF REPRESENTATIVE EDWARD MARKEY (D-MA)
ENERGY AND COMMERCE COMMITTEE
HEARING ON PANDEMIC FLU PREPAREDNESS
SEPTEMBER 15, 2009

This year, American children across the country are returning to school after summer break with more to worry about than just their homework. The H1N1 influenza virus, which swept across the country and the world with alarming speed earlier this year, poses a threat to the health and well being of all Americans, from students to seniors.

In my home state of Massachusetts, the H1N1 virus has infected 1,400 individuals, more than half of which were children under 18 years of age. Sadly, this virus has also caused 11 deaths in my state and nearly 600 deaths nationwide.

In 2005, when a new strain of avian flu was found to be spreading across various parts of the world, our nation was severely unprepared. Federal agencies were caught off guard, as they were still developing preparedness plans and struggled to coordinate their efforts, all while hampered by inadequate funding levels.

In the 109th Congress, I introduced the Global Trade Requires Unmitigated Truth in Health, or TRUTH, Act, to ensure that we address the global aspect of health risks in this era of unprecedented international commerce and travel. As our world becomes more and more interconnected, we also see an increase in harmful and dangerous diseases flying across our borders.

We all know that pigs can't fly, but swine flu can. It can fly across borders, infecting individuals all around the globe.

We were spared a major outbreak of the avian flu in 2005, but now, the H1N1 outbreak has already reached a pandemic classification by the World Health Organization. This time, however, we are much better prepared to combat the H1N1 virus than we were when faced with the avian flu.

A new vaccine is being developed and will be ready in the coming weeks. The Department of Health and Human Services has carefully coordinated efforts with education institutions, state and local authorities, travel industries, the business community, and health care providers. Five companies will be producing a large supply of the 2009 H1N1 vaccine and more than 670 Massachusetts providers have already registered to help administer it when it is ready.

To further reassure concerned mothers and fathers, the Massachusetts Department of Health is recommending an "MVP" approach to combat the H1N1 virus.

MITIGATE your risk by staying home when you are sick and keeping your kids home if they are ill.

VACCINATE yourself and your family once the H1N1 vaccine is available, especially if you are at high-risk.

And PREVENT the spread of flu by washing your hands frequently covering your mouth when you cough or sneeze.

Every one of us has the responsibility to be the MVP in our household, in our office, in our neighborhood.

I applaud President Obama, Secretary Sebelius, and thousands of health care workers and researchers for taking the necessary action to prepare our country against the H1N1 threat.”

Statement of the Honorable Anna G. Eshoo
House Committee on Energy and Commerce
Full Committee Hearing on "Preparing for the 2009 Pandemic Flu"
September 15, 2009

Thank you, Mr. Chairman, for holding this important hearing about the 2009 Pandemic Flu. As schools open and we approach flu season, it's more important than ever that we coordinate efforts to address preventing the spread of pandemic flu.

We live in a mobile society where an epidemic can migrate from animals to humans and sicken people in a different nation within a week. As we've seen in the past few months, a virus that originates in a small town in Mexico can spread across the world in the blink of an eye. When we first discovered H1N1 last April, we knew very little about it, but it dominated world news reports. The speed at which a virus now spreads breeds confusion, and confusion leads to panic.

I'm pleased with the work that the Administration has accomplished in preparing for the possibility of a new wave of cases and working with vaccine manufacturers to produce flu vaccines specific to the H1N1 strain. I'm proud that one of these companies, MedImmune employs hundreds of employees in my Congressional District. They are the first company to complete an H1N1 vaccine scheduled for availability of September.

I do have some concern about the possible diversion of funds from Project Bioshield to possibly fund flu preparedness. In the 109th Congress, Rep. Rogers and I introduced and helped pass the Biodefense and Pandemic Drug Development Act (BARDA) to create a new office within HHS to be the single point of federal authority for the development of medical countermeasures; Project Bioshield, which falls under BARDA, is a procurement program to develop chemical, biological, radiological, and nuclear countermeasures. Bioshield makes milestone payments to drug developers at key stages of their work, helping to reduce the financial risks of taking on this great challenge.

Given the risks involved, very few companies are willing to commit their limited resources to develop the vaccines and antidotes to respond to these attacks without some assurances of return on their investment. I worry that with limited funds left in Project Bioshield, additional research and innovation will be stymied while projects already in the works will never come to fruition

The President requested, and it has been included in the FY 2010 *Labor HHS Appropriations Act*, \$305 million to be transferred from Project Bioshield to BARDA. The *Labor HHS* bill also transfers \$500 million from Bioshield to HHS for basic research. I'm interested in hearing the Secretary Sebelius' views on how she plans to ensure adequate resources for Project Bioshield.

I thank the Secretary for being here today and I look forward to her testimony.

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Statement of Congressman Bruce Braley
Committee on Energy and Commerce
"Preparing for the 2009 Pandemic Flu"
September 15, 2009

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Thank you, Chairman Waxman and Ranking Member Barton,
for holding this important hearing today on preparing for the 2009
pandemic flu. I'm looking forward to hearing from Secretary Sebelius
today and learning what we can expect this flu season. I'm especially
interested in learning what the Department of Health and Human
Services, in coordination with other relevant government agencies, is
doing to respond to the expected surge in H1N1 flu cases, to protect
the health and safety of the American public, and to ensure the
communication of accurate information.

First, I'd like to thank Secretary Sebelius for working to ensure
that the Department and its components are identifying this flu by its
proper name, H1N1, and not the common misnomer "swine flu," and
to encourage the Department to ramp up these efforts. I'm glad the
Centers for Disease Control stopped using the term "swine influenza"

on their website shortly after I raised this issue at our April hearing on H1N1. But, unfortunately, this misnomer is still being used far too often – including by major and trusted news sources – and is continuing to harm pork producers in my state of Iowa and across the country. One estimation by University of Missouri economists has U.S. pork producers losing more than \$100 million a month, or about 10 percent of their expected returns, since the human flu cases emerged in April. According to the National Pork Producers Council, since the H1N1 influenza story broke this spring, U.S. pork producers' revenues have declined by \$991 million from the level expected before the crisis began.

It's unacceptable that, months after it has been clearly demonstrated that there is no connection between H1N1 and food safety, that this incorrect term is still used so predominantly, and with such drastic consequences. If we're hoping to effectively prevent and respond to cases of H1N1; we must work to ensure that all government agencies and officials – and the media – are communicating the most accurate information possible to the public. I'd like to encourage Secretary Sebelius to continue and to step up efforts to ensure that this flu is properly identified, and to work to stop

the spread or continuation of any misperceptions or misinformation about the virus.

I'm encouraged by last week's news that the first studies are indicating that the H1N1 vaccine is effective in adults with just one dose, and that the vaccine appears to be safe. I hope this means that more Americans will be protected more quickly, and that all of the members in high-risk groups will be able to receive vaccinations well before the flu's expected peak. However, I also believe we must be cautious and vigilant in *ensuring* the safety of the H1N1 vaccination before it is administered to a large number of Americans. I'm looking forward to hearing from Secretary Sebelius today about the steps HHS is taking to ensure that this vaccine is as safe as possible.

Again, thank you Chairman Waxman for holding this hearing, and thank you to Secretary Sebelius for being here today. I'm looking forward to hearing your testimony and learning about what you, the Department of HHS, and the other involved government agencies are doing to protect the public from the flu, ensure the safety of the H1N1 vaccine, and ensure that the public is receiving accurate information about the H1N1 virus.

QUESTIONS FOR THE RECORD - SECRETARY SEBELIUS
2009 H1N1 HEARING ON SEPTEMBER 15 BEFORE THE
HOUSE ENERGY AND COMMERCE COMMITTEE

Rep. Mike Rogers

QUESTION 1. From a preparedness perspective, how was the early funding of \$5.6 billion for pandemic flu provided in 2006 helpful in positioning HHS to combat the H1N1 threat?

ANSWER:

During 2004 and 2005, HHS developed a comprehensive pandemic influenza preparedness plan, which serves as a blueprint for all HHS pandemic influenza preparedness and response activities. The \$5.6 billion appropriated in Fiscal Year (FY) 2006 has been used to make significant progress implementing that plan. Specifically, these funds have been used to invest in expanded domestic vaccine manufacturing capacity; to support the development of new rapid diagnostic tests, new antiviral drugs, and medical countermeasures; and stockpile antiviral drugs, personal protective equipment, and vaccines for certain strains of influenza. HHS's progress in meeting these goals has allowed the United States Government (USG) to respond with unprecedented speed to the H1N1 pandemic threat.

Through HHS vaccine stockpiling efforts for H5N1, the USG has developed relationships and ongoing contracts with vaccine manufacturers worldwide. These relationships and contracts have made our current vaccination campaign much more responsive than it otherwise could have been. Our previous work with these manufacturers ensured that there was global capacity to produce vaccine as quickly as we have. HHS's existing contracts with these manufacturers ensured the USG a priority place in line as vaccine has been produced.

HHS has made investments in expanding domestic influenza vaccine manufacturing capacity. Through the building of the H5N1 vaccine pre-pandemic vaccine national stockpile and increase in the U.S. for seasonal influenza vaccine uptake, the number of influenza vaccine manufacturers doubled for the U.S. seasonal vaccine market and for pandemic preparedness. Retrofitting of existing vaccine manufacturing facilities in the U.S. for influenza vaccines supported by HHS contracts in 2007 resulted in increased U.S. vaccine production during the 2009 H1N1 pandemic. Additionally, investments made in cell-based influenza vaccine development and domestic vaccine manufacturing infrastructure led to the building and opening of the first cell-based influenza vaccine manufacturing in November 2009, which will provide a significant increase in U.S. influenza vaccine manufacturing by 2011. Other vaccines and facilities will follow in subsequently.

HHS supported the development of a new influenza antiviral drug called peramivir, which was stockpiled and used for critically ill influenza patients in life-threatening situations under the FDA's Emergency Usage Authority. HHS has also supported the development of several new

adjuvants, which were stockpiled as a contingency if the vaccine no longer matched the circulating virus, the disease become much more virulent, or the vaccine required more antigen per dose than manufacturing capacity allowed.

HHS has established and replenished stockpiles of influenza antiviral drugs (81 million treatment courses) and personal protective equipment, such as surgical masks (37.7 million) and N95 respirators (20.4 million). In response to the H1N1 outbreak, some of these stockpiles were deployed to states this spring. The release of antiviral drugs and personal protective equipment has served to help make states and local providers better equipped for the upcoming pandemic threat.

HHS awarded several contracts to develop rapid diagnostic tests for seasonal and H5N1 influenza viruses. In the clinical evaluation process for one of the rapid diagnostic tests that HHS funded and further specimen testing by CDC, the current 2009 H1N1 pandemic influenza strain was first isolated as a novel virus. This early detection of the 2009 H1N1 influenza virus in the United States has helped public health authorities across the world identify this pandemic threat.

When HHS became aware of the H1N1 pandemic threat, we were able to redirect remaining FY 2006 balances, along with FY 2009 Omnibus funds, from ongoing pandemic influenza preparedness projects to accelerate the H1N1 response. These funds allowed HHS to start the vaccine production process in May, even before Congress appropriated funds for the H1N1 response. If HHS had not been able to access the balance of the FY 2006 funds, the current vaccination campaign could have been delayed by a month or longer.

QUESTION 2. Given the additional funding over \$7 billion made available in the May War Supplemental to support efforts against H1N1, do you believe that you have adequate resources available to meet this threat?

ANSWER:

HHS has made significant progress in its response to the 2009 H1N1 pandemic, but we have yet to see how this flu season will develop. In addition to the \$1.85 billion in direct emergency appropriations for 2009 H1N1, HHS has notified Congress of plans to spend \$4.3 billion of the contingent emergency appropriation. These plans include \$3 billion for H1N1 vaccine and related supplies, and almost \$2 billion to support states and hospitals in their planning and preparation efforts. As of November 30, HHS has obligated over \$3.6 billion from the Supplemental, as well as over \$1.4 billion from remaining FY 2006 balances, the FY 2009 Omnibus, and other HHS funding, in response to 2009 H1N1; this includes \$2.7 billion to purchase 251 million doses of vaccines and related supplies.

Based on information from clinical trials conducted by NIH and vaccine manufacturers, a single dose of vaccine is sufficient for healthy adults to develop an immune response. Two doses are recommended for children under the age of 10, which is consistent with the recommendation for seasonal influenza vaccine. We anticipate purchasing sufficient vaccine for everyone in the priority groups and two-thirds of the American public. Based on current estimates of demand,

we will have sufficient vaccine for everyone who wants one. It is possible that demand will increase in the coming months, in which case we would need to purchase additional vaccine. We believe that such an increase could occur depending on the severity and prevalence of the H1N1 virus. At this time, the funds appropriated by the Congress are sufficient to support the immediate H1N1 response needs.

The federal government is working in partnership with states, territories, tribes, and local communities as well as the private sector to help distribute and administer the new H1N1 vaccine. We have distributed funding to states and localities to support planning and response efforts. HHS has also distributed supplies from the Strategic National Stockpile such as antiviral medications, masks and respirators. We have heard from many states who report they may not have sufficient funds from the Public Health Emergency Response (PHER) grants to complete their current H1N1 vaccination programs. In response, we plan to provide additional funding to states and localities that might need additional support.

If the virus should worsen, this could impact the level of federal, state, local and private sector response necessary. HHS continues to report obligations from the \$7 billion to Congress on a monthly basis. We look forward to working with the Congress as we move forward in the vaccination campaign.

QUESTION 3. Regarding H1N1 preparedness, what steps are you taking to make sure that we vaccinate critical members of the workforce? For example, in my district I have a company which plays an important role in safeguarding our preparedness from a bioterrorist attack by providing medical countermeasures to the SNS. Should they experience an outbreak, it could bring production to a halt and cripple our preparedness efforts. What efforts are you taking to make the H1N1 vaccine available to critical sectors of our workforce?

ANSWER:

CDC provides recommendations to states on vaccination, including prioritization of vaccine, but states and localities ultimately decide whether and how to implement these guidelines (*i.e.*, it is a state-by-state final decision on how to prioritize vaccine in each state). The CDC's Advisory Committee on Immunization Practices (ACIP) recommends that pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel, and all persons under age 25 and persons 25 to 64 years of age who have chronic medical conditions receive the vaccine before others. These ACIP recommendations, which have been endorsed by CDC, were developed with the goal of protecting those who are at higher risk for acquiring influenza or developing influenza complications. If there are situations unique to a district that warrant a local decision to include other groups as a priority for vaccination, that decision can and should be made by that state and/or locality. The ACIP recommendations were developed based on the epidemiologic data from the 2009 H1N1 outbreak, not on a person's occupation.

Across the nation, levels of pandemic influenza disease, demand for vaccine, and local availability of vaccine vary. Consistent with recommendations of the ACIP, many states and

communities have now shifted gears to expand vaccine availability to all who wish to receive the H1N1 vaccine. This shift is appropriate for areas that have been able to meet demand among the priority population groups.

QUESTION 4. Is the Administration still considering significantly depleting the BioShield Special Reserve Fund [SRF] to fund the development and /or procurement of H1N1 flu vaccine? How do you intend to balance two important priorities -- pandemic flu and CBRN threats? Can you please discuss your thoughts on proposals to use SRF funds for purposes other than CBRN medical countermeasures?

ANSWER:

In June 2, 2009, the Administration submitted a Supplemental Appropriations request to the Congress, to support our Nation's efforts to respond to the 2009 H1N1 virus. That request included new funding for response as well as authorities to transfer funding from other appropriations and to amend the purpose of Project BioShield's authority to include pandemic influenza as an allowable activity. On June 24, 2009 the President signed Public Law 111-32, providing \$7.65 billion to enhance our Nation's capability to respond to the potential spread of the H1N1 flu outbreak. At this time, the funds appropriated by the Congress are sufficient to support the immediate H1N1 response needs.

The Project BioShield program is not being considered for purposes other than CBRN medical countermeasures at this time. Already having procured countermeasures for anthrax, botulism, smallpox and radiation threats, Project BioShield continues to work, in conjunction with Biomedical Advanced Research and Development Authority (BARDA), to bring more product candidates through the pipeline to the Strategic National Stockpile.

QUESTION 5. What do you believe is the appropriate funding level for Project BioShield to support CBRN acquisitions and provide confidence to the biodefense industry that the Administration remains committed to biodefense?

ANSWER:

HHS/ASPR/BARDA remains committed in its mission to acquire a stockpile of countermeasures against all 13 material threats identified by the Department of Homeland Security. We are very cognizant of our responsibility to the health security of our Nation and committed to our partners in the biodefense industry.

The Special Reserve Fund for the late stage development and acquisition of CBRN medical countermeasures under the Project BioShield authorities has been appropriated \$5.6 billion. We note that products for consideration under a BioShield acquisition must be sufficiently mature such that licensure of the counter measure is anticipated within 5-8 years. Thus, essential to the success of Project BioShield, is the continued support for CBRN Advanced Research and Development. The \$305 million in FY 2010 will support the advanced development of anthrax vaccines and therapeutics, broad spectrum antibiotics, and radiological and nuclear countermeasures.

We again remain steadfastly committed to our statutory responsibilities and to those industries that will enable us to achieve our mission.

QUESTION 6. The bipartisan Commission on Weapons of Mass Destruction and others believe we should be investing \$1.7 billion in the Biomedical Advanced Research and Development Authority [BARDA] for 2010. How do you reconcile that need with the Administration's request for only \$305 million [as a transfer out of the BioShield SRF] in 2010?

ANSWER:

The FY 2010 President's Budget provides funding to further develop countermeasures in the priority areas of anthrax vaccines and therapeutics, broad spectrum antibiotics (BSA), and radiological and nuclear threat countermeasures.

QUESTION 7. The Department has been in negotiations for a second generation anthrax vaccine for nearly a year now. What is the status of that procurement?

ANSWER:

In February 2008, ASPR/BARDA released a Request for Proposals (RFP) under Project BioShield for rPA anthrax vaccine. A Project BioShield RFP was intended to take mature products (e.g., those in Phase 2 clinical trials and at commercial-scale production), and support them through the final safety and efficacy testing to achieve licensure, as well as deliver a certain number of initial doses to the Strategic National Stockpile. In this case, an RFP contract award would have required the contractor to achieve FDA licensure for an rPA vaccine product, in addition to delivering 25 million doses to the Strategic National Stockpile.

In order to ensure that potential awardees would be able to successfully meet the terms of the contract, BARDA completed comprehensive technical reviews of the proposals received. BARDA provided numerous opportunities for offerors to revise their proposals to meet contractual requirements. After site visits, reviews and lengthy discussions with Offerors, BARDA determined that no Offeror could meet the Government's requirement. As a result, BARDA has decided to cancel the rPA vaccine RFP. The current pipeline of product candidates is simply not mature enough to warrant awarding a Project BioShield contract at this time. Awarding such contracts would present a high risk of failure for both the contractor and the U.S. government.

Until candidate medical countermeasures are sufficiently mature for acquisition, the best mechanism for supporting their development is through milestone-based advanced development contracts. BARDA supports advanced development of CBRN medical countermeasures using a Broad Agency Announcement (BAA) that is continuously open for submissions. Contractors can submit proposals to the BAA at any time, which are then evaluated on a regular basis. For medical countermeasure programs of particular interest, BARDA issues Special Instructions that highlight desired characteristics of candidate products.

On December 7, 2009, BARDA released Special Instructions for Advanced Development of Recombinant Protective Antigen (rPA) Anthrax Vaccines under a BAA in order to support the advanced development phase and to re-stimulate interest in these products across the medical countermeasure industry. These special instructions are to specifically solicit solutions for developing Recombinant Protective Antigen (rPA) anthrax vaccines BARDA plans to award advanced development contracts for next-generation vaccines in the first half of 2010.

QUESTION 8. What steps is your agency taking to ensure that we are fully prepared for a bioterrorist attack and that we continue to stockpile medical countermeasures?

ANSWER:

Since 2004, BARDA has been building a portfolio of countermeasures against the 13 material threats identified by The Department of Homeland Security. BARDA has obligated over \$2.6 billion of the Project BioShield Special Reserve Fund (SRF) for the stockpiling of countermeasures against anthrax, botulism, smallpox, and radiation threats. Since 2007, BARDA has also utilized annual appropriations for advanced research and development (totaling over \$480 million) to broaden its portfolio of CBRN countermeasures to over 35 contracts and grants. In addition, BARDA will direct the \$305 million in new funding provided by the Congress in FY 2010 to improve preparedness in critical threat areas including anthrax and radiological/nuclear as well as for the development of broad spectrum antimicrobials.

While procuring products for the SNS can act as a deterrent to those who wish to impose terror on the American people, it does not fully ensure preparedness. To that end, BARDA, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), is working with the SNS as well as state and local officials to ensure that appropriate deployment strategies are in place and to facilitate a rapid response, diminishing the adverse effects of a bioterrorist attack. BARDA also works through the PHEMCE to define and prioritize medical countermeasure requirements and to coordinate research, early and late stage product development, and procurement activities.

Rep. Michael Burgess

QUESTION 1. In answering Congressman Deal's question, you stated the H1N1 vaccine would go to priority populations first. One of those priority groups are pregnant women. As a practicing ob-gyn for 25 years, I'm curious to know why trials for this vulnerable population just began. Why was there such a delay in trials for pregnant women?

ANSWER:

The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health, is conducting a number of clinical trials of 2009 H1N1 influenza vaccine, including testing the vaccine in pregnant women. NIAID planning and implementation of these clinical trials utilized the scientifically and medically accepted approach of initiating the trials in a sequential fashion. It was important to first obtain preliminary results on the safety of the 2009 H1N1 influenza vaccine in healthy adults, including women who were not pregnant. The initial data from the adult trial were reviewed by an independent safety monitoring committee to ensure that there were no safety concerns. Once these data were reviewed, NIAID-supported investigators began testing the products in special populations, such as children and pregnant women.

NIAID initiated three clinical trials of 2009 H1N1 vaccines in pregnant women, two in healthy pregnant women and one in HIV-infected pregnant women. The first NIAID-sponsored trial in pregnant women began enrollment on September 9, 2009, recruiting 120 healthy women 18 to 39 years old in their second or third trimester of pregnancy (14 to 34 weeks). On November 2, 2009, NIAID reported the results of a preliminary analysis of the antibody responses from 50 women enrolled in this first trial. The analysis showed that pregnant women had a robust immune response following a single dose of the vaccine. Blood samples taken 21 days after the first vaccination showed levels of antibodies directed against the 2009 H1N1 virus that were comparable to the levels seen in healthy non-pregnant adults ages 18 to 64. Specifically, 92 percent of pregnant women who received a single 15-microgram dose of vaccine showed antibody levels likely to be predictive of protection against infection. Among pregnant women who received a single 30-microgram dose of vaccine, 96 percent had antibody levels likely to be predictive of protection against infection. Safety is being monitored closely in the trial, by the study investigators and by an independent panel of experts known as a safety monitoring committee. As expected, the vaccine has been shown to be safe and well-tolerated in pregnant women.

QUESTION 2. You stated in your testimony that the decision to close school is a local decision. If these schools close during any and all testing as required under No Child Left Behind, will they be reimbursed any federal money that they would lose?

ANSWER:

As a general matter, a school that closes due to an H1N1 outbreak during the State's window for administering assessments required by the Elementary and Secondary Education Act of 1965 (ESEA) would not be subject to a loss of Federal funds simply as a result of such closure.

Among other factors, the ESEA requires that at least 95 percent of students in each demographic group identified by the law participate in such assessments for a school to make adequate yearly progress (AYP). Conceivably, a school closure described in the preceding paragraph could cause the school to not satisfy that requirement. Although the Department has the right to withhold funds for non-compliance with the ESEA, the failure to make AYP in and of itself does not constitute non-compliance. Rather, a school that fails to make AYP for two or more consecutive years must comply with the requirements in Section 1116 of the ESEA. These requirements are designed to help improve student achievement in schools that have been identified for improvement, corrective action, or restructuring.

The ESEA allows for the possibility of certain flexibilities with respect to the failure to make AYP under certain circumstances, and these flexibilities may apply to a failure to make AYP due to an H1N1 outbreak. In addition, the Department will consider requests to waive certain assessment and accountability requirements for schools or LEAs that fail to make AYP because of an H1N1 outbreak. Detailed guidance on the H1N1-related waivers that are available can be found at: <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html> (click on the document titled "Guidance on flexibility and waivers for SEAs, LEAs, postsecondary institutions, and other grantee and program participants" (September 29, 2009)).

QUESTION 3. What would be considered an "emergency use authorization" which would allow the FDA to permit certain unapproved uses of Tamiflu and Relenza? Is the emergency use authorization a sufficient legal authority? If so, then why is the FDA creating a legal fund to protect against emergency use authorization designations for Tamiflu and Relenza? Who is in charge of making the determination of emergency use authorizations? Who is in charge of the legal fund?

ANSWER:

a. What would be considered an "emergency use authorization" which would allow the FDA to permit certain unapproved uses of Tamiflu and Relenza?

FDA may issue an Emergency Use Authorization (EUA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents. Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb-3) permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met. The National Defense Authorization Act of 2004 amended the FD&C Act to include an EUA provision for military emergencies. The Project Bioshield Act of 2004 further amended the FD&C Act to allow an EUA not only for military, but also for domestic and public health emergencies.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the FD&C Act, the Secretary of Health and Human Services (HHS) determined, under section 319 of the Public Health Service Act (PHS Act), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 influenza) that affects or has significant potential to affect national security. The determination has been renewed. On the basis of such determination, the Secretary then declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals, oseltamivir phosphate and zanamivir, accompanied by emergency use information, subject to the terms of any authorization issued under section 564(a) of the FD&C Act (74 FR 38628, August 4, 2009).

Tamiflu (oseltamivir phosphate) is approved to treat uncomplicated acute illness due to influenza infections in patients 1 year of age and older who have been symptomatic for no more than 2 days, and to prevent influenza in patients 1 year and older. Relenza (zanamivir) is approved to treat uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than two days, and to prevent influenza in adults and pediatric patients 5 years of age and older. FDA has authorized the following uses during the declared emergency, subject to the terms and conditions of the EUAs (74 FR 38648, August 4, 2009):

- Tamiflu is authorized to be used to treat and prevent influenza in children under 1 year of age, and the EUA provides alternative dosing for children older than 1 year (based on age instead of weight). Because of limited experience, use of Tamiflu for prevention of 2009 H1N1 flu in infants less than 3 months of age is not routinely recommended but may be considered if the need is considered critical.
- The EUA authorizes distribution of certain Tamiflu oral suspension products deployed from the Strategic National Stockpile that have passed Shelf Life Extension Program (SLEP) testing for use beyond their expiration dates, regardless of whether or not they are relabeled.
- The EUA for Tamiflu and Relenza authorize the drugs to be used at later time points (i.e., in patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have “uncomplicated acute illness” per se).
- The EUAs for Tamiflu and Relenza authorize the drugs to be distributed or dispensed without all of the FDA-required prescription label information.
- The EUAs for Tamiflu and Relenza authorize the drugs to be accompanied by certain written emergency use information.
- The EUAs also note that public health officials or other volunteers may distribute Tamiflu and Relenza to recipients in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction. (The term “Authority Having Jurisdiction” is used in the Public Readiness and Emergency Preparedness Act declaration for antivirals and means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.)

In addition, on basis of the determination described above, the Secretary issued an emergency declaration justifying the authorization of the emergency use of the antiviral peramivir, accompanied by emergency use information, subject to the terms of any authorization issued under section 564(a) of the FD&C Act (74 FR 56644, November 2, 2009). On October 23, 2009, FDA issued an EUA authorizing the emergency use of Peramivir IV, an unapproved antiviral drug that is administered intravenously and that is still being evaluated in phase 3 clinical trials. Even though there were a number of limitations to the safety and efficacy data available at this stage of Peramivir's development and the data reported were preliminary in nature, based upon the totality of scientific evidence available, FDA determined that it was reasonable to believe that Peramivir IV may be effective in certain hospitalized patients. Specifically, Peramivir IV is authorized only for the following patients who are admitted to a hospital and under the care or consultation of a licensed clinician (skilled in the diagnosis and management of patients with potentially life-threatening illness and the ability to recognize and manage medication-related adverse events):

- Adult patients for whom therapy with an IV agent is clinically appropriate, based upon one or more of the following reasons:
 1. patient not responding to either oral or inhaled antiviral therapy, or
 2. drug delivery by a route other than IV (e.g. enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, or
 3. the clinician judges IV therapy is appropriate due to other circumstances.
- Pediatric patients for whom an IV agent is clinically appropriate because:
 1. patient not responding to either oral or inhaled antiviral therapy, or
 2. drug delivery by a route other than IV (e.g. enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible.

b. Is the emergency use authorization a sufficient legal authority?

As discussed in a. above, under section 564 of the FD&C Act, the issuance of such an authorization is sufficient to allow either the use of an unapproved medical product or an unapproved use of an approved medical product for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.

c. If so, then why is the FDA creating a legal fund to protect against emergency use authorization designations for Tamiflu and Relenza?

There is no FDA legal fund to protect against emergency use authorization designations for Tamiflu and Relenza. However, the Secretary has issued declarations with respect to both Tamiflu and Relenza under the Public Readiness and Emergency Preparedness (PREP) Act.

The PREP Act authorizes the Secretary to issue a declaration providing limited tort liability immunity to individuals and organizations involved in the development, manufacture, distribution, administration and use of countermeasures against certain pandemics, epidemic, or security conditions. The law also authorizes the Secretary to establish a compensation program,

known as the Countermeasures Injury Compensation Program (CICP), to compensate eligible individuals who suffer serious physical injuries or deaths from the use or administration of a covered countermeasure identified in such a declaration. A Secretarial declaration specifies the categories of health threats or conditions for which countermeasures are recommended, the period liability protections are in effect, the population of individuals protected, and the geographic areas for which the protections are in effect. The Secretarial declaration to include Tamiflu and Relenza under the PREP Act was published in the Federal Register on October 17, 2008, and amended on April 26, 2009, to clarify that it covers use of these antivirals for 2009 H1N1 influenza. The April 26, 2009 amendment was published in the Federal Register on June 19, 2009. In addition, the Secretarial declaration to include the antiviral Peramivir under the PREP Act was published in the Federal Register on October 2, 2009 (74 FR 50968).

The PREP Act provides that the CICP, with limited exceptions, will follow the Smallpox Vaccine Injury Compensation Program (SVICP) for eligibility and compensation determinations. The rules of the SVICP are specified in the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA). Under SEPPA, individuals have one (1) year from the date the vaccine or other covered countermeasure was administered to request compensation benefits. Eligible individuals may be compensated for reasonable out-of-pocket medical expenses and lost employment income at the time of the injury. Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of the covered countermeasure injury. The Department is developing a regulation for the administrative implementation of the CICP, which will closely follow the administrative regulation published for SVICP. Regulations for the SVICP are codified at 42 CFR Part 102 and are available at <http://www.hrsa.gov/smallpoxinjury/>. More information about CICP is available at www.hrsa.gov/countermeasurescomp.

d. Who is in charge of making the determination of emergency use authorizations?

The Secretary of HHS may declare an emergency justifying an emergency use. Once the HHS Secretary has declared an emergency justifying the emergency use, the FDA Commissioner may authorize the emergency use only if, after consultation with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the circumstances of the emergency), he or she determines that certain statutory criteria have been met.

e. Who is in charge of the legal fund?

The CICP fund described in the response to c. above is administered by the Health Resources and Services Administration (HRSA) within HHS.

