

PUBLIC HEALTH RESPONSE TO SWINE FLU

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED ELEVENTH CONGRESS
FIRST SESSION

SPECIAL HEARING
APRIL 28, 2009—WASHINGTON, DC

Printed for the use of the Committee on Appropriations



Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>

U.S. GOVERNMENT PRINTING OFFICE

49-368 PDF

WASHINGTON : 2010

For sale by the Superintendent of Documents, U.S. Government Printing Office
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PUBLIC HEALTH RESPONSE TO SWINE FLU

TUESDAY, APRIL 28, 2009

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 1:08 p.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Harkin, Kohl, Pryor, Specter, and Hutchison.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. We are here for a public hearing on the recent outbreak of the so-called swine flu in this country and around various parts of the world.

I first want to thank our witnesses for coming here today on such short notice—I only called yesterday—to discuss the current outbreak of the so-called swine influenza.

I wanted to have this hearing to get as much information out to the public as possible. There is a lot being written out there. There is a lot of anxiety, understandably so as to where we are in this; what is the threat; and where do we go from here?

Well, so far, this flu outbreak has centered in Mexico, as we know. As of just an hour ago, there have been 64 confirmed cases in 5 States. And I believe there are additional possible cases now being analyzed.

Many are already calling this a flu pandemic, because this is a virus for which people have little or no immunity and for which there is no vaccine, and it's capable, obviously, of sustainable human-to-human transmission.

Just for the record and for a little background, this subcommittee has provided over \$6 billion for pandemic flu preparedness activities since 2005. At that time, many experts, including Dr. Fauci, who's here with us, told us that it was not a matter of whether there would be a flu pandemic, but rather when it would happen.

Of course, at that time, we were all concerned about the H5N1 virus circulating among birds, primarily in Southeast Asia, the so-called avian virus. The H5N1 virus was described as a very robust virus which had been contracted by humans from birds, for which people had little or no immunity and for which there was no vaccine. However, the H5N1 virus had not yet and still has not mutated to a virus significantly capable of human-to-human transmission.

The current so-called swine flu virus is obviously a different virus. Like H5N1, it's one for which people have little or no immunity and for which there's no vaccine. However, unlike H5N1, the H1N1 virus is capable of human-to-human transmission. Dr. Fauci, I can remember you telling us that we may be preparing for an avian influenza pandemic, but the next pandemic could come from somewhere else. You were right.

The good news is that our investments in pandemic preparedness are paying off in this outbreak. We have been able to improve surveillance, which may have played a part in recognizing some of the early cases. We have stockpiled antivirals and other medical supplies, which are now being transported—later we'll get into that—to other parts of the country to help local governments' response to the current outbreak.

We have strengthened the capacity of the Centers for Disease Control and Prevention (CDC) to respond to pandemics and have provided funds to improve State and local government preparedness. We'll be talking about that with Dr. Jarris.

In addition, we have moved forward in developing this country's capacity to quickly produce vaccine in response to a pandemic. Where is that statement that I had?

As of August 2005—or I should say as of 2005, when we first started on this, there was one company in the United States that could produce flu vaccines, and that was an egg-based process, which took a lot of time.

Through our hearing process, it was decided that we needed to ramp up the construction of facilities so that we could produce cell-based vaccines. And I could stand corrected on the terms by Dr. Fauci or Dr. Schuchat, but cell-based vaccines would be more rapidly produced than using the old egg-based processes.

And so since that time we have put now over \$3 billion—of the \$6 billion I mentioned, we've put over \$3 billion in developing cell-based vaccines and the facility to make those. Now, I've been tracking this since that time. Periodically, I have people in my office talk to me about where we are in this process.

And so earlier this year, I put \$870 million—that's what it finally boiled down to—\$870 million into the stimulus bill to get money out to ramp up the building of these facilities. I was disappointed that the money was taken out of the recovery package, because the purpose of that funding was to develop our capacity to produce vaccines quickly in the United States in response to any type of influenza or any other viral pandemic.

This capacity is not there yet, and I'm not saying it would be if we'd put that \$870 million—I'm not saying that. But the current outbreak does remind us that we need to be prepared and to provide those funds as soon as possible so as not to delay the development of that capacity.

These things all take time to do, and that's the reason I fought so hard to include the money in that package. I thought it was critically important to get started on that work immediately to ramp it up. And I also thought it would have a stimulative effect, creating jobs in research and planning and developing new vaccine facilities.

I want to state this very clearly. That's why I will push to include this money in the supplemental appropriations bill that Congress will be considering later this month.

So the purpose of today's hearing is first, to get an update from you on the situation; secondly, to determine whether there is a need for additional Federal resources from this subcommittee to address this outbreak. And, I would also would like to learn how our investments in pandemic preparedness have made a difference. We may even make that the subject of a later hearing when we know more.

We have Dr. John Clifford, from USDA. There's been a lot of talk about swine and if you can get this from pigs or hogs or eating pork, and we want to get into that with you and what USDA is doing.

Given the short notice, I asked the witnesses not to prepare an opening statement. Just be ready to respond to questions. I will first recognize my colleague from Texas, Senator Hutchison.

Senator HUTCHISON. Well, thank you very much, Mr. Chairman. I'm very pleased that you've called this hearing, because in my home State of Texas, we have three confirmed cases in one school district, and the whole school district has now been shut down. So I am very concerned about the response and particularly, the response for incoming airplanes, as well as cross-border traffic with Mexico.

I do have to leave at 1:25 p.m. for a 1:30 p.m. commitment, so I want to hear—if we're going to be able to ask questions, then maybe I will have time to ask the questions of—that are mostly on my mind, which are the questions about are we doing enough and what should we be doing at the border that would duplicate what some of the other countries around the world are doing right now for traffic coming in, especially from Mexico, since we know that it is the genesis of much of this.

So I would certainly bow to your wishes, but if I could ask a question before 1:25 p.m., I would really appreciate it.

Senator HARKIN. Thank you very much, Senator Hutchison. I will try to honor that. We're hearing from four experts here today. Rear Admiral Anne Schuchat. Dr. Schuchat is the Interim Deputy Director for the Science and Public Health Program at CDC. She has spent more than 20 years at the Centers for Disease Control, working in immunization, respiratory, and other infectious diseases. She was named an Assistant Surgeon General of the United States Public Health Service in 2006.

We have again Dr. Tony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH). Dr. Fauci is certainly no stranger to this subcommittee, having testified here over the last 20 years. Dr. Fauci came to NIH in 1968 and, as I said, is the Director of the National Institute of Allergy and Infectious Diseases.

Dr. Paul Jarris has served as the Executive Director of the Association of State and Territorial Health Officials since 2006. Prior to that, he was the Commissioner of Health for the State of Vermont.

Dr. John Clifford is the Deputy Administrator for the Veterinary Services Program at the Department of Agriculture's Animal and

Plant Health Inspection Service. In this position, he provides leadership for safeguarding U.S. animal health.

PREPARED STATEMENT

Thank you all again for coming on such short notice.
[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Good morning. I want to thank our witnesses for coming here today on such short notice to discuss the current outbreak of swine influenza. So far, this flu outbreak has centered in Mexico but there have been 64 confirmed U.S. cases in 5 States and additional possible cases are being analyzed. Many are already calling this a flu pandemic because this is a virus for which people have little or no immunity and for which there is no vaccine. And it is capable of human-to-human transmission.

This subcommittee has provided over \$7 billion for pandemic flu preparedness activities since fiscal year 2006. At that time, many experts—including Dr. Fauci, who is here today—told me that it was not a matter of whether there would be a flu pandemic but rather when it would happen. Of course, at that time, we were all concerned about the H5N1 virus circulating among birds, primarily in Southeast Asia. The H5N1 virus was described as a very robust virus which had been contracted by humans from birds, for which people had little or no immunity, and for which there was no vaccine. However, the H5N1 virus had not yet, and still has not, mutated to a virus capable of human-to-human transmission.

The current swine flu virus is, obviously, a different virus. Like H5N1, it is one for which people have little or no immunity and for which there is no vaccine. However, unlike H5N1, this H1N1 flu virus is capable of human-to-human transmission. Dr. Fauci, I can remember you telling me that we may be preparing for an avian pandemic but the next pandemic could come from somewhere else. You were right.

The good news is that our investments in pandemic preparedness are paying off in this outbreak. We have been able to improve surveillance, which may have played a part in recognizing some of these early cases. We have stockpiled antivirals and other medical supplies which are now being transported to other parts of the country to help local governments' response to the current outbreak. We have strengthened the capacity of Centers for Disease Control and Prevention (CDC) to respond to pandemics and we have provided funds to improve State and local government preparedness. In addition, we have moved forward in developing this country's capacity to quickly produce vaccine in response to a pandemic.

The purpose of today's hearing is, first, to get an update on the situation, and, second, to determine whether there is a need for additional Federal resources from this subcommittee to address this outbreak. I also would like to learn how our investments in pandemic preparedness have made a difference—we may even make that the subject of a later hearing when we know more.

Given the short notice, I have not asked our witnesses to prepare an opening statement but have only asked them to be ready to respond to questions.

We'll be hearing from four experts. They are:

Rear Admiral Anne Schuchat, MD. Dr. Schuchat is the Interim Deputy Director for the Science and Public Health Program at the CDC. She has spent more than 20 years at CDC working in immunization, respiratory, and other infectious diseases. She was named an Assistant Surgeon General of the United States Public Health Service in 2006. Dr. Schuchat graduated from Swarthmore College and Dartmouth Medical School.

Anthony Fauci, MD. Dr. Fauci is the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. Dr. Fauci came to the National Institutes of Health (NIH) in 1968 after completing his residency at The New York Hospital Cornell Medical Center. He received his M.D. degree from Cornell University Medical College.

Paul Jarris, MD. Dr. Jarris has served as the Executive Director of the Association of State and Territorial Health Officials since 2006. Prior to that position, Jarris was Commissioner of Health for the State of Vermont. Dr. Jarris graduated from the University of Vermont and received his M.D. degree from the University of Pennsylvania School of Medicine.

John R. Clifford, DVM. Dr. Clifford is the Deputy Administrator for the Veterinary Services program at United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS). In this position, he provides leadership for

safeguarding U.S. animal health. Prior to joining APHIS in 1985, Dr. Clifford received his DVM and BS degrees in animal science from the University of Missouri.

Senator HARKIN. Dr. Schuchat, let me start with you. Again, as I said, there's a lot of anxiety right now across the country. Our offices—I'm sure yours too, Senator Hutchison—we're getting flooded with emails. People are calling our offices. What should they do?

People are very concerned. They're concerned about their children in school, because a lot of the cases have involved school children. And so the floor is yours. What would you like to tell the American people? How concerned should they be, where are we, and what's ahead, Dr. Schuchat?

STATEMENT OF REAR ADMIRAL ANNE SCHUCHAT, M.D., INTERIM DEPUTY DIRECTOR, SCIENCE AND PUBLIC HEALTH PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SCHUCHAT. Thank you, too. People are concerned, and we at CDC are also concerned. It's a difficult situation. It's a serious situation. We in the United States, as you've said, have 64 cases, now laboratory-confirmed, from the swine influenza virus. Five of those patients were hospitalized.

And we know that the situation in Mexico is a bit more severe, probably much more severe, based on the reports that we have. I think it's important for people to know that there's a lot we can do, and we're aggressively responding. The investments that have been made into preparedness are making a difference every day. We actually know many things that can reduce the illness and spread of transmission, and we're focusing on them.

We have teams in the field in the areas where there are outbreaks right now. We have deployed assets of antivirals to the States that—actually, we're on—they're en route to the affected States, and they'll be going to all the rest of the States. And we are making sure that people know they have a role too.

You know, I think that it's easy to think that the Government or the World Health Organization (WHO) is going to take care of everything, but actually, each of us has a role. We can reduce respiratory infections every day if we make sure that we wash our hands, that we cover our cough and sneeze, that if we're sick, we stay home from work or from school, that we don't get on an airplane and spread our infections to others.

Those are things that sound really simple, but they actually are effective. And so I think that when people are concerned about what's going to happen, I want them to know that there are lots of steps they can take themselves.

Unfortunately, influenza virus is very unpredictable, so I can't tell you exactly what's going to happen next. I wish that I could. But I can tell you that we are watching closely and that we're responding aggressively. We're making sure that we get guidance out to the clinical community, the public health community, to the workforce that may be in higher-risk situations, to schools and parents, and that as we learn more, we're going to share the information that we have.

So I think it's important for people to know that there's a lot you can do yourself. You can also be planning ahead in case things get

worse. But that we're really working hard to make sure that we have as strong a response as possible.

Senator HARKIN. I know you don't have a crystal ball, but in your judgment, do you think this virus will spread more in the United States?

Dr. SCHUCHAT. I do expect more cases, and I expect more States to be affected. I think we can't assume that we'll have as mild illness as we've seen at the beginning of the cases that we've detected. I think we really need to be prepared for a worsening of the situation.

And it's also important that people realize it's more of a marathon than a sprint here. Even if we do see cases come down, in the past, when there have been large-scale pandemics of influenza, sometimes we've seen a drop in the flu cases at the time that you would usually see a decrease with seasonal flu, but we've seen additional waves in the fall or winter.

So I think we have to be prepared that even if it starts to look a little better, it might get worse. But I don't want to over-alarm people, because we aren't in the same kind of situation as Mexico at this point.

Senator HARKIN. Just two follow-ups. If you knew someone who had planned a vacation or a trip to Mexico, had their plane tickets purchased and were going to go in the next week or two or three, what would you say to them?

Dr. SCHUCHAT. You know, yesterday, CDC officially issued a travel advisory asking people to defer nonessential travel to Mexico. We think that's a prudent response. If you are going to go, there are some steps that you can take to protect yourself to make sure that your health is good while you're traveling.

We didn't do that immediately. We waited until there was enough information that there was confirmed swine influenza causing severe disease in a number of places in Mexico. But we issued that travel warning.

Senator HARKIN. A practical question now, also another practical question. We are in the height of a kind of allergy season. A lot of people are sneezing. Count me as one of them. And, you know, you get a little raspy throat. So what would someone do—I mean, how do you know if it is it an allergy or is it something else?

Again, what would you advise people who find themselves sneezing a lot and perhaps have some irritable throat membranes, nasal passages? What would you advise someone like that?

Dr. SCHUCHAT. Yes. You know, respiratory symptoms are really common from both allergies, as you describe, and from a number of infectious agents, bacteria, and viruses. And most respiratory symptoms are not swine flu.

We've alerted people in the affected areas that if they have high fever, respiratory symptoms, like cough or sore throat, body aches, headache, and they have recently traveled to Mexico or one of the affected areas, that it's a good idea to consult with their doctor.

Part of the investments in preparedness for flu helped us develop some new diagnostic tests, so we're better able to tell if it's flu or not, and if it is flu, the State health department laboratories now can find out if it's this atypical influenza, and we at CDC can confirm if it's the swine flu or not.

So we don't think the allergy kind of symptoms need to be—you need to see a doctor for those. But we also think you should use your judgment. If you're feeling quite sick, then talk to your doctor.

Senator HARKIN. So you would have to have one of the other indications, a high fever or something like that to go along with it, before you might have an indication that it would be a swine flu?

Dr. SCHUCHAT. You know, it's not possible for any of us individually to know if the symptoms that we're having are swine flu or something else. You really need a doctor's visit and a laboratory test. But most people don't need to worry—that respiratory symptoms are pretty common. And as I said, you can do a lot to protect yourself from spreading those respiratory infections.

Senator HARKIN. I have more questions along the lines of getting the antivirals out around the country, but Senator Hutchison has to leave, and I want to defer to her for questions.

Senator HUTCHISON. Thank you. I do thank you, Mr. Chairman, because my concern is—I think you have answered a lot of the questions about what people can do. I have now seen that we have confirmed six in Texas.

I thought the Dallas County ones had not been confirmed, but they have been. And then the ones near San Antonio are confirmed and the schools are closed. Now—not in San Antonio, but in the Schertz-Cibolo-Universal City School District.

So we do have now a real impact, and it could get bigger. Some of the European countries are taking measures to screen everyone who would go on a plane from Mexico to their country. And, of course, we have border stations all through the South and Southwest between Texas, Arizona, New Mexico, and California with Mexico, people walking across every day.

My question is, what should we be doing to protect us in every possible way from people coming in from Mexico who might not have the symptoms right now? So asking the question of them may not be sufficient. What should we be doing—to either you, Doctor, or Dr. Fauci or any of you who would have an opinion.

Dr. SCHUCHAT. First I just want to say that I know it's a really difficult time in Texas, that schools are closed and people are kind of scared, and I feel for the communities there that are trying to understand what's going on in a very uncertain time.

Based on the pattern of illness that we're seeing here in the United States, we don't think that this virus can be contained, that we can stop it at the border, but we do think we can reduce the impact of its spread and we can reduce its impact on health.

And so what we've been advising and I know is occurring in Texas is what we call community mitigation, where an ill person should stay home and be isolated, not spread illness to others, that household contacts can take special steps to avoid getting ill and to avoid spreading illness they may be incubating, that when there are cases in a school, we've advised closure of the school, and that if there are community gatherings related to a school, that those should be cancelled for the short term.

So we think those are—from history, we have learned that even in the terrible 1918 pandemic, those kind of community efforts actually spared several communities. That's what we think is important.

We also have sent the assets, the antiviral drugs and the personal protective equipment to the States, and there is material en route to Texas now.

Senator HUTCHISON. So you're saying that you think we should not try to do what we can to keep people from coming in with the disease, but instead, just try to mitigate the spread?

Dr. SCHUCHAT. You know, I think it's important for people who are planning trips to Mexico to know that we have advised them to defer those trips unless they're essential. We do have efforts at quarantine stations and with the borders that are intensive, but not shutting the border down, and I think that those are prudent at this point.

Senator HUTCHISON. Well, we certainly don't want to interfere with commerce to any extent greater than necessary, but wouldn't having the ability to take temperature, for instance, for people who would be getting on a plane from Mexico to come into the United States, that would provide some kind of early detection that perhaps that person should not be traveling into the United States right now, wouldn't that be prudent, or is that what you consider to be too much?

Dr. SCHUCHAT. It's not really a question of too much, it's a question of where do we think our efforts can have the most benefit at this point. So as a public health expert and infectious disease specialist, looking at the pattern of illness that we have, the frequency of travel across the borders, the most effective efforts, I think, are at intensive detection for cases, strong efforts at that community mitigation, the detection and isolation, and—

Senator HUTCHISON. What—

Dr. SCHUCHAT [continuing]. Closing schools, as appropriate.

Senator HUTCHISON. I'm just not following this, I don't think. It just seems like an early detection that's relatively—would be, I would assume, pretty inexpensive, to take someone's temperature before they got on an airplane, and if it's heightened, that is one of the first symptoms even before you feel the symptoms of the flu.

It just seems to me that taking a little more precaution about someone coming in, because we've seen this spread pretty rapidly when it does get into our country, wouldn't there be something more prudent in between what you're saying, which is let it come in, but try to stop it from spreading, and stop it before it comes in?

Dr. SCHUCHAT. You know, the information about temperature screening is not very robust, in terms of the effectiveness. During the SARS epidemic, there were efforts to do that in some countries. We did pretty well here in this country without going to that step, and places that did temperature screening didn't necessarily have great results. There are some quality of testing issues.

So I think that people ask about that. It's important to know that here in the United States, our routine quarantine efforts, in partnership with Customs and Border Protection, are actually more intense than in most countries, the countries that now have introduced the temperature screening.

So I think that it's—you know, it's difficult, and I'm sure that it's a very difficult situation in Texas. But based on what I know, I think we're taking appropriate steps.

Senator HUTCHISON. Any other opinions on the panel that would—

STATEMENT OF PAUL JARRIS, M.D., EXECUTIVE DIRECTOR, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Dr. JARRIS. Senator Hutchison, what I think that was going on is there is passage [inaudible]. Somebody appears to be ill, they go through further questioning to determine if they are ill, and then that will be handled.

I think one of the difficulties we have, though, is there's anywhere between 24 hours and 5 days between exposure to the virus and actually becoming sick, and there's no way to detect that at the border.

So as Dr. Schuchat is saying, the system is very imperfect. In a situation like this, we're all going to wish that there's more we could do, but sometimes it's just not possible.

So I do think the CDC and the Border Patrol are taking the prudent measures based on what works at this time. And as you, we all wish there was more we could be doing.

Senator HUTCHISON. Well, I think what you've said is relevant, that the time period where it would show or—from the time you're exposed until you know you're sick seems to vary greatly. And so you wouldn't necessarily be able to tell exposure. It could be in the first couple or 3 days, but you wouldn't maybe get sick for up to 20?

Dr. JARRIS. Well, I believe that what I've been understanding is it's somewhere between 24 hours on the early side and up to 5 days on the late side, but I—

Senator HUTCHISON. Oh, 5 days.

Dr. JARRIS [continuing]. Defer to the experts here.

Senator HUTCHISON. So the whole—everyone on the panel agrees that we should not be taking further steps to test people before they get on a plane to enter our country from Mexico or in the border stations where people cross, that we are doing everything that would be prudent? Would everyone agree with that?

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FAUCI. Yes, I would support what Dr. Schuchat said. There's a delicate balance, as you've pointed out, about doing something that might not really be very effective, versus putting most of the effort on the kinds of mitigations that we were trying to do in the community.

So I would agree that this is something that has undergone a lot of discussion, and the decision that was made by the CDC, I fully support.

Senator HUTCHISON. And the temperature is not necessarily a relevant precursor?

Dr. FAUCI. It's not—I wouldn't say it's not relevant. It can be. It's imprecise. There are a lot of situations where we'd be getting people out that have nothing at all to do with the disease.

The decision was made not to go with what's called an active type of approach as opposed to a passive approach, where you say,

“How do you feel? Do you feel ill?” And right now, as was mentioned, we are taking more of a passive approach, rather than the active approach that was just mentioned.

Senator HUTCHISON. Mr. Chairman, thank you for letting me have that opportunity.

Senator HARKIN. Thank you. Obviously, Texas is on the firing line on this one, right down there. I asked about the playing field, but you’re right, so many people come across that border every day.

Senator HUTCHISON. Yes, our Southwestern border with Mexico, people are coming in every day. And if they show symptoms of being sick, of course, they are detained, but if they don’t, then they may have that early—

Senator HARKIN. Exposure, but—

Senator HUTCHISON [continuing]. Exposure, but not yet show any symptoms, and they’re coming in.

Senator HARKIN. Nothing we can do about it.

Senator HUTCHISON. Well—

Senator HARKIN. Right now, as far as I know.

Senator HUTCHISON. At least that’s what the experts are telling us. I—

Senator HARKIN. Well—

Senator HUTCHISON. I hope that we’re monitoring this very closely.

Senator HARKIN. Well, I assume CDC is at all the border points. Is that correct?

Dr. SCHUCHAT. You know, we have reinforced the quarantine presence at 19 airports. We’re not at every land border area, but what we do is training of the Customs and Border Protection, so that we actually have CDC people at the training center, so the staff are trained in public health.

And you’ve heard of many infectious agents being stopped at the border through this active effort of watching for illness and a secondary screening. So I think that we are doing things. We find people with infectious diseases that shouldn’t cross borders or shouldn’t get on airplanes. But we aren’t at every border, physical land border site.

DIFFERENTIATING THE H1N1 AND H5N1 VIRUSES

Senator HARKIN. Thank you very much, Senator. Now I’d like to just shift a little bit now to you, Dr. Fauci. And let’s go back a little bit. We’ve had many hearings and you’ve testified here many times about the H5N1 virus. Now I’m told this is the H1N1. What’s the difference?

Dr. FAUCI. Well, first of all, Mr. Chairman, I want to emphasize something that you mentioned in your opening statement that’s very important, and to thank you and the subcommittee for the kinds of support you’ve given us, the CDC, the NIH, the FDA, the whole Department, Homeland Security (DHS), in the preparation in general for pandemics.

Because the kinds of things that we did, as you mentioned, when we had discussions here and I brought up to you that we may be preparing for an H5N1, but it could be something else. A pandemic is a pandemic, and forget the letters and the numbers. It could be a pandemic.

So the difference and the similarities between H1N1 and H5N1, which, as you know, first appeared in China over 10 years ago. We've been very intensively involved with that over the last several years; it is a virus that is a bird virus.

It generally does not infect humans. When it does, it does so extremely inefficiently, and there's only very rare cases of human-to-human spread, usually very closely related within a family unit or someone who was very closely involved physically with the person. We don't see that kind of robust or even modest secondary and tertiary spread.

So it is a high degree of lethality. As you know, there are about 500 or so, 400-and-something cases reported and about 50 percent mortality. But the ability to adapt itself to spread is very, very marginal for the H5N1.

And as I mentioned, it's an animal virus. It's fundamentally a bird virus. But it has pandemic potential. And the concern that we've had at the CDC and every other place is will it evolve molecularly or genetically to acquire the capability of being able to spread to humans and to continue to cause disease?

Thank goodness, it has not done that. But importantly, we were preparing for that eventuality, which luckily has not occurred and hopefully never will occur.

In the preparations for that, what we now have is a virus that's an H1N1 that is interesting and very complex, because we've never seen anything like it before. It's what we call a triple reassortment. I explained to you about a year or two ago what a reassortment is. When you have more than one virus that might infect a species, be it a pig or a bird or a human, in the same cell, the genes of these particular viruses can mix and match and recombine, and then you get sort of a hybrid virus.

This is interesting, because we have three separate genetic components, one from human—a couple from human, from pig, and from a bird. So this is a master of that reassortment.

The thing about it that it has, that H5 doesn't have—it's called a swine flu because there are swine or pig genes in there. It is an H1N1. And historically, even though it's something we've never seen before, H1N1s have the capability in general, as a group of viruses, to be able to infect individuals clearly much more readily than something like an H5N1.

So even though it is an animal type of a hybrid, it has now shown us that it can infect humans and it can cause disease, again with pandemic potential. What do you mean by pandemic potential? Something we've never seen before. Something—in humans, that is. Something for which there is no background immunity in the population, and it's capable of widespread spread and disease.

So the potential is there, but what we're focusing on very much is to contain—by the methods that Dr. Schuchat has mentioned, contain the spread of this virus in an evolving, dynamic situation. So one is dynamic and moving, and the other one, I wouldn't say is stuck, but it's there in a very smoldering way. Southeast Asia, occasionally you'll hear of one or two infections. It doesn't have the very dynamic nature that we're seeing with this H1N1 Influenza A swine flu. That's fundamentally the difference.

ASSESSING THE GENETIC ORIGINS OF THE H1N1 VIRUS

Senator HARKIN. Well, Dr. Fauci, in my opening statement, I kept referring to it as the so-called swine flu. Now, please instruct me in this. I've been told that it doesn't necessarily come from pigs.

Dr. FAUCI. Right.

Senator HARKIN [continuing]. But it has a swine gene?

Dr. FAUCI. Right.

Senator HARKIN. Please explain this.

Dr. FAUCI. Yeah, sure. If you look at a virus, an influenza virus, there are multiple different genetic makeups, RNA and things like that, that form the genetic core of a particular virus.

Senator HARKIN. Right.

Dr. FAUCI. So viruses have it, bacteria have it, humans have it. It's just the genetic makeup. When you look at those segments through the mechanisms that I mentioned, when you happen to have the accidental infection of a species with multiple different types, these genes, because they're very good at it—influenza is really good at doing this—they tend to reassort and reconnect so that you have a hybrid that's made up genetically of genes from a number of different species. This one—a number of different viral species.

So this particular virus, this H1N1, what we're calling swine flu, has genetic elements from a human influenza, genetic elements from a pig influenza, and genetic elements from an avian influenza. They all come together, and now you have this brand-new virus that we've never seen before that, unfortunately, has developed the capability of infecting a human and causing disease.

Senator HARKIN. I've heard that a more correct terminology for this might be a North American virus, because it originated there.

Dr. FAUCI. Well, I think there will be a lot of confusion. I wouldn't want to go there, Senator.

Senator HARKIN. Because it originated in North America.

Dr. FAUCI. Yeah, yeah. But we don't designate influenza viruses that way.

Senator HARKIN. But why wouldn't it be called an avian virus if it has avian genes, as well as the swine genes?

Dr. FAUCI. Yeah. It's unusual because we don't—we rarely see viruses that have swine genes jump species and infect humans. So it's just gotten that taxonomic, we call it, of how you classify a virus. When it has a pig gene in it, you generally call it a swine—a swine virus.

The reason why we don't say swine-bird-human is that we don't usually see a triple reassortment. This is a very unusual situation.

Senator HARKIN. Okay. This is all very instructive, but for the public out there—

Dr. FAUCI. Right.

PROSPECTS FOR AN H1N1 VACCINE

Senator HARKIN [continuing]. I think what they would be concerned about it is how soon can we get a vaccine for this?

Dr. FAUCI. Right. That's a very good point, instead of worrying about names. That's a very good point.

Senator HARKIN. Don't worry about the names. How soon can we get a vaccine?

Dr. FAUCI. Well, right now, it's moving very rapidly. And we've put into effect the kinds of preparedness that you actually mentioned when you spoke about how we have been involved in investments in the technologies of being able to isolate the viruses and get them in a form to be able to grow them and get them ready for a vaccine that's usable.

Right now, the virus, as was mentioned, has been isolated and characterized by the CDC. It's in a form now where it's being sent to the companies as what we call a seed virus or a seed strain or reference strain.

Over a period of time—and that should be measured in weeks—that will be grown up to the point where you could actually start talking about the production of pilot lots that can be used in determining what's the right dose, does it induce an immune response that might be protective.

The pilot lot process generally takes about 8 weeks or so, and then once you get that, you can simultaneously ramp it up for production so that over a period of anywhere from 4 to 6 months or so, you may be able to start getting off the assembly a number of doses, so that we might have it ready for people several months from now, particularly in the situation that was mentioned by Dr. Schuchat. These kinds of viruses may come along in the spring and may or may not be severe and may or may not spread widely, but from history, we know that they can then, when you get to the flu season in the winter, come back with a vengeance. And, in fact, there are historical precedents for that, in what we saw in 1918, when the virus did that.

So those are the kinds of things that are going into the preparation of a vaccine, but the specific answer to your question is that vaccine development has—the bell has rung and it's moving along.

Senator HARKIN. Well, again, that was part of another question, the flu season coming up next year. So what I'm concerned about—and I think I can speak for members of this subcommittee—is what do we need to do to provide resources to enable us to move as rapidly as possible to develop this vaccine?

But then again, we don't know that it's going to happen. It's just sort of a preventative measure, right?

Dr. FAUCI. Right. Right. We—whenever we get in a situation like that, it is part of the plan that was drawn up years ago that you get the virus, you isolate it, and you proceed towards developing a vaccine, at least the seed pilot lots, to see where the situation is going.

Because as we've been describing, it's very dynamic, and it clearly is a high possibility, probability, that we would need and want a vaccine for this. And that's the reason why we are proceeding along the line that is a step-by-step process of getting a vaccine against this particular virus.

Senator HARKIN. So far, the virus seems to—except in Mexico, they have had deaths—

Dr. FAUCI. Right.

Senator HARKIN [continuing]. But not in the United States. Is there some difference why it seems to be more virulent in Mexico than here?

Dr. FAUCI. Well, we don't know the answer to that, but as Dr. Schuchat mentioned—well, I'll let her answer the question, because she alluded to that in her statement to you before.

Senator HARKIN. Yes. Dr. Schuchat.

Dr. SCHUCHAT. You know, I think it would be wonderful if there's something different about what's going on in Mexico, that for reasons like the genetics of the population or medicines that they're taking when they get sick or the care that they're receiving, there's a more severe course.

But I think that we are really at early days here in the United States, and we may see a worsening of the disease that we're seeing. Influenza viruses are notorious for changing. They can get more severe and less severe. And I don't think we have enough information yet from Mexico or from the United States or other countries to be confident that we won't also see a severe spectrum of disease here.

Dr. FAUCI. Yeah, what we call the "N", the number of cases in Mexico clearly is much larger than the number of cases in the United States. So it would be premature to make a definitive statement about what the pattern is going to be in the United States compared to Mexico. That's the reason why it's being followed so closely by the CDC and is in a dynamic state. You can't make a definitive statement right now. That would be premature.

Senator HARKIN. Okay. But what I take from what you've just said is that we should be very aggressive in pursuing the development of a vaccine.

Dr. FAUCI. Yes.

Senator HARKIN. And we should do that as soon as possible to get as many doses ready as possible for the next flu season.

Dr. FAUCI. That process is ongoing right now. The decision of whether to get—and this is something that is being literally discussed as we move along, of whether you're going to get a vaccine or need a vaccine as a vaccine against the pandemic or whether you're going to take that vaccine and incorporate it into a seasonal one for the next season.

And that's under very active discussion now of what the pathway would be. But the direct answer to your question is that the vaccine is and will be developed.

Senator HARKIN. Yes. Well, again, we need further discussions with you and with the CDC and, of course, with Health and Human Services to find out just how much resources we need to come up with.

The second part of this is the money the Congress put into this, we've developed I think a stockpile of about roughly 50 million, antivirals for pandemic flu. Are those antivirals effective against this swine flu, or so-called swine flu?

Dr. SCHUCHAT. You know, we're very fortunate that the viruses we've isolated of the swine flu are sensitive to the TAMIFLU and Relenza that are in the stockpile. Unfortunately, this past year, the seasonal flu strains that were H1—sorry, the H1N1 seasonal flu

strains were resistant to the TAMIFLU. But we're lucky that we have a lot of TAMIFLU now.

The stockpile, as you mentioned, is about 50 million doses, and we've deployed now about 11 million doses to the States, first to the affected States, and by May 3, we'll have it out there to all of the States.

But we're lucky that the current strains of virus are sensitive—you know, with influenza viruses, you do need to keep monitoring, and so going forward, we really have to keep our eye on this and make sure that new cases are still sensitive. But at this point, it does look like TAMIFLU will work for treatment.

Senator HARKIN. Well, that leads me to Dr. Jarris. Dr. Jarris, of that money I spoke about—I was looking at my data here—it looks like we've put out about \$350 million. Now, that's rough. About \$350 million is there for State—oh, I'm sorry, cumulative is \$600—\$600 million. Sorry. I looked at \$350 million—that was the original one. So we've got it up to \$600 million that has gone to the States. So we can get the antivirals out, plus I guess masks and—

Dr. SCHUCHAT. Face shields and—

Senator HARKIN. Breathing devices.

Dr. SCHUCHAT. Gowns and such, yeah.

Senator HARKIN. Pardon?

Dr. SCHUCHAT. Masks and then respirators, which are a better kind of mask for healthcare workers type situations, and gowns and so forth.

Senator HARKIN. So those are all going out to the States.

Dr. SCHUCHAT. Right, uh-huh.

Senator HARKIN. Now, tell me, Dr. Jarris, do the States then have the capability of getting that out rapidly?

Dr. JARRIS. Yes, well, Senator—Senator Harkin—excuse me, Chairman Harkin, let me first start by saying thank you for your wisdom when you, in 19—in 2006, put forth this funding so we could be at the point we are of preparedness today.

And when you did that, as you said, of the \$7 billion, you did, in the subcommittee, put \$600 million in for State and local pandemic influenza preparedness. That did come through in two increments, a \$250 million and a \$350 million increment, which we greatly appreciate, and it is, again, why we are today where we are, where every State has a pandemic flu plan, every State has drilled that pandemic flu plan, and right now, every State is activating that pandemic influenza plan.

Some of the assumptions we made in the original planning turned out not to be the case. We assumed that this virus would start overseas. It didn't. It started in North America. So we're actively working with the Centers for Disease Control and State and local government to modify our plans as we go forth.

So the investment is critical. We, unfortunately, are at the place where as in August 2008, that investment was expended, and since August 2008, there has not been any money for—to support State and local pandemic influenza planning.

So we're at a point of critical need where we have the plans, we're exercising them, but we've run into a situation where there's no further investment to continue to develop and refine these plans.

At the same time, we've seen declines in the Federal, State, and local preparedness money that comes out of CDC and declines in the hospital preparedness money that comes out of HHS, on top of which we all know the economic situations of the States right now are very dire.

Senator HARKIN. That's a question I have. The State budgets have been drastically cut over the last year or two. Again, is your association concerned about this? Have you seen any impact on their public health capacity?

Dr. JARRIS. Yes, we clearly have. We have seen—and yes, we are concerned. We have seen at the State and local public health level close to 12,000 layoffs in the past year.

Senator HARKIN. Wow.

Dr. JARRIS. We anticipate an equal amount in the coming year. We are seeing States drop whole programs, wholesale, as well as we are seeing cutbacks in services. Well, what not everyone may appreciate is we don't have a preparedness force ready and waiting for whether it's a pandemic or floods, as you had, or the hurricanes, as Senator Bailey had—Senator Hutchison had.

This is the regular public health workforce, the nurses, the epidemiologists, the laboratorians, who then kick into action and take on an entirely new job for preparedness, and that is what's going on in pandemic influenza—with the outbreak right now.

Senator HARKIN. But with all those layoffs and those cutbacks, how can you assure me that the States are ready to get this out in a hurry in case we have outbreaks in our State that multiply overnight?

Dr. JARRIS. I can assure you that we will do everything humanly possible. We have a very dedicated workforce. However, I think you are absolutely correct in identifying a vulnerability here, where in the face of these cutbacks and layoffs and vacancies, we don't even have the workforce we had two years ago when we had the preparedness funding to do our drilling.

Senator HARKIN. Well, Dr. Jarris, and I diverge here a little bit, there is a lot of talk about doing healthcare reform this year. And I'm not going to get into that at this hearing.

But I think what is happening right now makes it crystal-clear that the public health departments, both of our State and our Federal Government, have been inadequately funded in the past. They seem to be the first to be cut in budgets, and then when something like this rears its ugly head, we find we may not be as prepared as we should be.

And so I think that we have to remember this—we can't forget this—that when we move ahead now, we have to strengthen the public health sector—

Dr. JARRIS. Right.

Senator HARKIN [continuing]. Of our country, State, local, and national.

Dr. JARRIS. And I thank you for stating that, and I believe it's true. We don't look at our fire departments and say, "We haven't had a fire in a week. Let's shut it down."

Senator HARKIN. That's right.

Dr. JARRIS. We are facing the same issue right now in public health, though. We, I would say, are at a critical resource and

workforce point within public health at a time when the demands are tremendous.

Senator HARKIN. Well, that's why I say that I am very concerned about the ability of the States, I know they're going to do everything they possibly can, but with 12,000 layoffs and cutbacks in State budgets, I remain deeply concerned about their ability to rapidly answer a growing pandemic in some areas of some States.

Dr. JARRIS. And for that reason, I'd urge you, as you look at the appropriation—the supplemental appropriation—and we thank you for doing that—that we keep in mind that there are two types of funding here. There is certainly the type of money that goes for vaccine development, for research, for testing, and development of new techniques.

But equally important, we need the workforce on the ground so when we have that vaccine, we can put it in people's arms. When we have that TAMIFLU, we can get it out to people. And as Dr. Fauci and Dr. Schuchat said, even if this were to peter out right now, which it doesn't look like we could at all predict at the moment, if it were to come back in the fall and we had a vaccine available, we certainly need to make sure we have the public health workforce there to get that vaccine to people and deliver it.

And I think your—the stimulus supplemental funding that you're discussing, if it were to come forward in the near future, would allow us to meet that demand in the fall.

Senator HARKIN. Well, you could be very helpful in giving us some idea of what would be required in that supplemental. I mentioned earlier that I intend to put that \$870 million back in there. Now, what more might be needed—

Dr. JARRIS. Well—

Senator HARKIN [continuing]. To assist the States?

Dr. JARRIS. Thank you for asking. The \$870 million would actually not assist the States, in terms of preparedness.

Senator HARKIN. That's right. No, it was not intended—

Dr. JARRIS. Right.

Senator HARKIN. That was intended only for the vaccine development and to get our laboratories built more rapidly.

Dr. JARRIS. Right. We would propose—and this is conservative—the \$600 million that you had provided us in the past came at a \$250 million and a \$350 million. So conservatively, we would say the \$350 million as an additional increment for planning and preparedness would allow us to handle the situation right now, if it didn't become a full-fledged pandemic, but allow us to continue the planning.

Now, we would have to come back to you in the face of a full-fledged pandemic, as I'm sure the CDC and the NIH would, to really gear up for that. But \$350 million for State and local preparedness we think will allow us to resume the planning level we had until August of 2008.

In addition, we are about 8 million courses of antivirals short in the State stockpiles.

Senator HARKIN. That's right.

Dr. JARRIS. So we would need about \$122 million to bring the State antiviral stockpiles up to the benchmark goals that were established.

Furthermore, we are hearing—and Tom Harkin and your State—I'm sorry, sir. Tom, in your State, the State health official has been hearing from the hospitals. We've all been hearing from the hospitals. They are very concerned about the healthcare workers and the public health workers. So we are asking for \$563 million to purchase personal protective equipment and antivirals for the prophylaxis of healthcare workers, critical infrastructure workers, and public health workers.

There's a great concern—not only do we owe it to the people who are on the front lines to be protected, but we've been hearing from the hospitals that they're concerned about people showing up for work if they aren't offered personal protection when they put themselves in harm's way.

So those three, the \$350 million for State and local planning, the \$122 million to bring State stockpiles up to goal——

Senator HARKIN. Up to 31 million.

Dr. JARRIS. Excuse me?

Senator HARKIN. That brings it up to the 31 million, from 23 to 31 million doses.

Dr. JARRIS. That would get us to a total of 75 million, which was the goal of the stockpile nationally.

Senator HARKIN. Oh, I'm sorry. You're talking about the national. The current pandemic planning—States purchasing 31 million.

Dr. JARRIS. Okay. Yes.

Senator HARKIN. So far, States have purchased 23 million. That's 8 million less than what the plan was.

Dr. JARRIS. Yes, sir. So the \$350 million for preparedness, the \$122 million for State stockpiles, and the \$563 million so that we have the antivirals for first responders and hospitals. Antivirals and——

Senator HARKIN. Protective gear.

Dr. JARRIS [continuing]. Protective gear, yes.

Senator HARKIN. Well, I—we'll do what we can. We have a supplemental coming up. Much of that supplemental will be Defense related and Homeland Security related. I can't think of anything more—that would—near more to our defense than Homeland Security than making sure that we have adequate protection for our people in case of a pandemic.

Dr. JARRIS. And I would think history would bear that out.

Senator HARKIN. Absolutely.

Dr. JARRIS. The 1918 experience affected the military as much as the civilian population.

Senator HARKIN. Absolutely. When I come back, Dr. Schuchat, I have some more questions for you regarding CDC's response to this. Dr. Clifford, we haven't gotten to you yet, but I want to talk to you again about swine and what you're seeing, in terms of swine out there, and we'll get to that. Maybe some others have questions about that.

But when we started this process several years ago, building up our capacity to respond to a pandemic, to build the facilities needed for cell-based production, the chairman of this subcommittee was Senator Specter from Pennsylvania. We have been a great partner-

ship on this. We've changed back and forth from chairman to ranking member more times than I can probably count.

But it's been a great partnership. And he was one of the great leaders in, again, foreseeing and working together with so many others to make sure that we had the money in there to get us started on this pathway. So I would yield now to a great partner and a great friend and a great leader in healthcare, Senator Arlen Specter, Pennsylvania.

STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you very much, Mr. Chairman, and thank you for convening this important hearing on emergency basis. And thank all of you for coming in to testify.

Senator Harkin has gone over the financial needs, and we will try to be very responsive to see to it that adequate funding is provided. There is great public concern, as is evidenced by the front pages, news media accounts as to what the situation is. And there has to be a careful balance in what is said to inform the public of the problem, but not to articulate it in a way which might cause undue alarm.

We had these hearings, as the chairman has said, in the past. In 2005, we had the testimony of John Barry, who wrote the book "The Great Influenza", tracing what has happened in prior years, where they have had such cataclysmic results, with so many people dying in the United States and elsewhere in 1918 and in 1957 and 1968.

And when we looked at the issue before, there was concern about avoiding crowds or the issue of whether people ought to go to work or what kind of precautions ought to be taken. And that has to be stated from the experts, so that people have an idea as to what the risks are and what ought to be done.

But at that time, there was a lot of talk about stockpiling food, stockpiling water. Well, I don't know if that's warranted, but people are going to be starting to think about that. We don't want to cause a mass rush on those commodities, but we also want to be thoughtful. And the people who provide those commodities have to be on notice as to what requirements there may be.

I regret that I can't stay longer, but this is a complicated day for me. That's not a laugh line, by the way, but you can laugh. Who am I to say? But thank you very much, Senator Harkin, and thank you for your good words.

This subcommittee has operated at a very, very high level of concern for the issues of health. What this subcommittee has taken the lead on, on funding for the National Institutes of Health, Dr. Fauci may know something about that.

I spoke in Chicago on Saturday at a meeting of 600 scientists, and they were delirious. Not sick-delirious, but delirious for \$10 billion, which was in the supplemental. When this subcommittee took the lead in increasing the funding in NIH from \$12 to almost \$30 billion, a lot of reductions in deaths due to stroke and heart attacks. Not quite so much from cancer, but a lot to be done. So thank you for what you are doing. And I'd like to see my other colleagues here today.

PREPARED STATEMENT

Senator HARKIN. Again, Senator Specter, thank you so much for your leadership and friendship over the years.
[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

I want to thank Senator Harkin for calling this hearing to discuss U.S. efforts to combat the swine flu outbreak.

This subcommittee has been at the forefront of addressing the pandemic flu issue. This is the fourth hearing that this subcommittee has held on pandemic flu—we held our first hearing on November 2, 2005, and we also held hearings in 2006 and 2007. Senator Harkin and I—on October 27, 2005, during the floor debate on the 2006 Labor-HHS bill—offered an amendment which was adopted by the Senate to provide \$8.095 billion for pandemic flu.

To date we have appropriated \$6.1 billion for pandemic flu activities. As I understand there is still \$528.5 million from prior year funds and another \$507 million that was appropriated in fiscal year 2009 that is still available to be spent.

We have a distinguished panel of witnesses before the subcommittee today and I look forward to their testimonies.

Senator HARKIN. I will now recognize Senator Kohl.

STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Thank you very much, Mr. Chairman. Just to carry on and get some response from some of the queries that were posed to us by Senator Specter, what is the level of concern that we're trying to convey to the America people, in terms of what we know and what they need to be responsive and concerned about today, tomorrow, the next day.

Maybe you've covered this, but I didn't get—have you stated your level of concern, how serious this is? If people get sick with what is diagnosed as swine flu, how sick are they going to be? Do they simply stay home for a few days? Do we know the answers to those things? What are the practical things that the American people need to be told?

Dr. SCHUCHAT. Senator Kohl, the situation is concerning. People are concerned, and so is the CDC and the rest of Government, really. And I think it's a concern that can have focus.

The situation in the United States is that we have had 64 confirmed cases. Most of them have not required hospitalization, but now we have five that did need to go in the hospital, at least. And we really need to be prepared for a worsening. But unfortunately, we can't completely predict what's going to happen. It could really tail off or it could get worse, and it might even get much worse, looking to Mexico, where it appears that it is much worse.

The good news I think is that we've been preparing for years. We've been exercising—based on the efforts of Congress, really, we've been able to invest in preparedness and strengthen the capacity at the State and local level, at the Federal level, with a lot of good research, with investments in assets like antiviral drugs.

So I think that we have been planning for something like this. We hope that it won't get worse. There's a lot that individuals can do. They can stay alert to what's going on in their community. I think a difficult thing right now is that information may be conflicting. What's going on in New York City is not the same thing as what's going on in Virginia or Wisconsin.

So we need people to look to their local authorities, their public health authorities, for guidance where they are. At CDC, we've been trying to issue national guidance, and it's always interim, because we'd like to make sure we update our recommendations as we learn more.

But we have issued recommendations about community mitigation. Once a case of swine flu is identified in a new place, we've put some advice out about taking aggressive steps to limit its spread in that new place so that it doesn't get bad, it doesn't get like the Mexico situation.

And that guidance just went up yesterday, I think, about staying home when you're sick, isolating yourself, about how your household members should take care of you, designating one person in the family to take care of the person who's sick and take special measures to protect themselves.

If it's a school child who's sick with the swine flu, we think that closing that school is a prudent step at this point, probably closing gatherings associated with that school, but leaving it up to the local authorities to decide whether other schools need to be closed, or whether general community gatherings need to be cut back on.

We think it's a challenging time. At CDC, we're really committed to share information as we know it, to support the local and State health departments that are really at the front line, to make sure that clinicians have the information they need and that the laboratories have the test kits that they need.

But I think it's a time where we need to be prepared for change, and that we don't have all the answers today.

Senator KOHL. And isn't it also true—or isn't it true that this swine flu is going to be with us for some time. It's not going away next week or 2 weeks from now.

Dr. SCHUCHAT. You know, we mentioned a little bit earlier the idea that we might see an improvement. We might see cases go down, just like we see with the seasonal flu, but we need to be prepared that this strain is out there now and it might come back in the fall.

And so the scientific and public health community are planning and discussing contingencies. If it does come back, what does that mean? Issues like preparing vaccine strains that can be handed off to industries so that if we make a decision to go ahead and produce a lot of vaccine, we can figure out about that.

So there's a lot of dialogue and discussion going on to really use what we know about this particular swine flu strain, what we know from history when there were pandemics and how those evolved, and really I think preparing the country for a period of uncertainty and a commitment that we'll stay with you as we know more.

Senator KOHL. Thank you. Dr. Clifford?

**STATEMENT OF JOHN R. CLIFFORD, DVM, DEPUTY ADMINISTRATOR,
VETERINARY SERVICES, UNITED STATES DEPARTMENT OF AGRICULTURE**

Dr. CLIFFORD. Senator Kohl, you asked about what we should be telling the public. Dr. Fauci earlier explained the complexity of this particular virus, and while I know there's not concern on the

human side about the name of this virus, there certainly is on the animal agriculture side.

Calling this virus swine flu, when we have not even shown this virus to affect swine as of yet, is alarming, because it causes undue alarm to the public and to our trading partners with regards to the safety of pork.

We have not found this particular virus at all in swine as of yet in the United States, nor have viruses in swine been associated with any human illness as of yet. That's not to say it couldn't happen in the future.

At this time also, I'd like to state that with regards to this virus, it should be called something else, but I recognize because we're already calling it swine flu, it's likely to stay swine flu. But this is not a food safety issue. Pork is safe to eat. Thank you.

Senator KOHL. It's a very important point to make, and I'm glad you made that point. Dr. Clifford, you're the head of APHIS?

Dr. CLIFFORD. I'm the head of APHIS Veterinary Services.

APHIS RESOURCE NEEDS

Senator KOHL. Okay. Now, APHIS, as you know, has the responsibility of monitoring and responding to any outbreaks of animal disease. Your efforts are key to helping us understand and control this flu as it occurs in animals, as well as understanding and relating any potential transmissions between humans and animals.

So are we certain that APHIS will have sufficient resources and leadership to do its job during this time of surveillance?

Dr. CLIFFORD. Thank you, Senator, for that question. We're evaluating our resource needs, and certainly, as we evaluate those, we will be working with the Secretary and providing those needs to Congress.

But along that line, I would like to say that when we on the animal health side talk about swine flu, just like humans have flu seasons, swine have a flu season, as well. It's the same with poultry or avian.

A large percent of the adult swine in this country are vaccinated for swine influenza viruses, both H1s and H3s. Actually, about 70 percent of adult breeding swine are vaccinated.

We vaccinate for viruses that cause influenza in swine. Influenza in swine is endemic in the United States, so we will occasionally see cases, but we have not seen this particular virus.

We're actively reaching out to the States for any unusual cases and any cases associated with public health issues. We're working very closely with CDC and DHS on this. In fact, the secretary is meeting today with DHS at 3:15 p.m. to further discuss our response plans.

In addition, I'd like to add that we're working very closely with CDC in implementing—and actually, we started a year ago—implementing an enhanced surveillance program for swine flu influenza viruses in order to better adopt and develop diagnostic tests as well as better vaccines, both for the animal health side as well as potentially for human health.

Senator KOHL. Thank you.

Senator HARKIN. Thank you very much, Senator Kohl. Now I yield to the newest member of our subcommittee and our com-

mittee—not a new senator, but a new member of our committee, my good friend from Arkansas, Senator Pryor.

STATEMENT OF SENATOR MARK PRYOR

Senator PRYOR. Thank you, Mr. Chairman. It's an honor to be here today. Thank you for your leadership. Let me, if I may, follow up with our USDA witness. Just to be clear, you said that pork food products are safe to eat, and that as far as USDA knows today, there are no pigs in the United States that have been infected with this virus?

Dr. CLIFFORD. That's correct, sir.

APHIS SURVEILLANCE SYSTEM

Senator PRYOR. Does that mean that USDA will continue to test and monitor our pork population here in this country?

Dr. CLIFFORD. Actually, we have a very robust surveillance system in general for swine illnesses and swine issues. That's made up by both the private sector from the private veterinarians to the State animal health officials and Federal health officials.

If we see a degree of high morbidity or high mortality, those types of things are reported up and investigated, either through the private sector or the public sector.

Since the emergence of this virus, we have actively reached out with our State partners, again, as I stated, to make sure that we're investigating any unusual cases that may be detected out there today. But there has been no detection of this virus thus far in our swine population.

EXPORTS OF PORK PRODUCTS

Senator PRYOR. Thank you. There have been press reports about some of our trading partners being nervous about accepting U.S. pork products and, based on these press reports, it seems that some countries have already taken action on that. What are the USTR, USDA, State Department, et cetera, doing to try to ensure that our exports of pork products are not affected by this?

Dr. CLIFFORD. Senator, we actually reached out over the weekend to all the posts with our trading partners, both through the Foreign Agricultural Service and the U.S. Trade Representative, as well as our APHIS personnel abroad, to give them the latest information, to tell them that swine are not involved in this situation, and to make sure that they are following reasonable scientific standards, as far as trade.

And any country that takes action against the United States or any other country for the movement of pork or pork products is not following science-based standards, they're basing it on a non-scientific reaction.

Senator PRYOR. And have other nations taken those steps already?

Dr. CLIFFORD. Yes, they have.

Senator PRYOR. Okay. And is there any chance that they will lift those sanctions anytime soon?

Dr. CLIFFORD. Ambassador Kirk from the U.S. Trade Representative Office is working on this process and trying to work to reopen those markets.

HHS DECISIONS AFFECTING H1N1 VACCINE PRODUCTION

Senator PRYOR. This is a question for our CDC witness. My staff participated on an interagency conference call yesterday, and the participants on that conference call discussed the fact that vaccine production is not automatic, and that the decision has not yet been made to order production of vaccine for this particular virus.

My question is, first, what are the criteria for deciding whether to order production, and second, when will that decision be made?.

Dr. SCHUCHAT. There have been steps taken already to prepare for the potential production of a vaccine. CDC's isolation of the virus went on to prepare a vaccine seed strain that could then be handed off to industry for development of pilot lots that Dr. Fauci was speaking about that could be tested.

So there's a lot that is going on. But it's a different question to decide to prepare to make a vaccine than to actually go forward and produce large amounts. And even if you produce large amounts, to go forward with the idea of using them, there are some risks and benefits involved. And, of course, an important issue is understanding how well—how easy it is to make a vaccine.

Right now, what's going on is that experts from various disciplines are studying the issue, if we make a vaccine, is it best to make a swine flu vaccine alone? Would it be better to combine it with some of the seasonal flu strains that we usually use?

We have a much better production capacity than we had a few years ago based on the investments that have been made, but we really will need to make some decisions about what kind of vaccine or vaccines will we have several months from now in the fall.

So part of the criteria will be looking at what's going on and where this virus is in Mexico and in the several other countries now. Understanding more about immunity, there are questions about whether people who were exposed to the H1N1 strains or the vaccines back in 1976 might even be protected now, questions about whether there's any cross-protection from the seasonal flu vaccine against this.

So really in the days and weeks ahead, some major decisions will be made about that question. We're trying to be careful and deliberate. We are trying to learn the lessons of 1976 so that we learn and do as well as we can.

So I would say that we are being aggressive in making sure that we can make a vaccine, but I think we want to make sure that there's care and attention in the decisions as they go forward. I think Dr. Fauci should add—

Dr. FAUCI. Yeah, there's—and thank you, Anne. There are multiple steps, and I tried to articulate them early on, that the first thing you want to do no matter what, you isolate the virus the way the CDC did and you immediately make a seed. That's automatic. That has been done, is being done.

And then they're being handed over now to the pharmaceutical companies to begin what's called a pilot lot, and the pilot lots will

be used in tests to determine what's the right dose, is it safe, does it induce the kind of immune response.

The decisions of whether you are going to make millions and millions of doses and certainly, whether you're going to even use them, are things that are made in a step-wise process. But in order not to lose time, the thing you automatically do from the beginning is get that seed virus going so you could begin the process.

You mentioned and Anne mentioned the situation in 1976, where vaccine was made and then deployed and utilized, and there were some serious consequences from that. These are lessons learned about that there are things that you need to deliberate about and be careful about. So we're doing it in a step-by-step process.

Senator PRYOR. And one of the things that's obviously near and dear to this subcommittee's heart is funding. Do you need any more money to do this? Maybe you've covered that, and if so, I'm sorry. I was a few minutes late. But do you need more resources to do this?

Dr. SCHUCHAT. You know, I'll just begin and maybe there's—

Senator HARKIN. If I might—

Dr. SCHUCHAT. Okay.

Senator HARKIN. Is the Senator asking do we need more resources to address this situation, or to develop our whole capacity in terms of vaccine production in this country? If the Senator is talking about this particular problem that we have right now I was just notified that the White House is announcing today that they will be asking us on this subcommittee for \$1.5 billion to respond to this swine flu in the supplemental.

Senator PRYOR. Okay.

Senator HARKIN. They'll be asking for \$1.5 billion. And we kind of went through that before. I don't know if you were here for Dr. Jarris's testimony of what the States need, but it's really a question, I think, of how rapidly we want to ramp up our ability to have cell-based development of vaccines in this country.

As I said earlier, up until 2005, we only had one plant in this country that could make flu vaccines. It was egg-based and takes a long time. And we've been putting, as I said, more than \$6 billion into this—rather, more than \$3 billion into this, to develop the facilities to get cell-based development where we can—after they get the seed thing done and they identify it, then we can turn it around and make the millions of doses needed in a short period of time.

Again, my response on that, from everything I know and my staff knows on this, yes, we do need more money. Again, depends on how soon we want to do this. If we want to take another 5 or 10 years, no.

But I think that we've had enough indications—and I'm just saying this from my own standpoint—in the last several years, first with the avian virus and now with this so-called swine flu virus, and the different mutations that might happen, I really think it behooves us to move as rapidly as possible to get these facilities built, so that we can develop that vaccine as rapidly as possible to protect our people.

Senator PRYOR. Thank you, Mr. Chairman.

Senator HARKIN. I didn't want to put them on the spot on about this. So again, for the record, the White House will be requesting \$1.5 billion. Dr. Jarris, of course, we will look at that and see how that all fits into Federal and State efforts and what the States may need in that. So whatever information you have from your organization that you could share with us—you already gave us the broad outline—I would appreciate that.

VIRUS IN PIGS

Now, let me return here—and thank you, Dr. Clifford, for clearing up this. We don't have one hog in the United States that has this flu, that we know of.

Dr. CLIFFORD. That we know of, we don't have one single pig in the United States that has this particular virus.

Senator HARKIN. That's right. And as far as we know, we don't know any in Mexico either.

Dr. CLIFFORD. That's correct. In fact, I've received communication from my counterpart in Mexico, indicating that to their knowledge thus far, they have no pigs with this virus.

Senator HARKIN. That's why I'm really sorry that this seemed to take on the connotation of swine flu. I don't know how that happened. I opened up the newspaper this morning and there's a picture of pigs and hogs, as though all of them are affected with this.

So I'm glad we got that out here, and that's why I wanted you here today, to allay the fears of people, that pork is safe, it's safe to eat, and also to let our trading partners know that actions that they may be taking to cut off purchases of pork is not founded scientifically whatsoever.

Dr. CLIFFORD. Yes, sir. And I think it's very important, and hopefully, the media will get that story out, as well.

Senator HARKIN. Well, I sure hope so, because it's just took on a life of its own there. That's why I wanted you here today, to do that. And I thank you very much for your responses to that.

Now, I don't mean to get on a discordant note here with my friends, but Dr. Schuchat, in looking at this, there's an article that came out in the paper yesterday—I'm sorry, Sunday—that caught my attention.

And according to this article by David Brown, Mexican public health authorities sent their initial flu samples to Canada because, quote—here's a quote—“The only reason the samples went first to Winnipeg is because the paperwork is easier. We were in a rush,” Hernandez said.

Well, the article also states that U.S. officials were largely in the dark about the outbreak 2 weeks after it was recognized by Mexican authorities. So we have spent a lot of money, taxpayers' money, building up CDC's lab capacity, their ability to recognize these right away. Canadian officials knew about it before we did.

So why did this happen? Why did this happen? Why wouldn't they have gone—I mean, Centers for Disease Control and Prevention is the gold standard in the world. Everyone recognizes that. So why would it go to Canada before it came here? What's this about paperwork and they were in a rush? You mean to tell me CDC can't rapidly respond?

Dr. SCHUCHAT. Thank you. The CDC is one of four WHO international collaborating centers for influenza. We are reference laboratories for countries around the world, and we do receive many, many strains from Mexico all the time, as well as from many other countries, and from labs within the United States.

So it is our practice to receive and test isolates. I want to make a couple comments about the timeline here, because I think people have been interested in that.

On April 17, we identified the first swine influenza virus from California, from San Diego. And our scientists, whenever they find a novel flu virus, take steps to characterize it, and then to disseminate the information on this new virus, the sequence information, so that other scientists are able to look at it.

In fact, I believe that the Canadians were able to figure out that their virus that they were testing was similar to the one that we had already reported from California.

On April 21, at about 1 a.m. in the morning, we issued an MMWR dispatch electronically, reporting two cases of this new swine flu in the United States from California. They were just two cases, but it was a new virus, and we wanted people to know it was out there.

On the 23d, we held a press briefing about additional cases in the United States, again not really knowing whether this was a big deal or a small deal, but just wanting people to be on the alert and to look for unusual influenza viruses, to pass those along to their State labs, where they could test for typing of viruses, because we had provided them with training and kits to do so, and then to send all unsubtypable strains on to us.

It was at that point on the 23rd when Mexico, Canada, and CDC were able to connect the idea that the virus in Canada from Mexico was the same as the virus from—that we were testing in the United States. So in a way, really, our intensified surveillance in the United States brought to light the characteristics of the problem in Mexico.

Before that, reports of increased respiratory disease from Mexico were publicly being discussed and consulted upon. Respiratory infections are very common, and increases and decreases are hard to interpret. The testing that was being done at that point suggested a mixture of seasonal influenza virus strains, as well as many unknown causes.

So we get reports of increases of disease frequently, and we look into them and provide support. But I think in this case, our rapid dissemination of the U.S. situation has accelerated our recognition of the problem. We don't like it when people find our bureaucracy difficult, and I really am committed to making sure that we can serve communities here in the United States, as well as our partners outside of the country.

So I think I'm as disappointed as you are in the reports that our bureaucracy was difficult, and I would like to be able to do better. But I'm really proud of my staff and their aggressive work on identifying these first couple cases and issuing guidance or issuing a report quickly and getting the word out, so others could be looking for it.

Senator HARKIN. I might ask you, Dr. Schuchat, that—and I'll ask your superiors down there also at CDC to respond to this, and I want to find out why the paperwork is easier when it went to Winnipeg. Is Winnipeg one of the four?

Dr. SCHUCHAT. No. No, it's the United States and Australia and Japan and England.

Senator HARKIN. Huh. Well, I really want to follow through on this, and why—what's the paperwork difference? It would seem to me that—just—I—maybe I'm being a little chauvinistic here, but—because I worked so long with CDC for so many years, and I've traveled around the world, and everyone just looks to the CDC for—that's where you go. And so I'm just shocked that they would go to some other place, quite frankly.

Dr. SCHUCHAT. Well, and I think we'd be happy to respond on the record about that. And I know they have been sending us strains and we've characterized their viruses, as well.

Senator HARKIN. Right. Well, let's take a further look at that and see if there's anything else that we need to do. I do have a couple more questions that I want for the record here before we recess.

DISCUSSING THE WHO PANDEMIC INFLUENZA PREPAREDNESS PHASE
RATING

Again, I suppose Dr. Fauci would be the proper person to ask this to, is—both of you, I guess. The World Health Organization raised this from Level 3 to Level 4. Do you concur that it should have been done?

Dr. FAUCI. Yes. Yes. Yeah, but as the CDC has determined and actually publicly stated, we're proceeding along in a very rapid way in the kinds of interventions and the community mitigations and all the other things that we're talking about. And it really doesn't matter what that number was, I think you would agree, Dr. Schuchat.

But the answer is, we agree with elevating it, yes.

Senator HARKIN. As Senator Specter said earlier, we provided—again, with his great help and assistance, we provided \$10 billion, as you know, in the recovery bill, the stimulus bill for NIH.

And again, maybe this is something we need for the record later on, but I'd like to know just how much of that might be going for research, flu research, influenza research. As I've said many times in this subcommittee from this position, that we don't think about influenza, but it costs us a lot of money every year. A lot of people die of influenza every year. It costs us a lot of hospital stays. It's not only a very expensive, but a very life-threatening illness, and very transmissible.

So it seems to me we need to figure out how much of that we're actually—what are we looking at, in terms of flu? And that may be for another hearing later on, but I hope you'll be thinking about that, how much of that goes there.

Well, that's all that I really wanted to cover. Do any of you have anything to add or to illuminate on this issue at all for the public out there at all, that—anything that I haven't asked that I should get on the record?

ADDRESSING THE SUBCOMMITTEE'S ROLE IN PREPAREDNESS FOR
INFLUENZA PANDEMIC

Dr. FAUCI. Just one thing. I wanted to just reiterate what I said before, Mr. Chairman. Really, thank you very much for the support that this subcommittee has given over the years to get us to the point of preparedness where we are right now. That's critical, and I think the American public should know that we are where we are right now because of the support from a number of sectors, but certainly predominately from your subcommittee. Thank you very much.

Senator HARKIN. Well, Dr. Fauci, thank you very much. But again, I would return the compliments to you and to the Centers for Disease Control and to ASHTO, Department of HHS—all of us working together on this.

It's been a joint effort, and I appreciate all the great leadership that you have provided, Dr. Fauci, through all the years on infectious diseases, not just influenza, but on AIDS and everything else, that you've provided great leadership for our country, and I deeply appreciate your service.

To summarize—let's see if I can summarize. I've been taking notes here. The antivirals that we have stockpiled, plus other devices, implements and such, are being sent out to the States right now. That's going out.

The surveillance has been heightened, and the CDC is providing surveillance in this country and jointly along with Mexico and other countries to keep tabs on what's happening.

Third, we are developing a vaccine. Is that correct? We're developing the seed—

Dr. FAUCI. We're taking the steps to get us on the pathway to being able to develop a vaccine. The seed—

Senator HARKIN. Right.

Dr. FAUCI [continuing]. Virus and the initial growing it up to get it to be able to make a pilot lot is already launched.

Senator HARKIN. Right. Got it. My fourth number, I said people should not panic on this. But there are things each individual can do. Be careful about coughing and sneezing and washing hands and things like that. And if you do feel ill, if you have a temperature or any respiratory illness, stay at home, or at least consult with your doctor, your health professional at that point.

And number five, pork is safe. It's safe to eat, it's safe to handle, and no hogs in the United States has this, or anywhere else, that we know of.

Dr. Jarris, six, States are under a strain right now, as I understand it, to rapidly respond because of budget cutbacks and layoffs, and there is a drastic need, as I understand it—you can correct my language—a drastic need for some assistance in our supplemental, so that States then can take what the CDC is doing and what the Federal Government is doing and get it out to localities in a hurry.

Is that about correct?

Dr. JARRIS. Correct.

Senator HARKIN. Seventh—I just made this note. I said that President Obama—I knew it was a good thing that he was a former member of our Health Committee. President Obama has requested

\$1.5 billion in the supplemental and we will look at that to see how that should be divided up and whether there should be any more. From what we've added up, it might have to be a little bit more than that. I don't know. But we want to make sure that we don't shortchange what we have to do to protect our people in this country.

So with that, I thank you very much. You were very kind, all of you, to come on short notice. I believe this has been very helpful, both to us and information-wise, but also information to the general public, so that they know where we are, what's happening, and they can have the confidence that we are responding with every resource that we have available. And I thank you very much for—all of you, for coming.

CONCLUSION OF HEARING

With that, the subcommittee will stand recessed.

[Whereupon, at 2:38 p.m., Tuesday, April 28, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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