

ASSESSING THE NATIONAL PANDEMIC FLU PREPAREDNESS PLAN

HEARING BEFORE THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED NINTH CONGRESS

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ASSESSING THE NATIONAL PANDEMIC FLU PREPAREDNESS PLAN

TUESDAY, NOVEMBER 8, 2005

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

The committee met, pursuant to notice, at 10:10 a.m., in room 2123, Rayburn House Office Building, Hon. Joe Barton (chairman) presiding.

Members present: Representatives Barton, Hall, Bilirakis, Upton, Stearns, Gillmore, Deal, Shimkus, Wilson, Shadegg, Pickering, Radanovich, Pitts, Bono, Walden, Terry, Ferguson, Otter, Myrick, Sullivan, Murphy, Burgess, Blackburn, Barrett, Gingrey, Dingell, Markey, Eshoo, Stupak, Engel, Wynn, Green, Strickland, DeGette, Capps, Allen, Schakowsky, Gonzalez, Inslee, and Baldwin.

Staff present: Nandan Kenkeremath, counsel; Ryan Long, counsel; Chuck Clapton, chief health counsel; Brandon Clark, policy coordinator; Chad Grant, legislative clerk; Alan Slobodin, counsel; David Rosenfeld, counsel; John Ford, minority counsel; Dick Frandsen, senior minority counsel; Jessica McNiece, minority research assistant; Alec Gerlach, minority staff assistant; and Edith Holleman, minority counsel.

Chairman BARTON. The committee will come to order.

This morning we are honored to have the Secretary of Health and Human Services, the Honorable Michael Leavitt, before us to discuss the administration's concerns and plans to deal with pandemic flu. It is called the Avian Flu.

We are going to operate under our agreement that when we have Cabinet Secretaries testifying, Mr. Dingell and myself and Mr. Deal and Mr. Brown will get up to 5-minute opening statements, and all other members of the committee will get 1-minute opening statements so that we can get to the Secretary and hear his concerns.

An influenza pandemic has happened before in America, though probably not in the living memory of anyone in this room. Still, the odds are that it could happen again sometime, and so the Bush administration is certainly correct to send a warning to begin to prepare for the worst. We know that when it occurs, this pandemic could lead to widespread sickness, many deaths and serious damage to the Nation's economy.

We have an opportunity today to learn what actions we can take to prepare for this threat and minimize the risks associated with the deadly virus. This is a serious business, even deadly business,

and we are having this hearing to expand our basic knowledge about both the disease and the potential cure.

Authorities, including the President of the United States, are worried that the flu virus could spread around the globe. While the current strain of Avian Flu does not transmit easily from human to human, many scientists believe that it will mutate and be more contagious in lethal form.

In response to this threat last week, the President outlined the national strategy. Secretary Leavitt also has released recently an updated and detailed Pandemic Influenza Preparedness and Response Plan.

In today's hearing, Secretary Leavitt will tell us about the National Strategy for Influenza Preparedness Plan and other actions taken by the administration. These include increasing the program for global surveillance, cooperation with the international community and developing an H5N1 vaccine. Even though this particular vaccine is not the final vaccine for the actual pandemic strain, this step is an important step for preparing for surge production of the later vaccine. The Department of Health and Human Services is also working with State public officials for pandemic planning.

We are taking steps ourselves here in the Congress. The Public Health Security and Bioterrorism Preparedness and Response Act that passed the House last year provides improvements in preparedness. We have upgraded the National Strategic Stockpile, and we have provided incentives to develop countermeasures to biological threats under Project Bioshield. Some may argue that we failed to meet our responsibility by not providing unlimited money to respond to this potential crisis. Too often our response in Washington to anything new and challenging is to panic and just throw money after it. Too often our response to potential threats is to hide behind the wall of this money. The theory seems to be that every dollar will make the wall higher and thicker, and it will be that much safer, and when it gets high enough and thick enough, we can all calm down. It is the labor theory of value written into public health; the harder we work to spend your money, the healthier you will be. But I think wasting taxpayer money will not keep people from catching the flu. We need to sort out our real weaknesses from our imagined ones and determine where the application of money and good sense will actually improve our preparedness and stop the flu.

I particularly want to know how this country can increase our current manufacturing capacity for vaccines by creating incentives to adopt new production technologies and providing liability protections that will encourage manufacturers to enter this high-risk area. These steps will save lives and money.

The President is calling on us for legislation to respond to a global health threat. I look forward to hearing the testimony of the Secretary about the administration's ongoing efforts in working with him to develop a plan that delivers good science and good government. I am going to be especially vigilant in trying to come up with a plan to pay for whatever the costs initially are to prepare for the Avian Flu.

With that, I would like to recognize my distinguished Ranking Member, Mr. Dingell of Michigan, for a 5-minute opening statement.

Mr. DINGELL. Mr. Chairman, good morning, and thank you for scheduling this hearing.

Secretary Leavitt, and your associates, welcome to the committee.

Mr. Chairman, the threat of a flu pandemic has been known for a number of years. I begin by pointing out that we are a bit late in our response to the threat. Nevertheless, it is better late than never, and the plan issued last week is, in many respects, a good start. A good start is not a good ending; nor is it a good result.

The plan is long on directions and short on resources for non-Federal partners in pandemic preparedness. How are the States to pay for a substantial portion of the cost of purchasing enough antiviral medication to cover their populations? Where is the funding needed for the States, for the localities and for the private health care organizations to fully prepare for a pandemic? Where is the money to improve the availability of diagnostics and reagents? And who will develop a national effort to communicate with the public, with corporation America and with the health care community with specific messages about risks?

Why it is a good idea to shift so much of the financial burden on the individual States, despite the fact that the States are, without exception, ill prepared and lack the resources to comply with basic emergency preparedness of planning needs?

And where is the work that we will be doing with our neighbors to the north and south? The American Public Health Association, APHA, has said that the public health—rather the Department of Health and Human Services Pandemic Influenza Plan could save the lives of many Americans in the event of a pandemic; however, this plan will not be successful in saving thousands of lives without the necessary funding.

According to APHA, and I continue to quote, there will continue to be sufficient funds for States and local governments to fulfill their responsibilities as defined in the HHS plan. We will see.

Similar concerns with the administration's plan have been expressed by the National Association of City and County Officials. They commend the administration's comprehensive approach to pandemic influenza preparations, but they express concerns about the amount of proposed Federal resources to help the communities to prepare and respond. The National Association of Community Health Centers also shares these concerns.

Mr. Chairman, one thing is clear: When it comes to threats to our homeland from public health emergencies, there is a very serious preparedness gap in this country. A broadbased public health advocacy organization, Trust For America's Health, has conducted an assessment of each of the State's preparedness for public health emergencies, including pandemic flu. They tell us, no State is fully prepared to deal with pandemic influenza or, for that matter, a range of other public health emergencies. How much would it cost State and local governments to be fully prepared for the next pandemic?

The administration's pandemic plan funding request is limited to just \$100 million for State and local public health infrastructure. This appears to be a small fraction of what is needed. Spending more for State and local public health infrastructure is about more than just saving lives; it is a vital aspect of minimizing the ruinous cost to our economy in the next pandemic. The administration's plan acknowledges the crucial role of the private sector in the economy in general and particularly in providing life's necessities, such as food, shelter and transportation. How much will it cost the economy if pandemic hits at our current levels of preparedness?

The tax cuts that have been pushed by my Republican friends have put this Nation in a fiscal straitjacket, and the consequences of our resulting lack of preparedness could be most dire to our health and welfare. We need to be level with the American people about what needs to be done, about how much it will cost and who will pay for it.

I hope that this hearing will shed light on these matters. I hope it will lay the basis for us to begin to work together in a bipartisan manner to address the concerns that all of us feel. And I commend you, Mr. Chairman, for holding the hearing.

I yield back the balance of my time.

Chairman BARTON. I thank the gentleman.

The distinguished subcommittee chairman of the Health Subcommittee, Mr. Deal of Georgia.

Mr. DEAL. Thank you, Mr. Chairman.

I want to welcome the Secretary and his very distinguished supporting cast who are with him today. We have had several hearings previously in our committee, and their testimony has always been insightful.

We are at an important crossroads, I believe, in dealing with this issue, not just of Avian Flu, but of the whole issue of vaccines in general. Our country finds itself in a situation where, because we have not taken appropriate action to provide a climate and an environment in which vaccine producers can produce their vaccines profitably and thereby present themselves in our market, that our country is now almost devoid of any domestic vaccine producers. That is a situation that I believe the Secretary will address, it is one that I think is long overdue in our attention here. It probably is going to require some rather different approaches from the Congress with regard to the one aspect of the proposal of liability protections in order to encourage these manufacturers to get back into the market and to be able to adjust and adapt to the challenges that are ahead of us.

It obviously is a multifaceted issue that is going to be presented here today. It is one that in my particular part of the world that likes to call itself the poultry capital of the world, it is one that is of great importance to us. In fact, Dr. Gerberding, who is there with the Secretary, has so kindly agreed in a couple of weeks to be a part of a roundtable discussion with the major poultry manufacturers, producers, rather, in my Congressional district to look at it from that aspect. And we may find, unfortunately, that the animal—or the poultry side of the issue may be ahead of us on the human side of the issue in terms of their determination and their willingness to take the necessary steps to protect their product,

that is, the poultry flocks of this country. But it is a coordinated effort, both on the poultry side of it in terms of protecting that product, which is the transmission that we have seen in most other countries, the vehicle, but also from the standpoint of what we can do at a Congressional level to deal with the things that make the possibility of providing effective vaccines available to the American public. And that should be our primary concern, we should put, hopefully, politics aside in the light of this very serious threat that looms. And I appreciate the Secretary and all of those who are with him today being with us.

And, Mr. Chairman, I would yield back the balance of my time.
Chairman BARTON. Mr. Deal yield backs.

I don't see Mr. Brown here, so we will reserve his right to give a 5-minute opening statement when he does arrive.

And we go to the distinguished member from Massachusetts, Mr. Markey, for a 1-minute opening statement.

Mr. MARKEY. Thank you, Mr. Chairman.

Mr. Chairman, I am concerned that our country is not as prepared as we need to be in order to effectively carry out this plan.

Over the last several years, the Bush Administration and Republicans in Congress have hallowed out the very public health infrastructure that we will need in the event of a flu pandemic. In fiscal year 2005, President Bush asked Congress to cut \$113 million from the Centers for Disease Control and Prevention. This included \$105 million in cuts from programs to fund State and local public health preparedness. In his fiscal year 2006 budget, President Bush asked Congress to cut \$531 million from the Centers for Disease Control and Prevention. This includes \$130 million in cuts and programs to fund State and local public health preparedness.

After years of slashing our State and local public health infrastructure, the Bush Administration is now placing enormous responsibilities on the State and local health authorities that have suffered these funding cuts. Our doctors, nurses and emergency personnel will do their best to respond to a monumental health crisis if one does occur, but you can't cram for a pandemic.

Thank you, Mr. Chairman.

Chairman BARTON. I thank the gentleman from Massachusetts.

And we recognize the distinguished subcommittee chairman of Energy and Air Quality, Mr. Hall, for a 1-minute opening statement.

Mr. HALL. Mr. Chairman, we are here to pull together to fight a fearful threat to us. And Secretary Leavitt is here to help us, to work with us on a situation that we have no answer for. There is a lot of talk about the preparedness gap and finger pointing at what some people have done or haven't done. There is a preparedness gap for the Martians attacking us. That hasn't happened, but they would be complaining about it if it did, that you hadn't done anything about the Martians. A renewal of the dangerous biblical days when leprosy stopped the world, that might come back again; and then there is a preparedness gap there, something politically to shake and point fingers at. It might be another rain for 40 days and nights and not enough of Noah's Arks here in the United States or in our political districts to help us.

I think there is a lot of reasons to complain about something now threatening us, not heretofore in the headlines, but I don't think it is a time do to that or run the President down and point fingers when any time we are pointing fingers—a lot of us have been up here for 20 or 30 years. We haven't done anything about it, and to point the finger at a President that was in grade school probably when we got here or to our Secretary—I thank you for being here and plan to work with you to try to get an answer to this that seems to be no answer to. Thank you. I yield back.

Chairman BARTON. The gentleman yield backs.

And we now go to the distinguished lady from Colorado, Ms. DeGette.

Ms. DEGETTE. Mr. Chairman, some other members were here before I was, and I would certainly yield to them in the order of appearance—

Chairman BARTON. I am just going down—

Ms. DEGETTE. Mr. Green was here first, though.

Chairman BARTON. All right.

Mr. GREEN. Depending on the Chairman, I will be glad to defer to my colleague.

Chairman BARTON. I would be happy to recognize either of the two distinguished members.

Mr. GREEN. Why don't we just go down the line?

Ms. DEGETTE. I always try to defer to my elders, Mr. Chairman.

Chairman BARTON. It is good to defer to Texas; I will tell you that.

Ms. DEGETTE. I never go that far. I am from Colorado.

Mr. Chairman, I want to thank you for having this hearing.

And I particularly want to thank the Secretary and his staff for coming. I know you all are very concerned about this issue.

But I am more concerned about the fact that we have known about the looming Avian Flu epidemic and its potential devastating loss of life for years. And I am hoping we can do enough triage that we can put together a plan that will be meaningful. I am also hoping that we can do enough triage to develop a vaccine and to develop a plan that will work.

I was concerned last week when the plan was finally released that so much of the burden is put on to the States. We have \$100 million in aid to the States, but we are taking away \$130 million from other parts of this year's budget. And the States are in terrible shape, too. I got our State Avian Flu Plan after the Federal plan came out last week, and our State plan said the Federal Government was taking care of everything. But the Federal plan says the State governments are going to stockpile the Tamiflu and all of the other things we need to do. So rather than just be comfortable that we have plans everywhere, we need to make sure that the plans are going to work to protect the American public.

I yield back.

Chairman BARTON. The gentlelady yield backs.

The distinguished chairman of the Subcommittee of Telecommunications, Mr. Upton.

Mr. UPTON. Well, thank you, Mr. Chairman.

In preparation for this hearing, I have been consulting with a number of my county's public health department medical directors

and administrators to gain a frontline perspective on pandemic flu preparedness and what they see as the most pressing need. I am going to explore those in my questions, but basically, I have learned obviously we need more boots on the ground, particularly public health nurses. As one of my directors put it, we may have biohazard suits hanging on the wall but no one to don them. We may have stockpiles of vaccines but no one to give the shots.

Second, we need a rational vaccine and antiviral distribution process. I have been harping on this for a number of years, but we have still failed to put such a system in place. Today, as we sit here this morning, my public health departments have not received anywhere near the flu vaccine doses that they have ordered and need for priority populations, but yet the supermarkets seem to have more than enough to hold vaccine clinics for anyone who shows up for a shot. And, literally, I have got 9,000 in requests by my county. So we have got to figure this out. I look forward to working with the Secretary to make sure that we can get a place—a distribution system into place.

Chairman BARTON. Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman.

And thank you, Mr. Secretary, for being here.

Today we don't have enough vaccines for Avian Flu because, in part, they simply aren't profitable enough for drug makers. We don't have enough antivirals because patents have forced us to rely on the limited production of a single patent holding company.

At a Government Reform Committee hearing last week, Mr. Secretary, you rejected the possibilities of issuing a compulsory license for Tamiflu production if Roche fails to arrange voluntary licenses. You said, doing so would remove incentives for future R&D. But as we see with vaccines, companies won't spend on future R&D if they can't promise profits to their shareholders.

Companies in India, Taiwan, Malaysia, South Korea and elsewhere are preparing to manufacture generic versions of Tamiflu. However, Americans will not have access to the antiviral drugs produced in those countries because, in 2003, the Bush administration chose to make the U.S. Ineligible to import drugs produced under compulsory licenses per WTO rules. That is what the pharmaceutical industry lobbied for, but I believe it has placed our citizens at risk. I look forward to the conversation today. Thank you for being here.

Chairman BARTON. Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman.

And let me just read from USA Today, and this is from the World Health Organization: It is only a matter of time before an Avian Flu virus, most likely H5N1, acquires the ability to be transmitted from human to human, sparking an outbreak of a human pandemic influenza. This is the director of the World Health Organization. And then when you go back and realize—this is a quote now from the CDC, predicts that a medium-level epidemic would kill 207,000 Americans, hospitalize 734,000, sicken about a third of the U.S. Population, direct medical costs would be \$166 billion, not including the cost of vaccination, you realize the seriousness and how important this hearing is.

I would point out that we do have a specimen the Secretary indicated that he found in Vietnam. They have a specimen from Vietnam which they have matched with a specimen from the 1918 pandemic and through reverse genetics were able to come up with some solutions. So I guess the question is, how do we get that specimen into a vaccine and produced and available for Americans? And that is what we are here today about.

Thank you, Mr. Chairman.

Chairman BARTON. Thank you.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman.

I want to welcome the Secretary and his staff here today.

I support the administration's call for additional investment. In fact, the effort to have antivirals to cover 75 million people meets with the World Health's Organizations 25 percent of our population. My concerns, like other members have, is that the amount of what you are requiring the States to produce, \$510 million worth of antivirals, I don't know if my own State of Texas or other States have the funding available to be able to do that. We are still investigating, in Houston, Texas, some of this fake flu vaccine given to a bunch of our Exxon Mobil employees. So I am concerned about— to make sure that whatever we do with Tamiflu, that that is the correct vaccine.

Mr. Secretary, I thank you for being in Houston on Labor Day with the national emergency, the healthcare issues that we had with the Katrina evacuees, and I guess that is the closest I can imagine having to triage thousands of people at one time and how we were going to do it. I don't want to see us have to do that with antivirals because of the flu, but I also know that we need to be prepared for that. And I am glad the committee is having this hearing today.

Thank you, Mr. Chairman.

Chairman BARTON. Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. Chairman, I associate myself with many of the remarks, particularly those involving Mars, and certainly not with some of the demagoguery. You would think there would be some subjects which would not result in some demagoguery.

But in any case, Mr. Chairman, I guess what I would say, certainly hearing the Secretary earlier today on this subject, my biggest frustrations I think—or certainly among my biggest frustrations and disappointments in the Congress all these years has been the fact that we sort of concentrate on putting out fires, and we don't plan on a long-term type of a basis. Something—a problem develops in the Middle East, and the cost of gasoline goes up, and we have shortages, and all of a sudden we decide to get concerned about that subject. Then as soon as the price of that gasoline drops and the shortage is no longer there, we sort of forget about that particular point and go on to something else.

Now the same thing we had a couple of years ago; we had a shortage of the flu vaccines. And we were concerned about them, and we had hearings about them. And I am not really sure what all we have done about that to prepare in the future. We know a pandemic is coming, and I am just hoping whatever we come up

with here on a bipartisan basis will be something over the long hall, not just to put out this particular fire. Thank you.

Chairman BARTON. Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman, for holding this hearing.

And welcome, Secretary Leavitt—it is good to meet you—and the distinguished panel that has come before us before and does magnificent work for our country.

I think, Mr. Chairman, that the release of the national strategy and budget request is a clear demonstration that the administration is taking the pandemic flu seriously, and that is a very important first step to acknowledge what could be on the horizon, and then plan for it.

I think that there are some significant gaps, though, and I will raise those during my questioning. I think that there is a theme that has been developed so far this day—today in that we are concerned about the resources for States. \$100 million any one of us would love to have in our checking account, but when you divide that by 50, \$2 million per State—I am from the State of California; \$2 million would not go very far. And there are States that are poor. And how are they going to be able to handle that? Is the Federal Government going to step in?

So I think that there are some questions that can go to some of the issues that have already been identified so that the administration really will have the strongest plan possible for our country which this issue really demands. So I look forward to posing the questions and working with my colleagues on the committee, both sides of the aisle. We have to address this for the American people. I am glad that we are having the hearing, Mr. Chairman, and I am delighted with who is going to testify today. They are the best and the brightest, that is for sure. Thank you.

Chairman BARTON. Mrs. Wilson.

Mrs. WILSON. Thank you, Mr. Chairman.

Mr. Secretary, thank you as well for being here today.

I wanted to give you a couple of points just briefly. Our State has looked at your plan and thinks that it is better than the plans have been in the past, and it is a real improvement from what they have seen before. But like most States, New Mexico has a 60-day legislative session coming up, and what they really need—and they have gathered for their estate planning effort in late October—is better clarity on what the Federal Government expects to do and where the State links into that and local communities as well. So we need better clarity on where the gaps are and where the lines of demarcation are before this next legislative session.

The second thing I would ask you to continue to focus on is the broader concept of disaster preparedness and how we would respond, making sure the logistics are there. And you and I both know that the regional stockpile system is not going to work in a pandemic. We have got to figure out how to structure ourselves and get things set in advance so that we have the best likelihood of success when it really counts. And we can't do that on the day. We have to do that planning and organization and training and systems development long before the point of crisis. And I look forward to your testimony.

Chairman BARTON. Gentlelady from California, Mrs. Capps.

Mrs. CAPPS. Mr. Chairman, I wave my opening remarks, but add my welcome to Secretary Leavitt, Dr. Gerberding and Dr. Fauci.

Chairman BARTON. Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman.

Thank you, Mr. Secretary. I appreciate the fact that you are here today.

I would like to raise an issue that you only touch on very briefly in your testimony, and that is the distribution of vaccines. I believe that effective distribution is a very important link in the chain, and that is something that even today is somewhat problematic. I have heard from several doctors in my area telling me that even this year they are having a hard time getting their hands on the needed vaccine, and they also say that, in their regions, though, large distributors like Wal-Mart and other large retailers seem to have no problem getting access to those vaccines in a timely manner. So I just call that to your attention. And I am not sure exactly what the proper fix would be, but it is something that I think that probably needs our attention. And thank you for being here sir.

And I yield back, Mr. Chairman.

Chairman BARTON. Mr. Radanovich.

Mr. RADANOVICH. Thank you, Mr. Chairman. I wave my remarks, but do want to welcome Secretary Leavitt to the hearing. Thank you.

Chairman BARTON. Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman, for convening this hearing today on such an important issue.

While preparing for a pandemic flu requires a wide-ranging and comprehensive plan, I hope our witnesses will spend some time to address one particular issue, and that is liability protection for vaccine manufacturers.

On March 31st of this year, HHS issued a 5-year contract to Sinofi pasteur to develop and clinically evaluate a new cell culture technology that can be used to more rapidly produce vaccines. And this contract also establishes plans for creating domestic facilities with the capacity to manufacture 300 million doses of a pandemic vaccine using cell culture as opposed to the currently licensed process using chicken eggs. And this particular company, U.S. Operations are headquartered in my home State of Pennsylvania where it has made vaccines for over 100 years and influenza vaccines for well over 30 years. Of course, one of the particular issues facing manufacturers like this is the threat of litigation from potential outburst effects. Without proper liability protection, the manufacturers cannot move forward with actual testing and development on a large-scale production. So I look forward to your testimony on this issue.

And thank you, Mr. Speaker.

Chairman BARTON. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

This administration has been looking high and low for not existent weapons of mass destruction, going to war and spending hundreds of billions of dollars because of these phantom weapons. It turns out there is weapon of mass destruction; it is called the Avian Flu. And this administration has done pathetically little to

protect our people from a killer that could take the lives of 500,000 Americans.

Why do we have only enough antivirals on hand to treat 1 percent of the population? Why does the plan spend so little on international surveillance, the equivalent of fighting the war there so we don't have to fight it here? Why does the plan rely so heavily and give so little to States, at the same time cutting \$130 million from State and local health initiatives? Why is one of the first proposals from this administration one to shield drugs from liabilities and depriving those injured by the vaccine from fair compensation? Why do other countries have better, more detailed plans? And how do we justify to the American people these words from our plan, quote, It is unlikely that there will be sufficient personnel, equipment and supplies to respond adequately to multiple areas of the country for a sustained period of time, unquote? This is not a terrorist attack. This is not a hurricane. This is a long known and certain danger. Can't America, can't this administration do better?

Thank you, Mr. Chairman.

Chairman BARTON. I thank the gentlelady.

Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman.

I want to—it is hard to sit here and listen to all this, and we are blaming Bush before even have a flu outbreak, and it just gets a little old.

I want to commend the administration for announcing the international partnership on the avian pandemic. I have my own set of concerns. I think we have gotten so far to the point where, when a disaster breaks out, wherever it breaks out, we expect the Federal Government to come in and solve our problems immediately. The old Boy Scout in me says I need to be a part of that solution; I want to be prepared. I don't think we can create a distribution system that will function properly if a third of the population has a flu and an enormous number of them are dying from it. So I think we also need to look at individual preparedness. I want to know how I can get what my family is going to need and what my neighbors are going to need in our houses so we can take care of ourselves and stop thinking that some government agency is going to come in and rescue the day, because I don't think it is going to function in the end the way we would hope it would when a pandemic breaks out, if indeed it does. So I appreciate the plan of the administration and look forward to working with you and my colleagues to come up with real solutions.

Chairman BARTON. The gentleman from Washington.

Mr. INSLEE. I would just submit that giving everyone a Swiss Army knife and a compass is not going to solve this problem. The Federal Government is necessary to address this very significant threat, and I would just hope that our hearing would focus on two issues that I hope we have a chance to ask the Secretary about.

First, I hope that we take a more aggressive approach to Avian Flu in trying to prevent its transmission and the actual transmutation of the virus itself. I think there are several things we can do to reduce the prospects of that occurring by attacking it at its source in the avian populations before that transition takes place, one of which is to develop a biodetection system that can be used

around the world, including developing nations, that can determine the presence of even a single virus. And there is technology that is on the cusp of becoming commercialized to do that. I hope that we can at this hearing talk about how to bring that to the frontline right away.

Second, I hope that we can address the incredible decimation of the public health infrastructure in this country. Any of us, we can go to any of our districts, in this panel, to our public health officials, and they will tell us, good luck, we don't have any infrastructure to do it. You go to our public health facilities; they don't have a copy machine. They don't have a cell phone. I mean, to expect our local public officials to deal with this without very significant improvements in that infrastructure is really going to be hopeless. And with this administration, with all due respect, cutting—

Chairman BARTON. The time of the gentleman is expired.

Mr. INSLEE. Cutting, it is not the direction we need to go, thank you.

Chairman BARTON. Mr. Terry waives.

Mr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for being here today and our other panelists.

Over a year ago, Dr. Gerberding, who is here with us today, came before our committee, and we discussed many aspects of what would be required to prepare against a pandemic. I said then, I repeated it in multiple hearings we have had, and I will say it again here today, we are staring down the barrel of a loaded gun; the gun is ready to fire.

Expert after expert, including the many panelists we have had here at our hearings, have said we must not ask if but ask when. When will we have a strain of influenza virus that will cause a pandemic? And most importantly, will we be ready?

Mr. Secretary, I thank you and the administration for presenting us with a final comprehensive pandemic plan to ensure that our country is prepared and protected against a widespread outbreak of influenza.

With all of this focus in the media and the public at large, I think there is significant confusion on a number of key points in the plan. And I am looking forward to this opportunity to help our members learn more. In the end, my constituents and others around the country just want to know where they can get their vaccine shot to protect them against Avian Flu when it strikes or where they can get other drugs that might protect them in lieu of a vaccine. I have told my constituents that we have a two-prong strategy, dramatically improve our vaccine technology and the ability to rapidly manufacture it, as well as create a national stockpile of existing antiviral medicines. I look forward to hearing from you, Mr. Secretary, on our plans to do both of those things, how we are going to get the job done to ensure safe and orderly execution of the plan when a killer flu strikes. Thank you, I yield back.

Chairman BARTON. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

And thank you, Secretary Leavitt. I applaud the administration for finally releasing this pandemic flu preparedness plan, and there

are parts of it that I think are very promising, especially with regard to the investment in research. However, I do continue to have serious concerns about our state of readiness for a pandemic flu outbreak. Put simply, I am concerned this plan is too vague in a number of important issues to be reassuring right now. And I know this is a work in progress, so I hope we can improve on those. Let me just list a few of those concerns and hopefully get into others during the questioning.

The U.S. Isn't estimated to have sufficient vaccine production capacity for many years. What will we do if the pandemic hits before then? The same can be said about our production capacity for antivirals. What is the strategy to deal with fear and panic among the public? How are States supposed to afford new unfunded mandates that this plan assigns to them? I look forward to the hearing today, and hopefully, we will have the opportunity to explore this and other issues more fully in question and answer.

Mr. Chairman, I yield back.

Mr. DEAL [presiding]. Mr. Shadegg, do you have an opening statement?

Mr. SHADEGG. Thank you, Mr. Chairman. I want to thank you for holding this hearing, and welcome our distinguished guests, Secretary Leavitt and the other panelists that have joined him.

This is an important issue, and the President has put it at the forefront of our Nation, requesting some \$7.1 billion to deal with this. I am deeply concerned that we take the appropriate steps. I would like to, however, direct my remarks to some of the facts that have been stated here and some of the concerns that have been expressed. And one of the concerns has been that we are not spending sufficient monies in this area and that, indeed, to quote one of my colleagues on the other side, he says we have been slashing spending in this area. For the record, let me just insert what we have, in fact, done for the funding of the National Institutes of Health over the last 12 years. In 1992/1993, we were spending \$8.9 billion. We have increased every year since then. The subsequent year, 1993/1994, \$10.3 billion; 1994/1995, \$10.5 billion; 1995/1996, \$11.3 billion; 1997/1998, \$12.7 billion; 1998/1999, \$13.6 billion; 1999 to 2000, \$15.6 billion; 2001/2002, \$17.8 billion; 2001/2003, \$20.4 billion; 2002/2004, \$23.3 billion; 2003/2005, \$27 billion; and for the current fiscal year, almost \$28 billion. That is a growth from roughly \$9 billion to \$27 billion in a span of 12 years. We have tripled the amount of money sent to the NIH. Where in that we can find a slashing of the spending for these purposes, I don't understand; and how someone can come before this committee and use that kind of rhetoric concerns me. I think the facts are important to know. We need to look at this problem seriously and fund it appropriately.

Thank you, Mr. Chairman, I yield back.

Mr. DEAL. Mr. Gonzalez, do you have an opening statement?

Mr. GONZALEZ. I waive the opening, thank you.

Mr. DEAL. He waives.

Mr. Burgess, do you have one?

Mr. BURGESS. Thank you, Mr. Chairman, I have a statement that I will submit for the record.

But Secretary Leavitt, Dr. Fauci, Dr. Gerberding, Dr. Raub, it is good to see you here this morning, I am glad you are here.

Secretary Leavitt, you will recall, in September, after Hurricane Katrina, you visited Dallas, the 17,000 displaced persons who showed up there late one evening. The blast facts went out to the Dallas County Medical Society, and out of 3,600 physicians registered with the Dallas County Medical Society, 800 showed up for that first stay, truly a significant surge capacity that I don't think any of us were aware of, that people that would just show up if asked. And part of my concern and one of the reasons I am so grateful that you are here and talking with us today is that can we—are we going to be able to count on that ability of first responders to show up if we don't have the ability to protect them, whether it be with antivirals, vaccines, gear and what have you? As hard as it is for the first responders to show up, their significant others may prevent them from showing up. As I know it is very well and good to volunteer for something, but I also remember I have to go home and ask permission before I actually do that.

So I thank you for your attention to that. I think it is extremely important as we work through this problem and look forward to your testimony today.

Mr. DEAL. Mr. Stupak, do you have an opening statement?

Mr. STUPAK. Thank you, Mr. Chairman, I do.

Mr. Chairman, thank you for holding this hearing today on the Avian Flu, a topic which Congressman DeGette and I have been urging investigation and a hearing on for almost a year now.

Today we get our first look at the new pandemic flu plan, but this hearing should not be the end of our efforts. The committee must continue to exercise appropriate oversight of the administration to ensure this 396-page, \$7 billion pandemic flu plan adequately protects the American public and funding actually makes it out of Washington, DC., Unfortunately, the plan before us, period, is yet another example of the administration taking it, go it alone or going with the drug company approach instead of adequately equipping our State officials, doctors, nurses and police officers who will be on the front lines. This plan forces States to pick up \$500 million of the cost of drugs that may not work.

Michigan Medicaid is already facing a \$420 million cut underneath the reconciliation plan that we will vote for later this week. How is Michigan supposed to buy drugs that may not work when it struggles to afford drugs for people who are sick today? We saw with Hurricane Katrina that plans are only as good as the resources and training to back them up. The 426-page Department of Homeland Security plan did little good during Hurricane Katrina.

Pandemic flu could mean Katrina-like third-world health conditions in cities across the Nation for 6 months or longer. It could mean over 8 million dead, according to the administration's scenarios. The bottom line is that, with the pandemic flu, it is no longer a matter of if but when. We must make sure we have adequate surveillance and containment in those critical 6 months before there will be a vaccine. That requires more than just plans on paper. It requires training, and it requires resources for our States. Thank you, Mr. Chairman.

Mr. DEAL. Ms. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

I want to welcome our guests and to let them know that, in Tennessee, from my constituents, there are a few things that I have heard. They are very interested in knowing what our preparation plan is. And they want to know what the process for vaccination will be. And then they want to know what the communication and education plan that you are setting forth is going to be for all citizens of our country. If we have a pandemic, they want to know two things: Do you have a containment plan? Do you think it would work? And how is your management plan put in place to manage through a pandemic?

The other thing that they ask me as we talk about this: How do you plan to accomplish this, with respect to the taxpayers' dollars, to their funding, not adding to the deficit? And can you, within your existing budget, find a way to accommodate these expenses?

Thank you so much, and I look forward to your discussion.

Mr. DEAL. Mr. Barrett indicates he waives.

Any other member that I have overlooked that has an opening statement?

Well, if not, we are pleased to have Secretary Mike Leavitt, Secretary of Health and Human Services, with us today.

And Mr. Secretary, with that, we will recognize you for your opening statement. Your prepared statement is already a part of the record.

STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACCOMPANIED BY WILLIAM F. RAUB, DEPARTMENT OF HEALTH AND HUMAN SERVICES; ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; AND JULIE L. GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. LEAVITT. Thank you, Mr. Chairman.

Given that it is part of the record, I will simply summarize with half a dozen points.

The first one is, consistent with what all of you have suggested, pandemics happen. They have, over the course of centuries, happened. In the last 300 years, we have had ten of them that have been recorded. In the last hundred years, we have had three of them, 1968, 1957 and what is now referred to as the Great Influenza in 1918, which took as many as 40 million lives across the planet. They are very serious, and no nation can ignore the threat.

The dilemma that we all face is dealing with this in a way that informs but does not inflame; that inspires preparation and preparedness, not panic. The President has put forward the \$7.1 billion plan that we are here to talk about today.

The H5N1 virus that we are currently dealing with is moving across the globe, being carried by wild birds, infecting domestic flocks. As we speak, the Chinese Army has been deployed to cull their flocks. We have had 125, roughly, cases that have been confirmed, and about 64 of them have died. This is a very serious matter. But it is still primarily an animal disease. We do not know if,

in fact, it will make the leap from animal disease to a person-to-person disease, but we do know, at some point in time, a pandemic will occur. And so our discussion today isn't just about the H5N1. Our discussion, I hope, can be about pandemic preparedness in general.

Now, second, if I could just give an overview of the President's plan and the plan that we have put forward with HHS.

The first part is international surveillance. If you could think of the world as a vast forest that is dry and susceptible to fire, it only takes a spark. If a person is there when the spark occurs, they can contain the damage simply by putting it out with their foot. However, if it is allowed to smolder and burn over the course of an hour or more, it grows beyond containment. That is precisely the way a pandemic works. If we are able to be there when the spark occurs, when the virus makes that transition between an animal disease and a sustainable person-to-person disease, we are able to contain it. And that should be our first line of defense. What that means is, we need to have laboratory capacity, professionals from the CDC, in the countries where we are likely to see this. And we are now moving on that. We have a presence, but we need to expand it.

The second is domestic surveillance. We need the same capacity within the United States. We need to know when it arrives and how broadly it has arrived.

The third area deals with communications. Many of you have spoken about the fact that we could be dealing with a 1918 biology but with a 21st century new cycle, and that is a much different proposition than we fought before. We also have the capacity for people to travel around the world. So there are some differences between now and 1918 that work against us. We also have some aspects that are very positive. We have much better health care today than we did then. So there are offsetting levels of advantage.

The fourth area is antivirals. The plan calls for 81 million courses to be in collective stockpiles. We will get a chance to talk about that more later.

The fifth part is on State and local preparedness. One of the unique characteristics of a pandemic is the way it is managed. Katrina has been mentioned. We learned a great deal from Katrina. Katrina was over Mississippi, Louisiana. It was also part of Alabama, but at least it was in a contained area. As broad as the damage was, at least it was defined. A pandemic would not be a confined or defined area. It would be essentially an unlimited area. And it is very likely that we would be dealing with the kind of emergency situations we saw in the Katrina area all over the country and, in some respects, all over the world. So State and local preparedness, as many have mentioned, is of vital importance. And I will have a chance, I am sure, to talk more about that later.

The last part, and what I believe to be the foundation of this plan, is nothing short of a complete revitalization of the vaccine manufacturing capacity in our country. The good news is we have a vaccine. Through the professionals at NIH, we have identified a vaccine that produces an immune response that will protect people. The bad news: We don't have the ability to produce it in broad enough numbers in a short enough timeframe, and it is because the

vaccine manufacturing business has diminished to a point that that is the case.

Many of you have brought up the annual flu. It is the same problem with the annual flu. What we hold here, I believe, is not just an opportunity to protect ourselves from a pandemic flu but, for the first time, to literally take off the table the problem we have with the annual flu by being able to create a renewed vaccine manufacturing capacity.

Again, I want to emphasize, our discussion should not be, I hope as a Nation, simply about H5N1. Yes, there are very troubling signs that we cannot ignore. The certainty or the probability that it will transform into a person-to-person sustainable virus is unknown, but we do know pandemics happen and that we need to be ready. At some point, a pandemic will occur. Our current state of preparedness is not what it needs to be. And today our discussion continues.

We did not just start this conversation a month ago. This pandemic plan has been in place, we have been holding hearings and so forth for many, many months. We actually have a vaccine. We have people in place. We have the beginning of a surveillance system. So while we are not where we need to be, we are rapidly moving. And I look forward to discussing how we can look to your help to continue that discussion.

[The prepared statement of Hon. Michael O. Leavitt follows:]

PREPARED STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Mr. Chairman, Representative Dingell, and Members of the Committee. I am honored to be here today to present the President's request for funds for the HHS Pandemic Influenza Plan, which is an integral component of the National Strategy for Pandemic Influenza, which the President announced last week. In the event that an outbreak of pandemic flu hits our shores, it will surely have profound impacts on almost every sector of our society. Such an outbreak will require a coordinated response at all levels of government—Federal, State, and local—and it will require the participation of the private sector and each of us as individuals. HHS has been a leader in this effort. With this budget request and the release of the HHS Pandemic Influenza Plan, we are taking another major step forward to improve our preparedness and response capabilities.

The threat of an outbreak of pandemic influenza is real. An influenza virus strain with potential to cause a pandemic of human disease could emerge with little or no warning and in almost any part of the world, as occurred 3 times during the 20th century. Influenza viruses infect birds, pigs, and other animals, as well as humans. The ability of these viruses to cross the species barrier from time to time creates the possibility for the appearance of new viral strains that have the potential to be highly infectious, readily transmissible, and highly lethal. If a pandemic virus strain emerges, it is estimated that upwards of 30 percent of people exposed could become infected and the death rate will likely be considerably higher than that seen with seasonal influenza. Faced with such a threat, the United States and its international partners will need to respond quickly and efficiently to reduce the scope and magnitude of this serious health threat.

Today's threat is the H5N1 avian influenza strain, which is spreading widely and rapidly in domestic and migratory fowl in Asia and now in Eastern Europe. While the virus has not demonstrated the ability to spread efficiently from person to person, it has infected more than one hundred people in Asia and approximately 50 percent of these known cases have died. The virus is now endemic in many bird species and in several countries, so elimination is not feasible. The feared pandemic could become a reality if this virus mutates further, remains highly virulent, and acquires the capability to spread as efficiently from person to person as do the commonly circulating virus strains that produce seasonal influenza epidemics. But even if H5N1 does not lead to a pandemic, the likelihood of an influenza pandemic at

some point remains high. This is why we need to prepare now in order to swiftly and efficiently respond to an outbreak.

We are taking important steps forward. Last week, I released the HHS Pandemic Influenza Plan, which is a blueprint for pandemic influenza preparation and response. The HHS Plan provides guidance to national, State, and local policy makers and health departments. The goal is for all involved to achieve a state of readiness and quick response.

The HHS Plan includes an overview of the threat of pandemic influenza, a description of the relationship of this document to other Federal plans and an outline of key roles and responsibilities during a pandemic. In addition, the HHS Plan specifies needs and opportunities to build robust preparedness for and response to pandemic influenza. The preparations made for a pandemic today will have lasting benefits for the future.

A pandemic outbreak will allow very little time to develop new capabilities or build surge capacity for response if these efforts are not already in place. Unfortunately, current capacity for domestic manufacture of influenza vaccine and antiviral drugs can meet only a small fraction of the need projected for a pandemic response. If we are to have the capabilities and capacities needed when a pandemic emerges, the investments to bring them about must be made now. That is why the President is requesting additional FY 2006 appropriations for HHS totaling \$6.7 billion for the HHS Pandemic Influenza Plan. Our goals in seeking this funding are to be able to produce a course of pandemic influenza vaccine for every American within six months of an outbreak; provide enough antiviral drugs and other medical supplies to treat over 25 percent of the U.S. population; and ensure a domestic and international public health capacity to respond to a pandemic influenza outbreak.

First, we must establish the domestic vaccine production capacity our Nation will need to protect all Americans within six months of detection of a virus that begins to spread efficiently from human to human. In anticipation of an influenza pandemic, we must stockpile in advance sufficient quantities of pre-pandemic vaccine that is protective against circulating influenza virus strains with pandemic potential in order to be in a position to initiate vaccination of health care workers and front-line workers critical to the pandemic response. These pre-pandemic vaccine stockpiles must be regularly reevaluated and potentially replenished as the pandemic virus threat mutates and changes, and as vaccine potency degrades over time. In addition, as the virus strains evolve and potentially escape protection by the existing vaccines, newer vaccines that better match the current pandemic strain will need to be produced and stockpiled. The Nation must also expand its stocks of antivirals, personal protective equipment (masks, gloves, etc.) and other supplies to help provide a potentially over-burdened healthcare system with the means to treat and care for those who become seriously ill in an influenza pandemic.

Second, we must enhance the disease surveillance systems both internationally and domestically and train the personnel needed to reliably detect an outbreak quickly and to accurately determine its lethality and transmissibility. This includes obtaining samples of the virus from infected humans and animals and having laboratory capacity, personnel, and supplies necessary to conduct rapid analysis. Surveillance is our early warning system, and faster detection will enable public health officials to make recommendations about containment protocols, such as limits on travel and the assembly of large groups of people. Faster detection and identification of emerging influenza virus strains facilitate the conversion by industry to mass production of pandemic influenza vaccines. Better State, Federal, and international diagnostic laboratory systems will also allow for increased surge capacity needed to support front-line medical personnel, and effectively guide the use of scarce drugs, vaccines, and other resources.

Improved surveillance systems, including near real-time collection of data from hospital emergency departments in major metropolitan areas through BioSense, will allow us to continuously track the spread of the virus and the morbidity/mortality it produces and to evaluate the effectiveness of our intervention strategies. This information will be critical to determining the best uses of limited supplies of pandemic influenza countermeasures. We will also track vaccines and immunizations to ensure that we maximize its equitable use as well as its effectiveness and safety.

Third, we must develop in advance domestic and international plans for broad public education efforts that are culturally appropriate and provide critical information in ways that acknowledge different levels of health literacy. These efforts before and during a pandemic will help guide individual actions to prevent and reduce infection and clarify the need for prioritization of scarce vaccines and antivirals and other materials. Our request also includes funding for States and local municipalities to develop and/or update their pandemic influenza response plans and to integrate them with Federal plans.

INFLUENZA VACCINE

The Administration has been aggressively working to be able to acquire, over a two-year period, enough H5N1 vaccine and antivirals to protect 20 million people should they become infected with the pandemic virus. On July 15, 2005, the Administration submitted an FY 2006 Budget Amendment totaling \$150 million to implement our “20/20” plan. This strategy was designed to give us considerable experience with commercial-scale manufacturing of this new vaccine, and provide some pre-pandemic vaccine to our stockpile. However, as we are only able to obtain pre-pandemic vaccine during the few months of the year when influenza vaccine manufacturers are not running at full capacity making the seasonal trivalent vaccine, we are severely limited in the quantity of vaccine that we can stockpile. In addition to this limitation, since the submission of this Budget Amendment, we received results of H5N1 vaccine clinical trials funded by NIH. As part of this strategy, the NIH has funded clinical trials of H5N1 influenza vaccine—which provided good news and, at the same time, sobering news. The good news was that the vaccine we developed works—it provides a good immune response that augurs well for protecting people against the H5N1 virus. The sobering news was that to achieve the desired immune response, the vaccine needed to be six times as potent as the seasonal vaccine—90 micrograms of the hemagglutinin component instead of 15 micrograms—and that two doses are needed for the protective immune response. This has further driven home a point of which we were all aware—that the nation’s capacity to produce enough 90-microgram doses of pandemic vaccine was woefully inadequate. We need an aggressive strategy to achieve the needed domestic vaccine manufacturing capacity as quickly as possible, and to initiate similarly aggressive action to implement other immediate preparedness strategies beyond these critical vaccine needs. This budget request is just such a strategy, building on the July Budget Amendment and responding aggressively to the results of the NIH clinical trials and our growing concern that a pandemic could involve hundreds of communities across the United States and around the world.

Of this week’s \$6.7 billion funding request, approximately \$4.7 billion would go toward investments in creating pandemic influenza vaccine production capacity and stockpiles that will ensure that enough vaccine will be available to every American in the event of a flu pandemic. To accomplish this, HHS will pursue a multi-faceted strategy to create, as soon as possible, domestic influenza vaccine manufacturing capacity aimed at producing 300 million courses (two doses of vaccine per person) within six months of the onset of an influenza pandemic. With this immediate investment, the increased production capacity and related stockpile expansion will be achieved in phases between 2008 and 2013.

The initial component of this strategy is to expand the number of licensed domestic egg-based influenza vaccine manufacturers from the single one that currently exists. This would give the U.S. the ability to develop a 20 million course (40 million doses) pre-pandemic vaccine stockpile by 2009 without disrupting the production of annual seasonal influenza vaccine. In the event of a pandemic outbreak, or perhaps before, the vaccine stockpile would be used to immunize healthcare workers, front-line responders, vaccine manufacturing personnel, and others critical to the pandemic response. Once this capacity is developed, current egg-based production techniques could then provide about 60 million courses of vaccine within six months of an outbreak, or about 20 percent of our goal of 300 million courses within six months.

The ultimate surge capacity goal of 300 million courses of vaccine cannot be achieved from egg-based production alone. Our best hope for creating capacity in the U.S. for rapidly ramping up vaccine production at any point in time is expansion and acceleration of our investment in cell-based influenza vaccines—and much of our planned investment goes toward this initiative. While promising, success of cell-based influenza vaccine production and licensure is still years off, and not a guarantee. Therefore, our vaccine capacity expansion strategy invests in both cell-based vaccines and the traditional, tried and true egg-based vaccines. Therefore, HHS, in collaboration with the vaccine industry and its academic partners, will invest in the advanced development of cell-based techniques for manufacturing pandemic influenza vaccines. By financing the establishment of new cell-based vaccine manufacturing facilities that could open in 2010, our plan will develop the surge capacity needed to provide for the remaining 80 percent (approximately 240 million courses) of the population within six months of a pandemic outbreak.

The HHS Pandemic Influenza Plan also acknowledges that existing manufacturing facilities can be directed to this effort and finances the retrofitting of existing domestic manufacturing facilities that would enable them to convert to production of pandemic influenza vaccine production, in an emergency. HHS will establish con-

tingency arrangements with vaccine manufacturers in conjunction with the Food and Drug Administration so that, at the onset of an influenza pandemic, they will be able to readily adapt their facilities either to produce influenza vaccines or to provide a critical function, such as fill and finish bulk vaccine produced by other manufacturers.

We will also work with industry and academia to support advanced development of dose-stretching technologies, such as the use of adjuvants and new vaccine delivery systems. These investments, if successful, will extend the pandemic influenza vaccine supply and allow more Americans to receive pandemic vaccines sooner. We will also invest in research that may have potential to lead to broad-spectrum vaccines to protect against multiple and emerging strains of influenza viruses. This would allow for stockpiling of vaccines that could be useful even as the virus strains evolve and change.

However, as we seek to build domestic manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business. As we recognize the desperate need to create and expand vaccine manufacturing capacity, we have to remove such deterrents to participation by those with the knowledge and experience to accomplish this. It is crucial that those engaged in this work be shielded from unwarranted tort suits. Accordingly, the Administration is proposing limited liability protections for vaccine manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct. We believe this proposal strikes an appropriate balance of removing the liability risks that dissuade companies from producing pandemic countermeasures, while still retaining appropriate access to court remedies.

ANTIVIRALS

We also recognize the importance of having available a sufficient supply of stockpiled antiviral drugs to treat and care for infected individuals. For this, we request an investment of \$1.4 billion. These funds would help us achieve the national goal of having available 81 million courses of antivirals, which would be sufficient to treat 25 percent of the U.S. population (75 million courses) and a reserve supply (6 million courses) that could be used to contain an initial U.S. outbreak. Funding would also be used to accelerate development of promising new antiviral drug candidates in collaboration with academia and industry, since none of the antivirals today are likely to work perfectly against pandemic influenza.

Of the 81 million courses, six million courses will be designated to contain the first isolated domestic outbreaks. Of the 75 million courses that will be used to treat those who are infected with the pandemic virus, HHS would fully fund the procurement of 44 million treatment courses to provide protection to the highest priority groups in the event of an influenza pandemic. We will also work with our State partners to encourage them to acquire antivirals for rapid use for their populations. To help support these States efforts, we would establish contractual arrangements with manufacturers of approved antivirals whereby States may purchase up to 31 million treatment courses and HHS would pay for approximately 25 percent of the costs of these drugs. This arrangement will also ensure a more coordinated inter-governmental approach in the acquisition of antiviral drugs and pre-deployment stockpiles of antivirals around the nation. A guaranteed acquisition of up to 81 million courses of antiviral drugs will enable manufacturers to make significant expansion in its U.S.-based manufacturing capacity—thereby positioning itself to meet future demands much more readily than currently is possible.

I have personally been meeting with leaders of relevant vaccine manufacturers to determine how they might participate in preparedness for and response to a pandemic. To facilitate the development of new antivirals, HHS will collaborate with industrial organizations to develop, obtain approval, and establish commercial production of new antivirals that would help protect the citizens of our Nation.

DISEASE SURVEILLANCE, PUBLIC HEALTH INFRASTRUCTURE, AND RISK COMMUNICATION

In addition to the production and stockpiling of vaccines and antivirals, enhancing domestic and international resources to expand surveillance, strengthening public health infrastructure, and effectively communicating with the public about risks of an influenza pandemic are important components of the HHS Pandemic Influenza Plan, for which we are requesting \$555 million. A critical step in enhancing public health infrastructure and international collaboration will be to implement and refine surveillance and epidemiological response. These investments will help us detect, investigate, and respond to the onset of a potential influenza pandemic anywhere in the world without delay. Because influenza characteristically spreads beyond country boundaries, we have included in our request funding to be used inter-

nationally. These funds will follow the evolution of the virus in Asia, detect human cases, and help contain outbreaks, where feasible.

With an enhanced domestic and international early warning system, we will be better positioned to mount an immediate emergency response to characterize the outbreak; obtain viral samples for analysis and possible vaccine production; and we will have a greater chance to prevent, contain, and/or retard the spread of infection. The ability to continually analyze data to help predict the further course of the pandemic will help guide the choice and timing of interventions (drugs, vaccine, and public health measures) and will help assess the efficacy of these interventions.

Enhancing our public health infrastructure also includes expanding the science base at the Food and Drug Administration, thus allowing for expedited regulatory review of pharmaceutical industry initiatives to develop the necessary new vaccine technologies, as well as speeding the licensure of the facilities and vaccines produced within them.

Risk communication is another integral part of an effective public health response plan. We must have in place the capability to employ effective risk communication practices that will guide us in providing the American people with the accurate, timely and credible information they will need to protect themselves and help others during an influenza pandemic. To ensure that our communications efforts resonate with target audiences, we will solicit the public's active participation and involvement in our efforts to develop relevant, easy-to-understand information and materials regarding influenza in general, and pandemic influenza in particular. To help in this effort, we have established a website devoted exclusively to this topic, pandemicflu.gov.

Public participation and involvement may include engaging the public in discussions on State and local community preparedness; assisting communities in developing procedures for disseminating information and guidance for all segments of our diverse population; and developing targeted informational tool-kits for distribution to particular stakeholders such as educators, physicians, and employers.

STATE AND LOCAL PARTNERS

Pandemic planning needs to incorporate every department of the Federal government but must also go deeper than that. Every State and local government must have a pandemic plan. Unlike most disasters, a pandemic outbreak can happen in hundreds or thousands of places simultaneously. The Federal government will play an important role, but engaged state and local partners are necessary for our success. Over the coming days, I will be asking the governors, mayors and State and local health and preparedness officials to join me in a concern we all must share—preparing for a pandemic should one happen. Everyone in society has a role.

For example, the Federal government can deliver stockpiles of medication and supplies to a city in the U.S. in a matter of hours—but it is distribution at the State and local level that defines victory. In a moment of crisis, if we are not able to deliver pills to people over wide areas in short time frames, lives will be lost. We need to create a seamless preparedness network where we are all working together for the benefit of the American people. Of the \$555 million for surveillance and public health infrastructure, our Budget request includes \$100 million specifically for State and local pandemic preparedness efforts. And, as mentioned previously, we will provide incentives to States to purchase their own stocks of antivirals by allowing them to buy off of HHS-negotiated contracts and subsidizing about 25% of the cost.

The plan and budget request outlined above will greatly improve our short and long term preparedness posture. We are well-positioned to implement the plan and invest these new resources wisely and effectively only because of the substantial pandemic influenza activities already underway at HHS. Scientists at the National Institutes of Health and the Food and Drug Administration, working with industry, have developed a vaccine that produces an immune response sufficient to provide protection from the H5N1 virus. This bodes well for our ability to develop a vaccine against a pandemic virus that may evolve from the current H5N1 strain. In September, HHS awarded a \$100 million contract to manufacture 3.3 million doses of H5N1 vaccine, which at two doses per person would be enough for 1.67 million people. In addition, just last week we announced the award of a \$62.5 million contract to produce even more vaccine. We have also initiated contracts to secure an adequate supply of specialized eggs to initiate surge production at any time of year.

This is not a new undertaking. We are making progress, and with your help will continue to do so. We realize we are asking for significant funding at a time when the Administration and Congress are trying to control spending and reduce the deficit. We have controls in place at the Department, and within the structure of the funding request, to ensure that these funds are used wisely and responsibly. We ac-

knowledge that investing in this plan without perfect knowledge of the future is expensive, and not without risk. However, waiting until a pandemic begins would be much more expensive in terms of American lives and economic impact. In our view, waiting is not an option.

I look forward to answering your questions, and more importantly, to working closely with you as we move forward together to protect our citizens.

Chairman BARTON. Thank you, Mr. Secretary.

We do appreciate you and your staff attending today.

My first question is about Tamiflu. Is Tamiflu, by itself in its current configuration, an effective vaccination to the Avian Flu as we know it today?

Mr. LEAVITT. Mr. Chairman, I will respond. I am also going to call on my colleagues on occasion. I am able to plunk out a two-hand version of the melody, but you can get a full symphony from them. But let me respond, first of all, to Tamiflu.

Tamiflu has become, regrettably, in the popular writings as synonymous with preparedness, and it simply is not. There is no certainty that Tamiflu will work with the H5N1. There are indications that it has a very positive effect, but there is no certainty.

Tamiflu is an antiviral that is given once a person gets sick, but it has to be given within 24 to 48 hours for it to have the optimal effect. We will, in fact, have the needed doses of Tamiflu. We have had direct discussions and negotiations with the developer, the manufacturer. But I would like to go to Dr. Fauci to give a little more detail on Tamiflu and where it fits in a comprehensive pandemic plan.

Mr. FAUCI. Thank you, Mr. Secretary.

Mr. Chairman, Tamiflu, as you heard, is a treatment for influenza, seasonal influenza, and hopefully would have some benefit in the pandemic flu.

First of all, with regard to the broad picture, we consider this as one of a multi-component preparedness plan, including the public health measures that the Secretary mentioned. The foundation of our prevention and our preparedness is really vaccine, as witnessed by how we explain that in the plan as well as by the budget itself. And then, finally, there are antivirals.

The issue that we need to make sure we don't fall into the trap of equating on a one-to-one basis that stockpiles of Tamiflu equal preparedness, because from a scientific and medical standpoint, that may not necessarily be the case. It certainly is the drug, since the virus appears to be sensitive to it. It is the only thing that we have when you talk about antivirals. We have a couple of classes of antivirals. That is the one that appears to be, together with Relenza, which is of the same class, the one that we are focusing on. But if you look at the history that we have about the use of Tamiflu in seasonal flu, A, it needs to be given within 24 to 48 hours of onset of symptoms, which really is a burden when you have a lot of people who come into an emergency room already sick; second is that the data show that when you give it within that timeframe, it shaves off about 1.5 to, at the most, 2 days of symptoms. So if you were going to have a 7-day illness, you will have a 5- to 5.5-day illness. There are no very hard data yet that this antiviral will have major impact on the morbidity and the mortality of a pandemic flu.

Chairman BARTON. So it is not really a solution.

Mr. FAUCI. That is exactly the point we are making. It is the best we have, so we need to pursue getting doses and treatment courses in our stockpile. And we need to pursue the research endeavors that give us an additional number of antivirals that are what we call in the pipeline. But to rely on Tamiflu as the sole prevention-and-response mechanism, I think, is ill advised.

Chairman BARTON. Okay.

Mr. Secretary, as you well know, this committee has got jurisdiction over, I think, almost everything within your agency's jurisdiction. We have just gone through this in this committee, a process to reform Medicaid in which we have a plan that is going to provide some savings over the next 5 years. We are having a hearing in the next 2 weeks on Medicare physician reimbursement. Doctors of this country are expected to, if we don't change the law, to receive a 4 percent cut in their reimbursement under Medicare.

The proposal that you and the President put out on Avian Flu costs a little over \$7 billion, I believe, over the next 3 years. As we move forward with the legislative package to try to implement or modify the Avian Flu proposal, are you willing to work with us to find ways to offset the cost of this proposal?

Mr. LEAVITT. Mr. Chairman, having served as Governor for 11 years, I know the pressures of budget, and this committee weighs, in some ways, complex financial issues. We, of course, are going to be anxious to work with the committee in whatever work its going to be doing on this and other subjects.

I would like to emphasize, however, that the President has presented this as an emergency supplemental because he believes it to be an emergency. We need to be moving boldly in redeveloping this industry. We are not just asking this industry—we are not just proposing to fund the industry; we are asking them to put up substantial capital. We are asking them to devote substantial intellectual property. We are asking them to redirect their priorities to accomplish this task. And they need to know with some certainty that we are in the game as well, that we all have skin in this game and that we are going to accomplish it.

Now I recognize they are competing priorities and we are anxious to be as helpful as we can in looking at the bigger picture.

Chairman BARTON. Well, I understand that, and I just want you to know that if that supplemental came to the floor today and all that was in it was this, I would vote against it and would encourage others to vote against it. I don't think it is fair to ask all the other groups in the health care community to work with us to find ways to improve efficiency and find savings, and then on this issue, which is not yet, it has the potential to be catastrophic, but it is not yet catastrophic, that we are just going to waive all of that and add to the deficit. With that, I want to yield to my distinguished ranking member, Mr. Dingell of Michigan.

Mr. DINGELL. Mr. Chairman, thank you. Mr. Secretary and your distinguished associates, welcome. First question, has the administration estimated what it will cost to State and local governments to do what is expected of them in the administration's plan?

Mr. LEAVITT. Mr. Dingell, again, having just come from State Government, this is a subject I am quite sensitive about and know how my former colleague Governors are feeling and how State and

local health officials are feeling. I want to emphasize how important I think it is that we are, in fact, able to accomplish what is necessary because this disaster, I know—

Mr. DINGELL. Mr. Secretary, with all respect, I have almost lost a minute of my 5 minutes. Can you just answer the question please?

Mr. LEAVITT. If you will notice on that board, Mr. Dingell, you will see on the far right, enhanced public health infrastructure and international collaboration, \$600 million. Roughly, we know that it is going to require not just that but devotion of public—or rather local resources as well.

Mr. DINGELL. None of the States and local units of government have the resources to carry out these responsibilities.

Mr. LEAVITT. It is going to require effort on all of our part, and I believe a reprioritization on all of our parts well.

Mr. DINGELL. So the answer is, I think, then, you are telling me you don't really know.

Mr. LEAVITT. I think it is clear that they don't.

Mr. DINGELL. Now Mr. Secretary, do you believe that States—I am sorry. In terms of being prepared for the next pandemic, Mr. Secretary, do you believe that there is a gap between where the States are today and where they need to be in order to fully carry out the expectations of the plan that you have set forward?

Mr. LEAVITT. There are gaps, I believe, in our system generally and States and local communities would be among them.

Mr. DINGELL. Mr. Secretary, would you provide for the committee a State by State estimate of the cost of getting fully prepared in the next pandemic? Just submit that to the committee as opposed to doing it now.

And Mr. Chairman, I ask you unanimous consent that I be permitted to communicate with the Secretary and that if the answer is not available this morning, would be inserted in the record at the appropriate time and fashion.

Chairman BARTON. Without objection, so ordered.

[The information referred to follows:]

**Department of Health and Human Services
Questions For the Record For
The Honorable Michael O. Leavitt, Secretary
House Energy and Commerce Committee
Hearing entitled:
"Assessing the National Pandemic Flu Preparedness Plan"
November 8, 2005**

Honorable John D. Dingell

Question 1:

In terms of being prepared for the next flu pandemic, do you believe that there is a gap between where States are today versus where they need to be in order to be fully able to do all that is expected of them under your plan?

Answer:

Since FY 2002, approximately \$6.7 billion has been provided to States and localities for public health and hospital emergency preparedness activities. In FY 2005, CDC's Public Health Emergency Preparedness Cooperative Agreement required states to submit their pandemic influenza plans. These plans indicated that states are at varying degrees of readiness for an influenza pandemic. Although many states have had a pandemic influenza plan in place for some time, most anticipated revising their plans pending final Department of Health and Human Services guidance, which we released and made available in November 2005, along with the related State and Local Checklist for Pandemic Influenza Planning. This guidance is focusing states' efforts on those key criteria that are critical for pandemic influenza preparedness and planning. CDC is providing technical assistance to the states to strengthen their overall preparedness capacity.

Question 2:

Do you believe that State and local governments have the resources that they will need in order to do all the things expected of them in the Department of Health and Human Services Pandemic Influenza Plan? Please explain your answer in detail.

Answer:

Principally through HHS's Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), since FY 2002 approximately \$6.7 billion has been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of

hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting.

In addition, for the past two years, HHS has been providing States with explicit guidance and funding with which to prepare plans to counter a human influenza pandemic. States generally have made good progress. This supplemental request includes an additional \$100 million for States and local communities to update and complete their influenza preparedness plans and conduct preparedness exercises to evaluate their readiness. Further, with the release of the HHS Pandemic Preparedness Plan, States will have the benefit of considerably more technical assistance than was available heretofore. In particular, Part II of the HHS Plan, our "Public Health Guidance for State and Local Partners," provides detailed tactical information relevant to virtually every aspect of planning for and countering a human influenza pandemic outbreak.

Question 3:

Has the Administration estimated what it will cost State and local governments to do all that is expected of them in the Administration's plan? Please provide such an estimate and transmit it to me within the next 60 days. Please prepare those estimates on a State-by-State basis and include the facts and assumptions upon which the estimates are based.

Answer:

It is difficult to estimate with certainty how much an adequate level of preparedness will cost the States. From Fiscal Year 2002 through Fiscal Year 2006, HHS provided States and other eligible entities with more than \$6.7 billion to enhance the capabilities of State and local public departments, hospitals, and other healthcare organizations to prepare for and respond to terrorist events and other public health emergencies. Within these awards during Fiscal Years 2004 and 2005, HHS provided the States with explicit guidance with which to prepare their own pandemic influenza plans.

We believe that our national response to this threat is a shared responsibility between the Federal, State, and local governments. In the area of antivirals, for example, we propose to purchase 50 million treatment courses at the Federal level and to provide most of them to the States at no cost, thereby making the States the primary beneficiaries of this acquisition. This quantity is sufficient to cover critical workers such as healthcare providers and those responsible for maintenance and operation of other critical infrastructures. HHS proposes further that States wishing to have larger stocks of antiviral drugs than their share of the HHS distribution be able to acquire more (up to 31 million treatment

courses in the aggregate) by subsidizing 25 percent of their purchases and allowing them to purchase off the Federal contract. In consultations with several governors and other State and local officials, we have made it clear that States have discretion as to whether or not they avail themselves of this opportunity for subsidized acquisition of antiviral drugs and to reassure them that the HHS proposal is not an unfunded mandate.

Question 4:

The Administration is requesting \$6.7 billion to implement its pandemic flu plan. How long will this money last? Do you anticipate making subsequent funding requests for pandemic flu preparation? If so, please tell us when, how much, and for what purpose you anticipate making such requests. Does the Administration plan to submit revenue or spending proposals that offset any of its pandemic flu funding requests? If so, please provide details.

Answer:

The magnitude of this budget request speaks volumes on how serious the President views the need to be better prepared to deal with a potential influenza pandemic, and the request funds the critical items in our plan that we need to start now. In fact, of the \$6.7 billion requested for HHS, \$6.5 billion is sought in up-front one-time expenditures to demonstrate to manufacturers that the Federal government is fully committed to doing its part, so that these private entities can plan appropriately for their own economic investments and be willing to partner with us. We must partner with industry to address this gaping vulnerability in our preparedness. This means doing business differently, by giving a clear signal that we intend to support this effort for as long as it takes to secure our domestic vaccine production base.

The Administration will assess any additional other needs on an annual basis to ensure we stay prepared, but we would expect the results of these assessments to be handled in the context of the annual budget proposals.

Question 5:

Do you agree that maximizing flu pandemic preparedness will minimize the inevitable loss to our economy when the next flu pandemic hits? Have you estimated the cost to our economy of an influenza pandemic at present levels of preparedness versus levels of preparedness that would be achieved if all aspects of the Administration's plan were fully implemented? If not, please conduct economic modeling studies that compare the effects on the economy of a pandemic under current levels of preparedness versus what those effects would be if the entire Nation achieved the levels of preparedness called for in the

Administration's pandemic flu plan. Please provide me with the results of these studies as soon as possible and no later than 60 days after receipt of this request.

Answer:

The consequences of an influenza pandemic are difficult to predict. Pandemics occurred three times in the past century. The most recent (1968) was the mildest and killed about 34,000 people in the United States. The most severe influenza pandemic in the past century occurred in 1918 and killed about 500,000 Americans and up to 40 million people worldwide.

To put the impact of a pandemic in context, the seasonal influenza that we have today causes an average of 36,000 deaths each year in the United States, mostly among the elderly, and adds more than 200,000 hospitalizations.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus currently circulating in birds in Asia and Europe, or the emergence of another influenza virus of pandemic potential. However, it is still useful to model possible scenarios based on analysis of past pandemics. In a report released in December 2005, the Congressional Budget Office presents the results of modeling a severe pandemic scenario similar to the 1918 Spanish flu outbreak and a more moderate outbreak resembling the flu pandemics of 1957 and 1968. In the severe scenario, roughly 90 million people become ill and 2 million die in the United States and the impact on the real Gross Domestic Product (GDP) is about a 5 percent reduction in the year following the outbreak. In the "mild" pandemic scenario, about 75 million people are infected in the U.S. and about 100,000 of them die. The impact on the GDP is approximately a 1.5 percent decline. While there is substantial uncertainty associated with these estimates, they illustrate the enormous public health threat of an influenza pandemic and the need for effective access to vaccines, treatments, and a robust public health infrastructure to meet the challenge.

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

- A pandemic could occur anytime during the year and could last longer than typical seasonal influenza, with possible repeated waves of infection.
- The capacity to prevent or control transmission of the virus once it gains the ability to be efficiently transmitted from person to person will be limited.
- Right now, the H5N1 avian influenza strain that is circulating in Asia, Europe, and Africa among birds is considered the leading candidate to cause the next pandemic. However, it is possible that another influenza virus, which could originate anywhere in the world, could cause the next pandemic. This uncertainty is one of the reasons why we need to maintain year-round laboratory surveillance of influenza viruses. As is the case with the avian virus H5N1, pandemic influenza viruses often emerge in animals.

As they are transmitted among animals the viruses can potentially mutate to a form that can be transmitted to humans. Thus, it is critical to maintain constant surveillance of viruses worldwide affecting animal populations and that can potentially be transmitted to humans.

- We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have been many changes since the last pandemic in 1968, including changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes have made us more vulnerable.

Question 6:

The Administration's pandemic flu plan identifies a cohort of persons who should be vaccinated in advance of the onset of a pandemic. These are first responders and others who need to be well when the flu pandemic arrives. How many people do you estimate are in this group? Is the amount of vaccine you plan to stockpile sufficient for this many people?

Answer:

The HHS Pandemic Influenza Plan has a goal of providing a course of pandemic influenza vaccine for every American within six months of detection of sustained human-to-human transmission of a pandemic influenza virus and ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population.

Two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC), provided recommendations to the Department of Health and Human Services on the use of vaccines and antiviral drugs in an influenza pandemic. Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. The advisory committees' estimates of the numbers of individuals in these groups are as follows

- Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (~40,000).
- Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (8-9 million).
- Public health emergency response workers critical to pandemic response (assumed one-third of estimated public health workforce=150,000)

- Other public health emergency responders (300,000 = remaining two-thirds of public health work force)
- Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (2.99 million)

Question 7:

Do you believe the needed number of first responders and persons who should be vaccinated in advance will agree to be vaccinated with an experimental vaccine in advance of a pandemic "triggering event" if they or their survivors will not be compensated for serious injury or death caused by the vaccine? Please explain your answer in detail.

Answer:

The HHS plan does not assume advance immunizations. Policy decisions will be made based upon evolution of the changing disease and public health needs.

Honorable Vito Fossella

Much of the burden falls upon the hospitals in regards to planning, training and drilling staff in preparation for emergencies, and HRSA is the primary funding source for these efforts. Under the current system, while New York City ranks among the highest at risk of a public health emergency, it ranks last for receipt of HRSA's emergency preparation funding per capita (54/54). As the gateway for travel from many of the Southeastern Asian countries, this inequity in New York is alarming.

Question 1:

To what degree will funding, (particularly the \$555 million requested for surveillance and public health infrastructure) be allocated according to risk?

Answer:

The current funding allocation for the State and local bioterrorism preparedness cooperative agreements is based on risk, with population density being the risk factor - there is a base amount available for each state and the rest of the allocation is distributed based on state population. I would add, however, that the public health infrastructure has been improved in many ways with resources allocated through DHHS, both for a response to terrorist events, and natural disasters. Specifically,

- 98% of state public health departments report they have detailed public health response plans for biological outbreaks caused by agents likely to be used by terrorists or those likely to occur naturally, such as a new influenza pandemic;
- 93% of state public health departments report they have exercised those plans in the last 12 months;
- 97% of state public health departments report they have structured their response under the Incident Command System structure, as recommended in the National Incident Management Structure;
- 97% of state public health departments report having 24/7/365 capacity to investigate urgent disease reports; and
- 95% report having met the goal of having at least one epidemiologist for each metropolitan area with a population greater than 500,000.

Technology advances have made automation of disease reporting and tracking easier, and more complete,

- 98% of state public health departments report having designated facilities to receive, store and distribute contents of the strategic national stockpile;
- 82% of the state public health departments report having exercised some portion of their SNS plan; and
- 97% of the state public health departments report having crisis and risk communication plans in place.

Considerable gains have been made, but we will continue to work with State and local health officials to assure our Nation strives for the highest levels of emergency preparedness.

Question 2:

And as delegated to states, is it my understanding the \$100 million for state and local pandemic preparedness will be allocated to the 50 states and not the 50 states and four most densely populated as it is for bioterrorism funding?

Answer:

States and municipalities will use these funds to accelerate and intensify current planning efforts for pandemic influenza and to exercise their plans. The focus is on practical, community-based procedures that could prevent or delay the spread of pandemic influenza, and help to reduce the burden of illness communities would contend with during an outbreak. Our hope is that this funding will build on the previous efforts through the State and local cooperative agreements.

Mr. DINGELL. Mr. Secretary, the national strategy for pandemic influenza refers to novel investment strategies. That is a quote. What are these novel investment strategies?

Mr. LEAVITT. I will ask Dr. Fauci to respond to that in the specific, but I will tell you that in the vaccine area, generally we are looking for ways to develop cell culture developments of vaccines in addition to expanding capacity on egg based. We are always looking for adjuvant technology which is, I think, Hamburger Helper for vaccines. It allows us to take the vaccine and spread it among more people and then—so egg, cell and adjuvant.

Mr. FAUCI. Mr. Dingell, underscoring that, certainly the point that the Secretary made, but also that we have been over the last decades and decades involved in a rather standard way of make influenza vaccine which as the Secretary mentioned is egg based. And the future of that is going to try to grow the virus in a cell-based culture but—

Mr. DINGELL. I am going asking you what time it is Doctor, and you are telling me the theory of Sidereal time and you are giving me more than I want. What I really want to know is what are these novel investment strategies? Because I always have the dark suspicion when somebody gives me that, which I know comes from the Office of Management and Budget—

Mr. FAUCI. One of them is a novel approach of the—what we call the universal vaccine instead of having to change vaccines each year, you get the standard immutable component of the virus that doesn't appear to generally induce a strong immune response. If you can get that in a form that induces an immune response, the strategy may be that you do not have to, each year, chase the flu that is a little bit different than the year before.

Mr. DINGELL. Doctor, with respect, I am going to ask you to submit that answer in writing.

Mr. FAUCI. Will do.

Mr. DINGELL. Mr. Secretary, are there estimates of what the flu pandemic would cost this country in terms of lost productivity and the economic consequences of it? Do you have any idea of what that is?

Mr. LEAVITT. I have seen estimates. They range in large but it is hundreds of billions.

Mr. DINGELL. And essentially, they are sort of wild guesses. But would you give us your best wild guess on this matter, please, Mr. Secretary?

Mr. LEAVITT. Mr. Dingell, I would need to submit that to the committee. I don't have a wild guess.

Mr. DINGELL. And I understand that well. I have some numbers here that have been submitted to the committee from a very responsible organization. \$510,000 would be imposed on the State for the cost of purchasing antiviral medication, \$250,000 for contingency planning, surge capacity not funded in the request, improved availability of diagnostics and reagents not funded in the requests, 75 million.

Now, risk communication, inadequately funded, and that is estimated \$150 million. Are those numbers generally right or generally wrong?

Mr. LEAVITT. At the risk of giving you more about the time of day than you want let me say that, there is 1.4 billion on the antivirals, those antivirals are going to be get kept for the most part in the States. A billion dollars or roughly 75 percent of the antivirals would be placed, done at Federal expense. If we were going to the full 81 million courses, the States would need to contribute, the number that you have acknowledged would be in the ballpark.

Mr. DINGELL. Thank you, Mr. Secretary. Mr. Chairman, again, I repeat, may I have unanimous consent to submit some questions to the Secretary in writing and have both that and Mr. Secretary's response inserted into the record?

Chairman BARTON. Without objection.

Mr. DINGELL. Mr. Secretary, gentlemen and ladies, thank you.

Chairman BARTON. Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman, Mr. Secretary, I share your alarm and concern that we are not where we need to be, particularly in light of the director general's comments, the WHO, today, when he said that, quoted, it is only a matter of time before an avian flu virus, most likely H5N1, acquires the ability to be transmitted from human to human, sparking the outbreak of a human pandemic influenza.

And in your testimony, you referenced a new vaccine that is currently in trials. It does not yet have the FDA stamp of approval, as I understand it.

What is your expectation as to how quickly, we would be able to get this new vaccine to treat 25 percent of our population and what would be the cost?

3 years? 2 years? If this is looming over our heads now, so, it is going to come. I think we both agree it is going to come. So what is—

Mr. LEAVITT. Congressman, I am reluctant to use a timeframe or—not because I am unwilling to give you one, but sitting today, I am not sure I can respond with the specificity your question requires. We would be pleased to respond after it has been calculated. I will tell you, we believe it will be 3 to 5 years before we will have cell-based technology. And we are looking at ramping this up as rapidly as we can with egg based. Dr. Raub, do you have any insight on this?

Dr. RAUB. Sir, if the requirement today were to produce a vaccine against what would be the pandemic virus—not the H5N1, but the one that would let's say derive from it, in a 6-month period, we would likely only be able to produce about 13 million doses of the vaccine.

And we project that each person would need 2 doses. So that would be coverage for 7 million people—far below what preparedness requires. And therefore, the reason that the primary element in the budget proposal is a \$4.7 billion investment to revitalize and expand the capacity of vaccine production in the country to get every citizen covered in that 6-month period.

Mr. UPTON. So how many dosages does \$4 billion get us?

Dr. RAUB. The plan is in two parts. The plan for the egg based production, based on the tried and true technology, would get us two things. It would get us approximately 40 million doses of a vac-

cine against the H5N1 or something like it, but also, would get us the capacity to surge beyond that, when and if the pandemic virus occurred. The parallel investment in the cell-based facilities would get us the other 80 percent of the surge capacity. So the investment is less in buying vaccine now than it is creating the capacity to produce vaccine quickly when it is needed.

Mr. UPTON. Now do we not have, go ahead, Dr. Fauci.

Mr. FAUCI. We just want to add something that I think is important, because this is a moving target. That is based on the early clinical trial data that you need 90 micrograms followed in 4 weeks by 90 micrograms, which is about 6 to 12 times larger dose than we generally use for seasonal flu.

There are studies that are ongoing right now on adjuvants that might lessen that which would impact on the timeframe we are talking about. So that is a very important issue because those data are going to be coming out in the next several months.

Mr. UPTON. I am told that cell-based vaccine production is actually done now in some animal health labs. Is that correct?

Mr. FAUCI. That is correct.

Mr. UPTON. So we have the technology we just have to—

Mr. LEAVITT. Cell-based vaccines are used in other areas, but we have not achieved it in flu. Okay. The estimate is it will be 3 to 5 years before we will be able to.

Mr. UPTON. My last question in my opening statement, I shared my frustrations with the current distribution of this year's flu vaccine. Where are we in terms of looking at some type of new demonstration or new distribution system that we could use for what may be coming? And what are the costs associated with moving to a different distribution type of system?

Mr. LEAVITT. I will ask Dr. Gerberding from CDC to respond.

Ms. GERBERDING. Because we have not been able to substantially increase the production of vaccine, even though we now have four companies in the market, and actually have at least 20 million more doses this year than last year, we cannot have the adequate match between the three factors, the demand among people for vaccine, the geographic distribution at the micro level to the doctor or the clinic that needs it, and the supply timing coming out of the factories over the flu season. The investments that are proposed in terms of modernizing our vaccine would allow us to have a robust supply and really eliminate a lot of these distribution mismatches that are so upsetting to so many people including CDC.

Mr. UPTON. Thank you. Now my time has expired.

Chairman BARTON. Mr. Markey.

Mr. MARKEY. Can I pass?

Chairman BARTON. Sure.

Mrs. DeGette.

Ms. DEGETTE. Thank you Mr. Chairman. In the opening statements, a lot of folks kept talking about this should not be a partisan issue. And I agree. I think it is too important to our constituents and our citizens. And I would note that if you look at the history of avian flu preparedness, the first draft of the plan was presented to Donna Shalala in 1998 under the Clinton administration, and then in 2001, when we had the outbreak of avian flu in Southeast Asia, Tommy Thompson was Secretary of HHS. And he, ac-

ording to The Washington Post this week, was livid that he didn't have a plan and he wondered why it was taking so long. Then we had 2 years after that, no plan, a lot of hearings in Congress, as the Secretary alluded to.

And now, here we have Secretary Leavitt and unfortunately, the administration is the administration, and they are the ones that are tasked with being ready for this. And it does happen to be the Bush administration. So, you know, if Secretary Shalala was here, I guess I would be asking her these questions.

We finally have this plan. I have got it here. It looks like it was in development for a long time because it is slick and long and all of that. But my question is, Mr. Secretary, why has the plan taken so long to finally be released?

Mr. LEAVITT. The plan is still in development. There are many parts to it. And let me describe what I mean. What you see there is the HHS medical and public health corps.

In addition to this, there are currently plans being developed, for example, at the Department of Transportation, at the Department of—

Ms. DEGETTE. So what you are saying is this isn't even the full plan, right?

Mr. LEAVITT. There are plans being developed in State and local governments. In order to have a national plan, we need to have an ongoing planning process. And we have a plan. But it is a plan that can be improved and that will get better, we are better prepared today than we were yesterday and we will be better prepared tomorrow than we are today.

Ms. DEGETTE. And let me talk to you about that, because now I have the Colorado plan, too, which was actually promulgated in 2003. It is not as slick. But one thing the Colorado plan says is that with the exception of a few antivirals, which I now know don't work for this particular strain of avian flu, the Colorado plan says that the Federal responsibility is, Number 1, deployment of federally purchased vaccine and Number 2, deployment of antiviral agents in the strategic national stockpile.

Do most of the States have a similar plan for how they are getting antivirals and vaccines?

Mr. LEAVITT. Most of the States do have a plan that references the Federal stockpiles.

Ms. DEGETTE. We don't have a Federal stockpile, do we, Mr. Secretary?

Mr. LEAVITT. We do. It is just not as big as we want it to be.

Ms. DEGETTE. How big is it?

Mr. LEAVITT. We have currently in place or to be received soon about 5 million courses of Tamiflu.

Ms. DEGETTE. Right. And how many courses of Tamiflu do we project that we need?

Mr. LEAVITT. Our first target is to get to 20 million.

Ms. DEGETTE. By what time?

Mr. LEAVITT. We will achieve that by the fourth quarter of 2006.

Ms. DEGETTE. That is with full Federal funding?

Mr. LEAVITT. We have vendor representations that we will achieve that by the fourth quarter of 2006. And we have a target

of 81 million courses, and we have vendor representations that we will achieve that by the mid part of 2007.

Ms. DEGETTE. And my question is, is that with full Federal dollars or is that relying on the State match?

Mr. LEAVITT. The Federal plan that you have before you would put 50 million courses of Tamiflu that would be distributed throughout the country that would be at Federal expense. If the States chose to go beyond that, then we would participate under this plan by subsidizing their purchase by 25 percent and allowing them to use the Federal price to do that.

Ms. DEGETTE. Okay. And the vendors have agreed to that plan?

Mr. LEAVITT. Well, we have vendor representations that they can produce at that level.

Ms. DEGETTE. And it would be at the Federal price, the antivirals that went to the States?

Dr. RAUB. The concept is doing it through a Federal contract. And I don't believe it is an issue with the vendor. In many ways, the larger the order we can make at once, the faster we can get delivery because the vendor will invest in new production facilities.

Ms. DEGETTE. I have just one more question, because I am almost out of time. What happens, say, if Colorado decides to participate in this optional 75/25 percent match, but Wyoming doesn't. What happens if you have a patchwork of States? Isn't that why we need a coordinated Federal approach?

Mr. LEAVITT. First, let's remember that Tamiflu is one component of a comprehensive plan. Second, let's emphasize—I would like to emphasize that every State will have access to a stockpile of Tamiflu. Some States may decide to have a larger stockpile for reasons that are unique to their plan. And if they do choose to do so, we are prepared to subsidize their purchase by 25 percent. If they choose not to, they will have very significant stockpile of Tamiflu available to them. They simply will not have purchased more. It will be a judgment call that States needs to make.

And this is an important part of the plan, because States have got to become engaged on this plan. If they can put in their plan the Federal Government will take care of it, they are not engaged. And they need to be engaged in this. They need to—they can't be counting on the Secretary of HHS to decide whether their local school is going to open or close. Likewise, they ought not be counting on the Federal Government, in my judgment, to make certain that they can put a pill in everybody's palm at the right moment, because the Federal Government simply—

Ms. DEGETTE. My time is up and you are exactly right. The problem is the States don't have any resources. And we are just getting ready to cut their Medicaid programs by, I think, \$10 billion. It is a problem all around. And I appreciate your commitment to it.

Chairman BARTON. Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. Dr. Fauci, we have about 11 million illegal immigrants in the United States. That is what they project, plus or minus. And we have a lot of illegals coming in today.

How will we screen in the event we have legal immigrants coming, what will we do about the illegal immigrants, in your opinion, to protect us, and keep this under control?

Mr. FAUCI. Mr. Stearns, that certainly is not in my area of expertise or activity. So I would have to—

Mr. STEARNS. CDC?

Mr. LEAVITT. The question you are really asking is better answered by CDC.

Ms. GERBERDING. Two short perspectives, and we can provide more for the record. First of all, we do have responsibility for our quarantine stations at the borders and that is where we look for people with illness coming into our country by any means. Second, in terms of anyone presenting with an illness that may be infectious, our State and local communities have traditionally taken on the responsibility of providing the appropriate public health treatments and services for those individuals at their expense.

Mr. STEARNS. But you would agree, though, at this point a lot of people coming in that are illegals every day and we don't have control of our borders. So isn't that a difficult thing for the United States? Doesn't that even make it more clear why we should control our borders in the event that we have a pandemic in the United States, and yet our borders are porous and we have a lot of illegals coming in, and we have no idea whether they have the avian flu or not? Wouldn't that be a concern of yours?

Ms. GERBERDING. It would be a misrepresentation to think that this is a border issue because the virus doesn't understand borders. It is really the connectivity from people from one region of the world to another regardless of whether they are moving legally or illegally.

Mr. STEARNS. But if the United States had the Tamiflu vaccine but Mexico didn't. Or Mexico didn't equip their country as well as we do, wouldn't you have Mexico—a lot of these people perhaps having this avian flu come into the United States, and you would have no way of controlling our borders, and this would represent a threat to us no matter what you did.

Mr. LEAVITT. We are in an active conversation with the health ministry and all also the head of State level with Canada and Mexico for that very reason. So.

Mr. STEARNS. So don't you have to work in tandem with Canada and Mexico so as much as we have to say to ourselves, United States must be prepared, if you don't prepare Mexico, possibly, Canada, and you have a lot of people immigrating into Canada and from Canada coming in—

Mr. LEAVITT. Actually it needs to go beyond that. The President has formed the international partnership for pandemic influenza and we now have 88 countries that are a part of an effort to create a global or international surveillance system where we are able to determine that if it happens in Southeast Asia in a remote village of Cambodia that the moment they have it, we need to heard about it. And obviously, there are lots of cross pressures, economic cross pressures, that work against that. But we are working very hard for that reason to assure that we have transparency and cooperation among nations.

Mr. STEARNS. And the other question I have is dealing with Posse Comitatus, the homeland security was looking at this in trying to control the borders. They never did anything with it. In the event that we had to mass distribute vaccines, in the event of a

catastrophic outbreak of pandemic influenza, is there any thought to relaxing Posse Comitatus and to, as a viable option, to help the military deliver the medication, or at least help in the process?

Mr. LEAVITT. There has not been discussions of that. I will tell you that as the others have mentioned, there is a need, at times, to be able to deploy in any natural disaster, military assets, primarily for transportation.

Dr. Raub, do you have anything to add to that?

Dr. RAUB. Sir, in our preparedness working with our other colleagues in the States on bioterrorism, in our planning with our colleague and other agencies including the Department of Defense and States with respect to distributing antibiotics on a bioterrorism event, the preferred modality for the Department of Defense is the National Guard, with the means where the Department of Defense would underwrite a substantial part of the cost of the activation of the guard. But it would be under the control of the State officials not the Pentagon.

Mr. STEARNS. In 1918, when we had the pandemic, was the military used at all back then?

Mr. LEAVITT. Actually in 1918, it was the military through which most of it spread, it began in.

Mr. STEARNS. Thank you, Mr. Chairman.

Chairman BARTON. Gentleman from Maine, Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman.

Mr. Secretary, in your previous comments, were included responses to the gentlelady from Colorado that we have the vendor is promising 20 million courses by the end of 2006, and 80 million courses of Tamiflu by mid 2007. I take the point that Tamiflu isn't the complete answer. But it is the first line of defense.

How confident are you in those projections? And do you know whether or not the vendor—well, first of all, is the vendor Roche? Or does this include some other companies being licensed or any other steps that you might take?

Mr. LEAVITT. Roche has made very clear that they do not intend for intellectual property issues to become a barrier in their meeting those recommendations. And they have indicated a willingness to work with other manufacturers who are prepared and willing to do so.

And we have asked the FDA—I have dispatched the FDA to work with them and any potential vendor to do so.

I will tell you that while I am not a chemist, I have pressed hard enough on this issue to understand the process. And it is a very complicated multi part process that includes, in some cases, rather dangerous explosives processing. And it is not likely, in my judgment, nor those who advise me, that we will see any other manufactures of Tamiflu certainly within a year, and more likely, 2 years.

And that would be true in this country or in any other country.

Mr. ALLEN. Well, let me go back. There are companies in other countries that are ready, able—well, ready is the question—but who have expressed an interest in manufacturing a generic version of Tamiflu and are seeking and have been inquiring with Roche. The problem I mentioned in my opening is that it seems pretty

clear we have an insufficient manufacturing capacity for anti flu drugs today. Would you agree with that?

Mr. LEAVITT. That is true, yes.

Mr. ALLEN. Back on August 30, 2003, World Trade Organization members adopted the so-called Paragraph 6 agreement. And it spelled out the rules by which countries with insufficient manufacturing capacity could import needed pharmaceuticals produced under compulsory licenses. The U.S. Government chose to opt out, and persuaded—the U.S. Persuaded the EU and Japan and Australia and other countries to opt out of that system. That means that if Indian or other companies developed a source of Tamiflu that the U.S. Government would not be able to import those antivirals into this country. And I guess my question is, does that, in retrospect, look like a wise decision or not?

Mr. LEAVITT. Mr. Allen, let me make clear that in a pandemic situation, I think all those who have modeled and studied it believe that whatever—you will get what is produced domestically. That is one of the reasons we have pushed so hard for Roche to develop the domestic manufacturing capacity which they have agreed to do and are in the process of developing. I don't believe that will be an issue in a pandemic, because I think people who have it within their borders will keep it.

Mr. ALLEN. That may well be if it is global and not concentrated in one country or another.

Back when we had that Cipro scare—when we had the anthrax scare here and Cipro was the available drug to treat it, Secretary Thompson said—essentially threatened the compulsory licensing.

Would you be prepared to do the same? And I grant you, what you have said before, I grant you the manufacturing process is long and difficult and complicated. But would you prepared to issue a compulsory license if Roche failed to provide inadequate authority for to expand production here?

Mr. LEAVITT. I do not contemplate that being a circumstance that would present itself. It is important, however, that people in this country know we will do everything necessary to protect them.

Mr. ALLEN. Thank you. One final thing. Back on May 20 of 2004, I wrote to the Department seeking information about the Department's analysis of the U.S. Australian free trade agreement and its potential impact on Medicare and Medicaid programs. That intersection is, I think, great importance. I haven't had a response to that. I submitted a question for the record to you at this committee's hearing on February 15th of this year asking for an update. I sent a follow-up letter to HHS on April 20, 2005, also seeking an update. I still don't have a response.

I would urge you, Mr. Secretary, to respond to that. It is a matter, I believe—the intersection between our health care programs and our free trade agreements, I think, is a matter of great importance, and I would very much appreciate a prompt response.

Mr. LEAVITT. That does not sound like the type of response that we aspire to give, and I will follow back up on that.

Mr. ALLEN. I am sure it is not. Thank you.

Chairman BARTON. Before I go to Subcommittee Chairman Deal, my understanding is that Roche has applied for a license and given

a third party the opportunity to produce its Tamiflu in the United States, and that has been approved, isn't that correct?

Mr. LEAVITT. They have indicated a willingness to provide licensure for anyone who can meet the standards of production that are necessary to produce it. To my knowledge, no license has yet been completed. We have, in fact, indicated to them that the FDA would work to cooperate and develop that.

Is there anything that has happened that I don't know about Bill?

Dr. RAUB. No.

Chairman BARTON. Subcommittee Chairman Deal.

Mr. DEAL. Thank you, Mr. Chairman. When we talk about traditional flu, we talk about traditional flu season, which would be the fall and into the winter. When we talk about avian flu, does it, likewise, have a seasonal threat, or is it a year round threat?

Mr. LEAVITT. I will ask Dr. Gerberding to respond to that.

Ms. GERBERDING. There is a seasonal pattern to the avian outbreaks in Asia right now among the poultry. We are coming into the high season now where we would expect the most transmission in the poultry, and, of course, then secondarily the most transmission to people. Whether or not that pattern would hold true in the context of a pandemic is not something we can predict. In the last pandemic there was very little seasonality. The pandemic occurred in 2 or 3 waves. And they were relatively independent of the season.

Mr. DEAL. Once the virus is able to obtain the ability to be transmitted from human to human is when the real pandemic threat occurs, as I understand it.

Does that virus, when it acquires that ability in a mutation, I assume, does it then become immune to the vaccine that was created for the original H5N1? Is it a different virus at that point?

Mr. LEAVITT. I will ask Dr. Fauci to give you the answer.

Mr. FAUCI. The answer is highly likely yes. So there is a high degree of protection of a certain virus. And it changes to become more efficient in going human to human. It is likely that it will change enough that the protection will diminish. It may not going down to zero, but it will be clearly less efficient than it is in protecting against the original virus, which is the reason why we emphasize, including in the plan, that what is critical is not necessarily a vaccine against this H5N1, but building the capacity so that when that virus, and we hope it never does, but if and when it changes, that the capacity will be building up, that you can take that updated version of the virus, plug it into the system and make that your vaccine.

Mr. DEAL. What is the lag time on that component?

Mr. FAUCI. The lag time on that is generally, traditionally is about 6 months when you are dealing with seasonal flu from the time you plug in a new vaccine. How long it is going to take to get to the doses levels that we need is going to depend on a lot of things that I mentioned a few minutes ago are a moving target, namely whether or not for example and adjuvant would allow us to get to a reasonable dose as opposed to the quite high dose that we are dealing with now.

So it could take anywhere from a year or even more or if you really have a good system going you could do it. And that is the ultimate goal in the plan to get to that 6-month time from the time you press the button. We are certainly not there right now.

Mr. LEAVITT. That includes the manufacturing he is speaking of. Were you asking about the development of the virus vaccine itself.

Mr. DEAL. Both of them yes.

Mr. LEAVITT. Vaccine would be a shorter period, manufacturing would be on top of that.

Mr. DEAL. For those of us who have children or grandchildren who are in schools, we all know that that is one of the environments in which diseases are transmitted and flu is no exception. In my household, we have the disease of the week, depending on what my granddaughter has picked up in play school for the week.

Would the decision to have a schoolwide inoculation be a component of, and would that be assisting in preventing any kind of spread, not only of this kind of flu, but also other flu viruses, if we had a pattern that would inoculate the entire school-based population, and would that also maybe incentivize some of the vaccine manufacturers to ramp up to accommodate that? Because I don't think that is the pattern now, is it?

Mr. LEAVITT. I will ask Dr. Gerberding to answer, and then I would like to add to that.

Ms. GERBERDING. Thank you. The experts in immunization evidence are currently assessing whether or not a school-based program or a universal vaccination of children for seasonal flu is now warranted. And it looks like more and more of the data are taking us in that direction.

In the context of a pandemic, we would certainly want to be able to immunize people in all kinds of venues, and schools would be a logical place, A, because kids are there and it is easily accomplished. But second because children are one of the major forces of respiratory illness transmission. They bring these illnesses home to their parents and their grandparents. And it really is an important hot spot in the community. So that makes a lot of sense.

Mr. LEAVITT. Go to the next.

Mr. DEAL. My time is just about out. Quickly, we have invested with two manufacturers I believe to develop the H5N1 vaccine at the current time, is that correct?

Mr. LEAVITT. That is correct.

Mr. DEAL. And are they going to be the primary suppliers that we look to for any vaccine?

Mr. LEAVITT. Actually the strategy we are deploying would call for us to look for what was referred to earlier as innovative strategies. We are going to invite the entire marketplace to give us ideas. We would then invest in those that were the most promising with benchmarks.

We would then require they bring the benchmark points back and we will continue to invest as they continue to show progress. Our model calls for us to have multiple manufacturers, four or more, in order to get to 300 million courses in the 6-month period that we aspire to achieve.

Mr. DEAL. Thank you, Mr. Chairman.

Chairman BARTON. Mr. Green of Texas.

Mr. GREEN. Thank you, Mr. Chairman. Mr. Secretary, just before Tom Allen left, he is from Maine and my neighbor to my left is from California, but my State of Texas, we have 1200 miles of border with Mexico and multiple cities straddling it. I am interested in whether the administration has planned a specific consideration for surveillance in those local governments or State governments along border areas, particularly United States and Mexico, because that is our neighbor, I am sure. Mr. Allen is interested in Maine and Canada. And what would be the States' financial responsibility with regard to that surveillance, and does the plan afford any special consideration for, again, those local governments that border—because most of our health care is actually not provided by the State. It is by the county health departments or the city health departments along the border, just like it is in my urban area.

Is there any special consideration for those border areas?

Mr. LEAVITT. Your question points out the fact that public health is a State and local responsibility primarily, and that under current circumstances, State and local health departments are required to monitor and screen for disease in different ways. It would fall into that same category. Obviously if the plan does not make specific provision for borders beyond the fact that we have a specific need, generally, in those areas.

Mr. GREEN. There is no other resource for example? Because—and I always use the example if someone has infectious tuberculosis in Matamoras, Mexico, it will be in Brownsville, Houston, Dallas or San Antonio because of the nature. So there won't be anything differently done because of the—

Mr. LEAVITT. Dr. Raub with like to add some to that answer.

Dr. RAUB. Sir, over the last 3 years, we have had a special project for early warning infectious disease surveillance along the U.S. Mexican border, not limited to flu, but to other infectious diseases, among others those that could be result of bioterrorism. We have been investing about 4 million a year on the U.S. Side through our four States, and we made a one-time award about 3 years ago to our Mexican colleagues of about 5.5 million, such that there could be some complementary activities in the six Mexican States that border the Rio Grande. That continues to be an effort that is not part of this budget, we see it as strongly complementary and pertinent to your question.

Mr. GREEN. I was impressed during Katrina with the amount of CDC personnel and the public health services actually came to the Houston area and Dallas and to other areas where evacuees were, so I would hope they would also be activated if we get to that point in the future.

Mr. Secretary, the plan provides \$100 million in funding to the States and local jurisdictions to help them develop the preparedness and response plan for the pandemic flu. This is the same time the administration this year proposed 130 million cut in the CDC's public health preparedness program. Even with that \$100,000 in funding for State, local and public health, it would still be a loss of \$30 million in preparedness.

How does the administration reconcile this cut to the CDC's public health and preparedness program with the obvious need for State funding to prepare for a pandemic flu?

Mr. LEAVITT. It would be important to reconcile the 130 million. It is being referenced as a cut. The reality is it was changed from one line to another. It went into a national stockpile and the number and the money literally went from one line item to another. It was not a cut.

I would like to recognize as well that the 100 million that is being spoken of is simply to help them update their plans and to exercise them. If you look at what is in this plan for State and local governments, the billion dollars in antivirals for example, most of that will go to States. \$600 million listed in the category of surveillance and public health preparedness all be going to States—are going into stockpile for the use of States. So to suggest that 100 million is the limit to which we are working to assist local governments would not be consistent with the facts.

Mr. GREEN. My last question in 30 seconds is, our community health centers are all over the country, and again we are working in the Houston area for more. How will they be part of the—will they also be a repository or depository for integrated and surveillance and outreach notification and also will they be able to receive the avian flu vaccine like any other public health agency?

Mr. LEAVITT. This—your question, again, points out the importance of having State and local preparedness plans, because the community health centers will be an integral part of every one of the State's plans. They will be used differently in every State because every State has a different circumstance.

Mr. GREEN. So for the few I have, I want to make sure I need to go to the our State health commissioner, Dr. Sanchez, to make sure they are integrated. I don't think we will have a problem with that. Thank you.

Mr. BILIRAKIS [presiding]. The Chair recognizes himself.

Mr. Secretary, we have talked a lot, and you have just now, about the roles and responsibilities of the Federal Government and of the States and the reason why the States have to be and the local governments have to be a large part of the process. But let's go into the roles and responsibilities of individuals in preparing for and preventing the spread of a flu pandemic, and I guess I would ask, since there have got to be roles and responsibilities that you are going to share with us, are we planning, or is HHS contemplating communicating those preventive ideas to the public?

Mr. LEAVITT. Thank you, Mr. Chairman. Creating a clear sense of division of labor is enormously important, because there will be so much decentralization. I think generally in our emergency response, it is important to recognize that there will be limits in a pandemic to what the Federal Government can do and ought to represent it can do.

That will be true, to some extent, to local and State communities as well, and there will be a responsibility for individuals. That is endemic in citizenship.

The personal preparedness, having the ability to sustain oneself for a period of a couple of days, for example, would be important without going to the grocery store. We live in a 711, 24-hour grocery store mentality where we use it for our pantry as opposed to having a small supply of food or having a supply of water, or having a 72-hour kit. All of these things will apply in a pandemic in

the same way as they would for a hurricane or tornado or any other medical emergency.

Mr. BILIRAKIS. Well, basically what you have said is that when the American public knows that a pandemic flu is eminent, then of course that is when those individual roles would come into play.

Will there be, or should there be, any roles or responsibilities in the meantime between now and then? Let's hope that never happens. But as you have already indicated, I guess it is coming, maybe not this particular flu, but something, pandemics will come some time in our future, I suppose?

Mr. LEAVITT. This is a good example of why it is so important that we are talking about this in a way that informs but does not inflame and that inspires people to prepare, but does not create a sense of panic. This is today essentially an animal disease. We worry that it could become something else, and if it isn't this virus, it will be something else that will ultimately occur, it is a broad pandemic preparedness, a major part of our plan involves how do we communicate with people during those periods.

In many respects, we have the biology that existed in 1918, because we have no human immunity, but at the same time, we have a 24-hour news cycle, where people are going to find out about it. And the ability to manage that communication is part of what every State, every local community needs to deal with, and frankly something that we need to be thinking about, both in Congress as well as at HHS and throughout the administration.

Mr. BILIRAKIS. Well, thank you, sir. It is certainly critical that Congress play a constructive role in all this. And I am sure there must be areas of particular importance in the preparedness plan in which Congress could focus to benefit both annually, if you will, and anti-influenza preparedness and I am not going to really—there are a lot of areas that take more than the minutes that I have left. But I would hope that maybe you and your great staff there would share with us what we can do up here from a legislative standpoint, and any other ways to be helpful in what you are planning and your preparedness plan.

Mr. LEAVITT. Thank you, Mr. Chairman. These plans will continue to develop and improve. One area that is not receiving as much attention as it ultimately deserves is animal health. This is an animal disease right now. And as long as we can keep it—as long as it stays an animal disease, people are, for the most part, unaffected. But it has a profound impact economically, and it could, in fact, become the source of the problem. So we need to focus on animal health as well as human health.

Mr. BILIRAKIS. Well, sir, Mr. Secretary, questions have been asked about the dollars not being adequate as far as the States' roles are concerned. And how much money has been appropriated pursuant to the Public Security Act, subsequent appropriations to enhance State, local and hospital preparedness under grants from the Centers For Disease Control and health resources and services administration, and I guess I would ask if you have an answer to that, how has this funding helped prepare us up to now for pandemic flu preparedness and how much of that funding has actually been used by the States and local governments?

Mr. LEAVITT. Some 3 years ago, the Congress appropriated a \$5 billion amount to go into State and local mass casualty preparation. A good share of that has not yet been drawn by the States. We believe that those dollars can, in fact, and should be used to enhance their broad preparedness, but every dollar they spend in their broad medical preparedness for mass casualty preparedness will help on pandemics as well.

Mr. BILIRAKIS. So that money is available but it hasn't been drawn by the States?

Mr. LEAVITT. That is correct.

Mr. BILIRAKIS. That is interesting. Thanks very much Mr. Secretary. Let's see, Mrs. Eshoo.

Ms. ESHOO. Thank you Mr. Chairman, Secretary Leavitt and everyone that is here. Thank you, again, for being here. This is a very important hearing and discussion.

Secretary Leavitt, the plan calls for stockpiling 75 million doses of the antiviral medications. We have gone through this, but I just want to set this down for the record and go back to what I referenced in my opening statement.

Of that amount, 44 million would be purchased by the Federal Government, State and local governments would be responsible for 75 percent of the cost, it is a 75/25 share, as I understand it, for the remaining 1 million doses.

What I don't think the plan provides for or doesn't have any details, on what would happen if a State can't afford to pay its share of the cost? What do you have built into the plan to address that?

You know, in listening to some of the comments that I have heard today, I think that members are leaving out the first description of our country, and that is United. We are not just the States of America. We are the United States of America. And over and over again, our success, in meeting so many of the challenges that have confronted our country, is that we partner, and partner strongly with the States. This is not about some big daddy handout or States trying to grab what they can.

You know, some things, might be characterized that way. But that is not the best about us.

So I think that your plan as it is drafted right now, this is isn't a final plan, is it? No.

Mr. LEAVITT. It is continually being improved.

Ms. ESHOO. Continually evolving, and we are going to improve it. I think this is a real shortcoming. I am not going to ask you to answer that. I think that there are many members that have set this down. And I think that we can do much better than this. As a matter of fact, I think we have to. So, that is my first point.

Mr. LEAVITT. Would it be helpful if I reconciled or a portion of that financially for you? Would you like me to do that in a different way.

Ms. ESHOO. You can write to me about it. Let me get the rest of my questions out.

Mr. LEAVITT. Let me make clear that we are not just leaving our States on their own. There will be 50 million courses that will be distributed in large measure among the States, and they won't pay for any of that. If a State chooses to go beyond that, we are pre-

pared to help them with their responsibility for public health by subsidizing it—

Ms. ESHOO. So if they can't afford that percent, then we are going to step?

Mr. LEAVITT. They will all get a basic allotment of Tamiflu. And they will have it available to them. If they, in their planning, conclude, that they would desire to have more, then we will subsidize that. And in addition to that, we will have 6 million courses that are deployable wherever we need them that haven't been—

Ms. ESHOO. So regardless of a State's circumstances—let me take Louisiana.

Mr. LEAVITT. That's correct. Regardless of their circumstances, they will have access. There may be some States—

Ms. ESHOO. Is 50 million enough? How did you come up with the 50 million?

Mr. LEAVITT. We came up with it by looking at previous pandemics and the percentage of the population generally that is infected. But it is impossible to say where those will occur. So we are developing a strategy so that we could deploy additional resources if we needed it into an area that was particularly hard hit. On the other hand—

Ms. ESHOO. If I might—excuse me for interrupting—I think it is, you know, it is broader than this in many ways, because when you look at where the split is and the share and what you are describing and what I understand the plan represents, there are not the kinds of resources that we hear from, in local government, and on the ground at home, where there has been more and more responsibility placed on first responders, on our public health system, and so, you know, those are pressures and burdens that are there, you are a Governor, you know what this is. I came from county government. I certainly have an appreciation of it.

So I am emphasizing this, because, you know, if they don't get what they need, then we are not going to have a successful plan, period.

And if I might raise something else, I think my time is just about winding down, the plan mentions risk communication is an integral part of the effective public health response. Mr. Bilirakis and I have introduced legislation on acts, on 211. Only 47 percent of the Nation has access to it. And it is a telephone number for community, volunteer, Health and Human Services information and referral. And it is a very important linkage.

I would ask that you look at the 211 system, and consider, very seriously building it into the plan.

We will, you know, if you haven't seen the legislation, we will make sure you get a good summary or your staff can give it to. Because I think that this is something that could be built in and worked to implement different parts of the overall plan that you have put forward as secretary. So I would just, you know, note that. And I wanted to get to Dr. Fauci. I am not going to have time.

Dr. Gerberding, the last time you were here—

Mr. BILIRAKIS. The gentlelady's time has expired.

Ms. ESHOO. If I might just throw this in or ask that you respond to the question that I raised in the hearing that we had on the cuts to the CDC and how they would effect. You didn't have time to—

Mr. BILIRAKIS. Can you do that conceivably in writing?

Ms. ESHOO. That is what I am asking for, in writing, Mr. Chairman. Thank you.

Mr. BILIRAKIS. The 211 pointforce is a very good one. I just wanted to get clear, if I may follow up with Ms. Eshoo's. I have asked you about the Public Health Security Act and dollars that are available there. And as I understand it, approximately 2.5—about 50 percent of that money is still available, \$2.5 billion is available for the States to draw on?

Mr. LEAVITT. 50 percent would be more than it represents. They draw, period. They draw part of the 04, they commit it, and so it is not—that would be an exaggeration, but it is roughly 20 percent. Mr. BILIRAKIS. So that money is available for these purposes that we are now talking about, States preparedness?

Mr. LEAVITT. That is correct.

Mr. BILIRAKIS. And not drawing on them, and yet we apparently hear, and it is true, that the States are not getting enough money in there. There are problems there and that sort of thing. But there is money sitting someplace there that that they can draw.

Mr. LEAVITT. This would be a great way for them to use it.

Mr. BILIRAKIS. Mr. Ferguson—Mr. Walden.

Mr. WALDEN. There is a news report out today about a new way to detect flu that can occur in 11 hours rather than a matter of days, and CDC apparently has or has approved. Can any of you describe that for me, because that can certainly make a difference in detecting an outbreak?

Ms. GERBERDING. We are using several new strategies for diagnosis of cases of flu, including a PCR-based rapid test that can diagnose the genome of the organization that doesn't require you to culture it in the test tube. Many of these rapid tests are already available commercially, and can be done at the bedside. But what is specifically relevant right now is a rapid test that can tell you if it is H5 or so, other strain of flu influenza.

And that test is not being used right now, but the manufacturer has made some representations that the test would be useful in this regard. We haven't validated that at CDC.

Mr. WALDEN. But it is something somebody is working on?

Ms. GERBERDING. Absolutely.

Mr. WALDEN. That is good to know. Mr. Secretary, you were a Governor for 11 years in Utah. As the administration put together this plan, was it done without any consultation with the Governors?

Mr. LEAVITT. We are in constant discussion with the Governors. I do now intend, once the national or the Federal HHS core is in place, to begin meeting at the President's direction with every Governor in every State. We will be having, very shortly, a meeting with the Governors or with Governors' representatives in Washington, and then we will literally be going to communities saying to them, here are the components of preparedness. Let's hold it up against where you are and see how we can be helpful.

It will need to be a broad-based community plan because it is, as indicated, it deals with schools, transportation, et cetera.

Mr. WALDEN. In terms of the international outreach, was it this administration's initiative to pull together this coalition of coun-

tries, to be able to identify the outbreak of a pandemic? Was this administration the one that organized that?

Mr. LEAVITT. The President initiated the international partnership. And there are now 88 countries, and, I believe, 12 international organizations that are part and it continues to grow.

Mr. WALDEN. Do those countries—and I know you may not know this for every one, but do they have a flu plan similar to what we have or are they developing them? What is the status there?

Mr. LEAVITT. Some do, but many do not.

Mr. WALDEN. There is a conference going on in Geneva today, I believe some 600 participants. What is our role in that conference?

Mr. LEAVITT. We have a delegation there. I was in Ottawa last week. In the spring, I called the health ministers together from the affected countries to begin a conversation. We are—I am leaving next week to go into Rome to meet about the seven health ministers of the G-7, plus Mexico. So this is a matter of great international activity, and the United States is very clearly not just contributing, but in many cases leading.

Mr. WALDEN. I mentioned in my opening comments the need for self preparedness, and my friend from Washington sort of made light of it about a Swiss army knife and a compass, and that, I guess, is fine. It is obviously more than that and that wasn't what I was saying. What about individuals? Most of us, watching what is happening, frankly, after Katrina and Rita and other national disasters, realize the limitations of the government at any level to take care of us when a real problem breaks out.

What is it we can do individually to protect our families, our home—I mean, our neighborhoods. Is it possible to get Tamiflu, which could reduce the outbreak—is it possible to get the detection tests so we know so we can, I mean, what would it take? What is the best thing we can do individually?

Mr. LEAVITT. Well, Congressman, you have appropriately identified distribution as the place where victory is won. The Federal Government can drop stockpiles into a State or community, but it is actually getting the pill into the palm of the person that creates safety and security.

This is an issue not just with Tamiflu, but it is an issue in any of our stockpile remedies.

We are currently, exploring 5 different alternatives on how we can assure the distribution is done properly. One of them is to have stockpiles in local communities. Another is to provide for things, such as postal distribution of them. A third is to have first responders of some supply.

Mr. WALDEN. Are there some of those that could be presupplied out or preshipped out to individuals—

Mr. LEAVITT. Those are the alternatives we are looking at. And we want to find the best model because, frankly, I am not persuaded that the model of simply having stockpiles around the country will work because you have to get them there so quickly.

Mr. WALDEN. Here is my concern is that if a third of Americans are going to fall ill to this very, very—what could be a very dangerous and deadly disease, it may be that the entire supply lines for everything we have are disrupted, from food to medicine to medical care. What if a third of the people in the hospital, a third

of the doctors, third of the nurses, third of the fire fighters, are all dying from this flu bug? That is why I am so passionate about—I want to have command and control to the extent—thank you, Mr. Chairman.

Mr. BILIRAKIS. Ms. Capps to inquire.

Mrs. CAPPS. Thank you, Mr. Chairman.

Mr. Secretary, a few years ago, I was able to see the emergency response, though it was new at that time at HHS, and it was impressive in part because of the ability of the center to track how many beds there are at any given moment in every health facility around the country. But as I asked then Secretary Thompson, I was told that it isn't able or we are not able to gauge whether or not there is adequate staff at each of these health facilities around the country to respond to a crisis.

Now, as we prepare, assess our preparedness for a pandemic, I will ask you, how many of the health facilities that I know you can document have adequate staff to meet such a need?

Mr. LEAVITT. We actually had an opportunity to see that system tested with Katrina. We were very quickly able to identify many thousands of beds in that region, and we were able to track literally on a day-to-day basis how many of the beds were occupied and how many had capacity.

Our ability to track those—the staffing requirements for them was less exact, though it improved as time went on. We actually established a command center where we were able to deploy various components of volunteers from one place in the country to another to be able to assist in getting giving respite.

Mrs. CAPPS. Could I ask you the question then, are we adequately staffed to meet a pandemic at the various facilities now around the country?

Mr. LEAVITT. The difficulty in a pandemic is people would not be as anxious to go from one part of the country—

Mrs. CAPPS. Right. So I assume your answer is, no.

Mr. LEAVITT. Well, I think it would be different from one area to the other.

Mrs. CAPPS. And this is the fact that was made known by the American College of Healthcare Executives in October of 2004 when they reported that 72 percent of the hospitals in this country are experiencing a nursing shortage. I am using nurses as an example of health care workers, one of the largest numbers in any community. If we are even close to that number, we are a long way off from being prepared to respond.

Now, I want to talk about nursing recruitment and education. We are currently spending about \$150 million. I don't believe that is enough to address the shortage that we have to meet our needs today. Current funding levels fail to meet the growing need for nurses. In fiscal year 2004, HRSA was forced to turn away 82 percent of the applicants for the Nurse Education Loan Repayment Program and 98 percent of the applicants for the Nurse Scholarship Program due to lack of adequate funding within this part of our Federal Government. And in 1974, which was our last serious nursing shortage, Congress appropriated in today's dollars \$592 million, approximately four times what we are spending now.

It is not if we are going to have a pandemic; it is when. We don't know the particular strain, but we do know who we need to have in the front lines in every community to respond to this need. So I am asking if you would support a substantial increase in nurse education funding?

Mr. LEAVITT. The need for more nurses is well documented.

Mrs. CAPPS. Could you support an increase in funding?

Mr. LEAVITT. Well, in the context of large budgets, obviously, there is a need for more nurses. I am not in a position—

Mrs. CAPPS. But we have seen budget cuts in this particular area. Is that an adequate—is that the kind of response that our country needs to see from the Congress?

Mr. LEAVITT. Well, the need for more nurses is easily documented, and—

Mrs. CAPPS. And I am assuming that because it is well documented—this is one thing that is documented—that I can count on your support for increasing—I am saying now to the panel—

Mr. LEAVITT. Well, you can count on my enthusiasm—

Mrs. CAPPS. Enthusiasm and support are very different things.

Mr. LEAVITT. Obviously, we are dealing with specific budget proposals that will need to be made, and I am not in a position to say I will support—

Mrs. CAPPS. You do acknowledge that we have a shortage.

Mr. LEAVITT. I do.

Mrs. CAPPS. Thank you.

I have another topic that I would like to bring up. The President has submitted legislation that would give manufacturers of a pandemic flu vaccine liability protection. However, the administration has not supported any mechanism for meaningful compensation for people who are injured by the vaccine. The last time the President called for mass vaccinations—I know because I got one—was when the administration launched a smallpox immunization program. This program was an almost total failure. And I am generalizing from this experience to something we might expect in the future. The heroic first responders being asked to risk their health for their country were not being given any assurance that they or their families would be taken care of in the case of an adverse effect. They didn't sign up as a result, and they refused to be vaccinated. We can't afford to have that happen in a pandemic flu.

Given that so much less is known about a pandemic flu vaccine, the risks are even higher for our first responders—I am speaking now of the people who will man the health facilities around the country who would also be at risk of exposure. We clearly need to compensate first responders if they are harmed when doing what we ask of them.

And with regards to vaccine injuries, one effective model of compensation is the Vaccine Injury Compensation Program for Childhood Vaccines. This is something that exists. This is a no-fault approach which allows people injured by vaccines to receive compensation. I am asking, will this administration support a compensation program that gives fair compensation to people who may be injured by a pandemic flu vaccine?

Mr. LEAVITT. The proposal, as it currently exists, deals with the liability. I feel confident that the compensation issue will continue to be a matter of—

Mrs. CAPPS. Could I get—I think I also may be entitled to an extra minute I since I didn't give an opening statement.

Mr. DEAL [presiding]. He says you have already been given that.

Mrs. CAPPS. Well, I feel like this is very essential to moving any kind of program—if we are going to put a lot of money toward developing vaccines, we certainly must be thinking about the ways in which it is going to be delivered, and that includes not only liability to the companies that make it but also compensation for risks that are undertaken by those given it. And I would like to have a written response from you as to what we might expect from the administration. If this is a plan in process, this plan that you are here to explain, I certainly believe that one essential ingredient to it needs to be a compensation plan.

Mr. LEAVITT. Thank you.

Mr. DEAL. The gentlelady's time is expired.

Mr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman.

I thank, again, the Secretary and your colleagues for being here again today. This is a very tough, complex issue, and you know it better than anybody. And it is going to really require an enormous amount of work on all of our part. You have a huge responsibility. We have a responsibility to work with you on this, and I very much appreciate your and the administration's willingness to take this on because it is so crucially important.

If you will forgive me, I would like to use my time to make a few points. I do have a question when I get to the end of that, but I want to make several points that I think are important to make. And since we had limited opening statements, I just want to get a couple other things on the table.

Mr. LEAVITT. I will just sit back and enjoy it.

Mr. FERGUSON. Thank you, I hope you do.

Earlier, someone was asking you about the acceleration or development of the cell culture technology and how long it would take. You had said 3 to 5 years. That is the kind of timeline that we are dealing with. So, obviously, we are talking—the plan calls for making a lot of investments in the new technology to get vaccines in the pipeline, to get them available and to mass produce them as is going to be necessary. Given this extended time line that I think we are acknowledging is a part of developing a vaccine, the plan also calls for, I think, a billion dollars or a billion and a half, I think, for stockpiling of antivirals. We talked about Tamiflu. We talked about the role of antivirals. The plan that the administration put forward said that vaccines and antivirals, quote, have the potential to significantly reduce morbidity and mortality during a pandemic, unquote; and, quote, may also limit viral spread.

I think we all understand that there is no silver bullet in this. I think we all understand that Tamiflu has some limitations, as Dr. Fauci talked about before, but also something that everybody acknowledges, it is the best thing out there. Given some limited options, it is the best thing we have going for us right now. And when we are talking about 3 to 5 years of technology that is going to en-

able us get to a vaccine, and when we are talking about, you know, the pandemic plan states that vaccines and antivirals are going to be in short supply in the event of a pandemic, it states that a pandemic vaccine can only be made once that pandemic virus is identified. That could take 6 months or more. Assuming that the capacity for large-scale production of a vaccine is already available, it could take 6 months or more once the pandemic hits for us to develop the vaccine and then mass produce it. We are talking about a lot of lives, and I am not telling you anything you don't already know. It just seems to me antivirals are a crucial tool in preventing the spread of this virus and treating patients during the course of the pandemic.

I am sure—I would imagine you saw this op-ed in the Washington Post. It may have been yesterday. I know it was the last couple of days. Sebastian Mallaby—I don't know who this columnist is. I don't know his background or if it is a man or woman even. I don't know anything about this columnist. Maybe you do. And I am going to quote extensively from this column. It says, I quote, the United States has failed to get in line early. It has been weeks since panicky soccer dads began stockpiling Tamiflu, but the government has so far ordered enough of the drug and a similar medicine, Relenza, to cover just 1.5 percent of the population. Last week's Avian Flu blueprint from the Bush Administration belatedly proposed to procure treatment courses for 75 million Americans. Congress has yet to come up with the money, and the plan assumes that the State and local governments will contribute \$510 million to the procurement effort. The scope for argument and delay seems endless. Meanwhile, and indeed for the next several months, the United States will have no significant stockpiles of Tamiflu. If the Feds and the States resolve their burden sharing arguments quickly, the earliest conceivable point at which the Nation may have stockpiles equivalent to that of Britain or France appears to be mid 2007. In terms of getting access to Tamiflu, the United States has been a failure.

I want to get your response to that because I don't know—I want to know if that is fair. But also, very quickly, I want to say some have suggested, even today, I think my friend, Mr. Allen, suggested that just stealing the patent from a company is a good idea, as some other countries have suggested we do. Clearly, that may be a decent short-term solution, but it is a terrible long-term solution. It gives no incentive for anybody to research these problems and to look to the future. We are shooting ourselves in the foot if we are going to start stealing folks' patents in the interest of short-term public health. Clearly, if we have a long-term strategy, if we are using real forethought, we don't need to steal anybody's patents; we can work with the private sector to make sure that these great products that they are investing in and developing are available on a broad scale. So I would love to get your reaction to that, to be fair.

Mr. LEAVITT. First, those who have—some of our friends in other nations have ordered large stockpiles. They haven't got them. They have just ordered them. We are in a similar situation in that we started ordering Tamiflu before anybody. In December of 2003 and 2004, we started stockpiling it.

I have been assured by those who make it that we will have a sufficient supply of Tamiflu. This is a place where our rhetoric needs to inspire preparation and not panic.

Now, with respect to other antivirals, of the \$1.4 billion you see in this budget, \$400 million of it is for the development of new antivirals and improved antivirals that could be more specifically oriented at the virus we end up dealing with. No one is going to develop a new antiviral if they know that we are just going to take their patent and start producing it otherwise. That is a very important part of this, is maintaining the integrity of that intellectual property.

Mr. DEAL. The gentleman's time is expired.

Mr. Markey, I believe you wish to be recognized at this time.

Mr. MARKEY. Yes, thank you, Mr. Chairman.

First of all, Mr. Secretary, congratulations on the program, and it is a tremendous advance of where we have been. And I congratulate you for that.

Again, a couple of questions that were—you know, there are, in my opinion, some gaps. I remember in the 1950's how reluctant my mother was to have me take that first polio vaccine shot. And I remember the conversation she had with Sister Superior where Sister was assuring my mother that it was safe. And my mother said, how do you know, Sister. And she said, well, the experts tell me. And I am sure that conversation goes on all over the country, not so much for the nurses or the doctors, but for their children, you know, what impact will it have upon their kids.

So we have a situation here where there is already in place—and Mrs. Capps has already referred to it—a program for childhood vaccination compensation. This program would not have a compensation program for our children, for our families if something went wrong with the vaccination in terms of its impact on family members. And so while this other program is universally acclaimed as a success, the Child Vaccination Fund, here we are going to have a gap on something that is probably considered by parents to be even more problematic; that is, with the measles, the mumps and rubella, they probably figured, well, most of that has been worked out. They figured that out. Here is something that is going to be brand new.

So, Mr. Secretary, how can we work together to have a compensation fund here? Because I am afraid that you will have hundreds of thousands and maybe millions of parents who are going to say, I am going to wait for the first year or so for my kid because I don't want to run the risk. Can't we figure out some way of having a compensation fund so that the family will at least know that they will have something there to rely upon that will help their family toward something that they don't want to occur but would consider because the government was urging them to take this drug that didn't have the full FDA approval process?

Mr. LEAVITT. The proposal, as it is currently advanced, is for liability only.

Mr. MARKEY. Liability for the manufacturer.

Mr. LEAVITT. And your conversation and others make clear that the need for a compensation fund is a discussion that will continue and, I feel, will be an active conversation.

Mr. MARKEY. An active—I am sorry.

Mr. LEAVITT. An active——

Mr. MARKEY. An active conversation. And do you think it will bear fruit in the end in terms of putting together a fund?

Mr. LEAVITT. I know it will be a conversation that we will engage in, and we look forward to a conversation on it.

Mr. MARKEY. Well, I urge you, Mr. Secretary, just from my own personal family history. My mother was convinced that if every other kid in the school was inoculated, that there was no one from whom my brothers and I could catch it. And she made that point to Sister Superior, which was not welcomed, and she was essentially sitting in your chair to try and convince my mother, which she did, but reluctantly.

On the issue of Indonesia's 2-year lapse in notifying the WHO that the Avian Flu had already hit their country, it seems to me that it goes hand and glove with their membership in the World Trade Organization. That is, as we are trying to speed up trade, travel, tourism, which is an American interest, you also have these concomitant responsibilities on the part of these countries that then get the benefits of the World Trade Organization to realize that is how disease is going to be spread. And to hide it for a couple of years actually makes a mockery of the World Trade Organization membership.

So I was just wondering, Mr. Secretary, if we could talk about having penalties in the World Trade Organization that harm countries, that penalize countries who don't comply with WHO requirements, that they immediately notify that there is a pandemic disease that could affect other countries in the world. Do you believe that that kind of a linkage makes any sense?

Mr. LEAVITT. I have met with heads of state and with health ministers all over the world, and I know there is a great concern. And this is a matter of terrific priority. And I know the State Department is working directly in ways to assure through the partnership that there is cooperation and transparency.

I will tell you that that, having walked through wet markets and sat down on the edge of a bench with farmers in Southeast Asia, my biggest concern isn't what will happen at the national government level. My biggest worry is the cross pressures that are felt by farmers in small Southeast Asian countries who depend on it for their protein and their livelihood.

I mentioned earlier, one health minister told me that, last year, they had 14,000 deaths from rabies, something we don't ever see or rarely see, I should say, in the United States. I worry that that farmer, if he sees 4 or 5 dead chickens, isn't going to be nearly as concerned as that farmer needs to be, and our effort needs to be to create an ethic that goes very deep in those nations.

Mr. MARKEY. My only point is that the only way to create that ethic is to let the government know there is going to be an economic penalty at the World Trade Organization, and then they have higher incentives to make sure they have a more intrusive, enforceable regime within their own countries. And without that linkage, I am afraid too many countries will just turn a blind eye. But anyway, I thank you for your good work, and I thank all of the people who you are working with.

Mr. DEAL. The gentleman's time is expired.

Mr. Shadegg, you are next.

Mr. SHADEGG. Thank you, Mr. Chairman.

And welcome, Mr. Secretary. I would like to go over the numbers. I have actually gotten separate reports regarding the \$7.1 billion. From my understanding of your testimony here today, that being that this is a \$7.1 billion emergency appropriation, it is correct that we will be appropriating that entire amount this fiscal year; is that correct?

Mr. LEAVITT. You would be authorizing that amount this year and appropriating, yes.

Mr. SHADEGG. Authorizing and appropriating.

Mr. LEAVITT. It would actually be used in over 3 years, but you would be authorizing and appropriating it this year.

Mr. SHADEGG. So the authorization—

Mr. LEAVITT. You are appropriating this year.

Mr. SHADEGG. So we would be appropriating the \$7.1 billion this year. Can you explain to me, just because I need to communicate to my constituents, in the given fiscal climate we are in, why that full sum is needed this year if it is going to be spent over a period of 3 years?

Mr. LEAVITT. Congressman, we are asking vaccine manufacturers to step up with substantial capital of their own, to put substantial intellectual property on the table and to redirect many of their open priorities. They are simply not going to be willing to do that unless it is very clear that the United States government has skin in the game and is prepared to respond and can be counted on to respond. And the way that certainty is created is if we appropriate the money.

Mr. SHADEGG. And so what you are saying is that they will not do the research necessary or the production necessary to have these vaccines available if this money isn't put up in a single lump sum this year.

Mr. LEAVITT. It is my judgment that their investment will not be forthcoming unless ours is.

Mr. SHADEGG. How much of that is related to their concern about, if any, about future liability? That is to say, if they were assured that there were no liability at stake, that there was a plan or that people given this vaccine would be part of a compensation plan so that these manufacturers wouldn't be at risk, would that change the numbers at all?

Mr. LEAVITT. I have met with each of the manufactures individually, and then the President and I met with them collectively. Each of those conversations have made clear to me that there are three prerequisites to our success: The first is the liability component. They need to be relieved that their stockholders could be imperiled by rushing some kind of vaccine to market and then having to bear the financial burden of that, and there is good reason for their concern.

The second is, they need to know that there is a market for the product that is produced, not just this year but on an ongoing basis, because we are asking them to put capital up and intellectual property and to give up other opportunities. That is where our

work with the annual flu comes in, to be able to keep that capacity going.

And the third is, they need to have a streamlined regulatory environment in order to meet the deadlines that we are putting forward to create this vaccine fast enough. We can meet all three, but we need to meet all three if we are to meet our objectives.

Mr. SHADEGG. And the \$7.1 billion figure is simply one of the three, I take it? That is to say—

Mr. LEAVITT. That is right—

Mr. SHADEGG. The liability piece doesn't produce the number, to answer my question.

Mr. LEAVITT. It is essentially knowing there is a market for it and that the United States government is going to be there with certainty.

Mr. SHADEGG. Let me ask a separate question. I think that all Americans are concerned about the ability of the government—particularly the Federal Government—to step into these situations and solve the problems. Katrina, I think, demonstrated that. Certainly FEMA, as its currently structured, cannot succeed on its own. It requires the effort of State and local governments. And it requires them to have planned and been prepared to do their job so that if they are not prepared and if they have not put plans in place and if they don't have the proper personnel and the proper training in place, FEMA can't succeed on its own. Indeed, one would argue it is not equipped to do that mission.

What have you done or what are you doing kind of in layman's terms for me to give to my constituents to assure that in a worst-case scenario the preplanning has been done not just by Federal officials, but the initial steps toward coordination for State and local officials to do their jobs has been done?

Mr. LEAVITT. Within a matter of weeks, we will have in Washington the first of what will be many meetings with State and local officials to begin planning and coordinating the integration of these plans. That will include not just meetings in Washington, but we intend to take teams from CDC and NIH and from HHS into the States to say, here, let us help educate not just your public health officials—frankly, public health officials get this—it is being able to communicate to the county commissioner and to the city councilmen why this ought to be a priority, why they ought to be worried about preparedness and not just a swimming pool. Because until they understand why we are concerned about this, they are not likely to act. Part of that will need to be a template, saying, here is what a prepared community looks like, and here is a way that you can evaluate yourself so that a citizen in a local community can say, my government is prepared because they meet this criteria. That will take time to put into place, but it is clearly part of the plan and an essential part of the victory.

Mr. SHADEGG. I thank you and your colleagues.

My time is expired.

I actually have a comment. I think we have seen in these last hurricanes how some communities are prepared, and some aren't. I think in your planning, you need to think through whether or not you warn Members of Congress that their State and local officials aren't ready where you have detected, or you warn the local popu-

lation that their State and local officials aren't ready. Because in most instances, in these hurricanes, the State and local officials were ready, but sadly, in some other instances they weren't, with tragic consequences.

Mr. DEAL. The gentleman's time is expired.

We do have votes on the floor at this point, four I understand, and we will return as soon as those votes are completed, and we will complete the questioning by members at that time. So we will stand in recess pending the completion of the floor votes.

[Whereupon, at 12:35p.m., the committee recessed, to reconvene at 1:30 p.m., the same day.]

Mr. DEAL. The committee hearing will come back to order. We will have members, I am sure, who will return, but since we have some who are here who have not asked questions, we will proceed with them.

Mr. Gonzalez, I believe you would be next.

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

First of all, to Secretary Leavitt and Dr. Gerberding, I want to say thank you so much for coming to San Antonio during the time that we were welcoming the evacuees as a result of Hurricane Katrina. You all were absolutely wonderful. I know the community really, really appreciated it.

I want to start off by reading from the last page of, *The Great Influenza*: So the final lesson, a simple one yet one most difficult to execute, is that those who occupy positions of authority must lessen the panic that can alienate all within a society. Society cannot function if it is every man for himself, by definition civilization cannot survive that. Those in authority must retain the public's trust. The way to do that is to distort nothing, to put the best face on nothing, to try to manipulate no one. Lincoln said that first and best.

So the challenge is great for us, but we have great examples throughout history that we can follow. My question really is based on information that actually has appeared in editorial pages of the *San Antonio Express News* as well as from our metropolitan health director and so on. The first thing is the difference, of course—and I know this sounds so elementary, but to get it straight, obviously, if we are looking at vaccine, that is immunization. That is prevention. If we are looking at antiviral, that is treatment after the fact. What this plan proposes, my understanding, is from the time that there is an emergence—and let's just talk about the Avian Flu—an emergence of that, that within 6 months somewhere down the line—and I am going to piggy-back on what Mr. Ferguson stated earlier, it is a little different take on it—that within 6 months, we would be able to immunize. We would be able to vaccinate the entire population of the United States. And this is something that appeared in a recent column in the *San Antonio Express News*. And the interview was with our metropolitan health director. And I am just trying to understand how you produce and manufacture a vaccine. And it says vaccine production cannot begin until the mutant viral strain is isolated, and then it will take 6 to 9 months to conventionally produce the first vaccines. There may also be other complications to producing the tens of millions of doses needed. Just acquiring the chick embryos needed to produce the vaccines

needed will be a real challenge, the doctor observed, and then there is a good possibility that this virus could kill the embryos. Bird flu, after all, kills chickens.

And I was just thinking this in terms, logically speaking, your own interpretation of that, whether that is a valid concern that Dr. Guerra has there in San Antonio.

The second part of my question will go to—my understanding this whole plan, as important a role as you have, Mr. Secretary, and your department, really is going to be under the charge and responsibility of Homeland Security. And do you see any problems with that? And I know there are some strengths to it, but our experience with FEMA coming under the umbrella with Homeland Security has not been a good experience. And I am just wondering what your department, what you would be doing under the worst-case scenario, in other words, what are the minuses to that particular arrangement if, in fact, I am correct in assuming that this Department of Homeland Security will be first and foremost in charge?

Mr. LEAVITT. I will ask Dr. Fauci to answer the matter related to the vaccines, and then I will deal with the second question.

Mr. FAUCI. One of the advantages of a new technique called reverse genetics, which is the way we isolated and made the seed virus for the current H5N1 vaccine, is that you can actually selectively pull out the various genes that you want from the viruses so that you could make your vaccine, is that you can actually cut-off, molecularly, the component of the virus that would kill the eggs, the virulent component that would kill it.

So you might have a broader problem theoretically that viruses would kill all the chickens so you wouldn't have the chickens to lay the eggs, but once you have the eggs, you could cleave out that virulent part of the virus that would actually destroy your eggs.

Mr. LEAVITT. With respect to your second question, once a triggering event has occurred—and we define that in our doctrine in the plan as sustained person-to-person transmission of the disease—the National Response Plan will be triggered. Under the National Response Plan, the Secretary of Health and Human Services, under ESF-8, has responsibility for medical and public health issues, which would be the vast majority of the issues related to a pandemic. The Department of Homeland Security would then be the coordinator between HHS and other national departments—national government departments, that is to say, the Department of Transportation, Department of Defense, Department of State and so forth. They act as a coordinator, but quite specifically, under the National Response Plan, the Secretary of Health and Human Services has responsibility for public health and medical issues.

I will tell you that my biggest concern isn't the coordination among the Federal agencies, though I believe we have a long ways to go before we have perfected that. My biggest concern is the coordination between HHS and other Federal departments and State and local governments. Our plans need to be integrated. A pandemic unique to all natural disasters will need to be managed at the State and local level. You don't want the Secretary of Health and Human Services deciding whether the schools in San Antonio, Texas, are open. You don't want the Secretary of Health and

Human Services trying to make a decision on whether a parade ought to be held or not. Those are calls that the State and local officials need to make. That is the reason we will spend a lot of our time over the next several months meeting with State and local officials, connecting them with their own health departments. Because the health people get this, it is the need for us to energize the State and local officials to understand the nature of the planning that needs to occur at all levels in society.

Mr. GONZALEZ. Yes, sir.

Mr. DEAL. Secretary Leavitt needs to be out of here by 2 p.m., so the time is expired.

And if you don't mind, I am going to have to call the time, and we will try to try to move along so we can accommodate the schedule we promised we would try to adhere to.

Dr. Burgess, you would be next.

Mr. BURGESS. Thank you, Mr. Chairman.

And again, thank you all for being with us yet one more time this morning.

Mr. Secretary, as I understand, the cost—when the President talked about it a week ago today, that this cost will actually be over a 3-year timeframe, but the authorization, the appropriation Chairman Lewis introduced last night, will be for this fiscal year. Is there no money in the Bioshield project that we passed 2 years ago, or is there no money in HHS? Or Homeland Security to deal with an outbreak of illness, such as this, where those—the Chairman talked about offsetting funds; is there any opportunity there?

Mr. LEAVITT. I will ask Dr. Raub to answer that question specifically, and then I would like to comment on one point.

Dr. RAUB. On the Bioshield, you may recall the appropriation was laid out over a 10-year period, with a plan for various incremental availability of those funds over that time. The concern from the administration's perspective is we gave a very strong signal to the industry, especially those involved in developing drugs and vaccines and other medical countermeasures, that this was part of that certainty and stability for planning—

Mr. BURGESS. And I do understand that, I don't want to interrupt you, but time is short.

Dr. RAUB. And doing that prior commitment.

Mr. BURGESS. And I realize that we need to make the commitment to the manufacturers, but going forward over time, are there perhaps places where we can offset that?

And actually, if you don't mind, I am going to ask you to get back to us with a written response to that.

Mr. Secretary, let me ask you, too. We have talked a lot about Tamiflu and Relenza this morning, are there newer antivirals out there in the pipeline that may come into play in the next year, 2 or 3?

Mr. LEAVITT. Yes. And we have included \$400 million for their development to bring them to the point of manufacturer.

Mr. BURGESS. One of the older antivirals, Amantadine, which was introduced back in the 1980's, my understanding is that has been used extensively in bird populations to prevent an outbreak of influenza in bird populations. Is that one of the reasons that Amantadine is no longer useful as an antiviral for the H5N1 virus?

Mr. LEAVITT. The short answer is, yes. The long answer can come from Dr. Fauci.

Mr. BURGESS. But before we get to the long answer, let me ask a question. Is there a danger inherent in allowing other countries to produce the antivirals? If they are not produced to exacting standards, do we run the risk of creating viruses that then are more resistant to our stockpiles of antivirals?

Mr. LEAVITT. Short answer is uncertain. The long answer comes from Dr. Fauci.

Mr. BURGESS. Maybe we better have the long answer to that one.

Mr. FAUCI. I will give you the short answer to the long answer.

The fact is that the use of any antiviral like Amantadine in trying to prevent infections in chickens almost certainly contributed to the resistance of the H5N1 that we currently have to Amantadine or Ramantadine, not certainly the only factor, but certainly that is a well known factor that when you feed it to chickens, that is the first thing.

With regard to the resistance, there are evolving forms of the H5N1, and there are a couple of different subspecies, as it were, not all of which were resistant to Amantadine. But the reason for the Amantadine resistance that we saw in our hands for the H5N1 that we isolated was multifactorial. One important factor was that you gave it to the chickens inappropriately.

And when you make an antiviral, you are concerned, I believe, Dr. Burgess, if you make it by a company that doesn't make it very well, you may make a weakened form of it. That is certainly theoretically possible that if you don't have the right strength, for example, you could wind up undertreating and then selecting for resistance. That is not something that I would specifically worry about as my high priority, though.

Mr. BURGESS. In the pandemic plan, in chapter S-5 on page 7, we talked about the reverse transcriptase polymerase chain reaction for identifying the virus, but that only being available in State health departments and the CDC. I would like—it was referenced earlier today, and I would like Mr. Chairman to introduce this for the record, a newer rapid test that is now talked about, and just underscore that the quicker we can get this type of technology in people's hands who are in the field, I think that is going to be a big part of our overall preparedness.

I guess, Mr. Secretary, in the 10 seconds that are left, where can we get the maximum bang for our buck in liability reform in vaccines?

Mr. LEAVITT. I don't mean to waste your 10 seconds, but I'm not sure I understand your question.

Mr. BURGESS. Well, if we are going to go with liability reform or if we are going to include liability reform as part of this as we go forward, what type of liability reform do we need? Where would we get the maximum impact to get manufacturers of vaccines back in this country in a meaningful way?

Mr. LEAVITT. Well, we need to have a statutory—the capacity for the Secretary to provide a statutory shield to liability to the manufacturer.

Mr. DEAL. The gentleman's time is expired.

Mr. BURGESS. I thank the Chair for his indulgence.

Mr. DEAL. Mr. Stupak, you are next.

Mr. STUPAK. Thank you, Mr. Chairman. I thank the witnesses for being here today.

With the traditional flu, it seems like the victims are the young or the old or those with a low immune system. In the pandemic of 1918, the victims there were usually young people who were previously healthy. Have you developed what kind of attack is going to be—what subgroup of our population is going to be vulnerable to this H5N1 virus?

Mr. LEAVITT. Dr. Gerberding?

Ms. GERBERDING. It is not predictable. And what we have seen in Asia so far is that there is a disproportion affliction of young healthy people, but part of that is because those are the people who have the most contact with the sick chickens. And that is the primary mode of transmission right now. But you can't say for sure.

Mr. STUPAK. Okay. The H5N1 virus, when it hits, like other pandemics, it will come in waves, will it not? You will have the H5N1 virus, and then maybe a couple months later, you will get a new viral subtype that could come off from this; is that correct?

Mr. LEAVITT. Dr. Fauci.

Mr. FAUCI. Not necessarily. That is what happened in 1918. But as Dr. Gerberding said about lack of predictability, you really can't predict. You can have it in one blast or you can have—

Mr. STUPAK. Are we seeing any subtype yet?

Mr. FAUCI. There are more than one H5N1; it is evolving. If you look at the one we isolated a year and a half ago in 2004 and the one that is now spreading in some of the chicken flocks—

Mr. STUPAK. It is completely different.

Mr. FAUCI. Not completely different, but it is an evolved virus.

Mr. STUPAK. If there is going to be like these different waves, when we talked a lot about personal responsibility and being ready in 72 hours, that wouldn't really work if we are going to have wave after wave of this stuff coming through an area; is that correct?

Mr. LEAVITT. It is. As we study the pandemic of 1918, it is clear that there are waves, and it will affect different communities at different times, and it is possible that it would affect one community at a different time.

But in terms of the capacity for public health officials to manage in that community, it is likely that many communities could go through a period where those traditional public health tools would be used, one of which could be restriction of movement under certain circumstances.

Mr. STUPAK. Let me ask you this, it is my understanding your short-term strategy on the vaccine, it is the H5N1 vaccine; you are producing that now. And if I heard Dr. Fauci testify earlier—I thought you said that you don't know if it will work once it mutates from human to human; is that correct?

Mr. LEAVITT. We know that the virus will mutate. We know that means that the vaccine that we are creating now will not be of optimal effectiveness, but it will be the best we have, and it will allow us to give at least first responders—

Mr. STUPAK. So then I take it the vaccine we have now has been not been tested for efficacy but probably more for safety and only on small population groups.

Mr. LEAVITT. Dr. Fauci should respond to that.

Mr. FAUCI. Since there is no flu around that you can test it for its clinic efficacy, the parameter of efficacy is, if it induces an immune response, the characteristic of which would be predictive of protection, and the answer to the question then is, yes, it has induced an immune response that would be predictive of protection.

Mr. STUPAK. In what kind of a population? From children to older adults?

Mr. FAUCI. Right now—that is a good question. We tested it in healthy young adults less than 64 years old. We are currently testing it in individuals older than 65, and in December, we will start it in children.

Mr. STUPAK. What is the number of people you need to have a long-term study? Will it be based on number, or are you going to base it upon the vaccine and different strains you get out of it?

Mr. FAUCI. It is statistically significant—since this is considered by the FDA as a strain change with many of the characteristics of the seasonal flu that we look at every year, there are many similarities, the numbers that are in the trial now are about 450 per phase or stage of trial.

Mr. STUPAK. Mr. Secretary, you said your concern is liability, capacity and streamlined regulations. On liability, we already have a Vaccine Injury Compensation Fund; do we not?

Mr. LEAVITT. This is part of the ongoing conversation as to whether or not it is liability and compensation, and that is in fact an ongoing conversation.

Mr. STUPAK. But other vaccines, we put them under the Vaccine Injury Compensation Fund, why not this one? Why do we have to have some special deal? We didn't do it with Cipro when the Anthrax scare was here?

Mr. LEAVITT. You mean on liability?

Mr. STUPAK. Yes.

Mr. LEAVITT. Well, I think the idea is to provide in some fashion a capacity of the Secretary to grant that—

Mr. STUPAK. Why do you need it if we already have a compensation fund?

Mr. LEAVITT. Apparently, the statute does not extend far enough that I have the authority to do it, and it requires a statutory extension.

Mr. DEAL. The gentleman's time is expired.

Mrs. Blackburn, you are next.

Mrs. BLACKBURN. Thank you, Mr. Chairman. And thank you all for your time and for being here with us today.

I have got just a couple of questions that I wanted to kind of see where you were. In listening to your responses today from all of you, it seems like that if we were to have a pandemic, that one of the things that we will be addressed with is individuals figuring out if they have the Avian Flu or another flu and being able to decide who actually is infected and who is not. Therefore, you could separate your population if there was a quarantine needed or if you needed specific treatment in some way.

And I had read in your testimony where you said that 48 State and local public health departments had received the PCR training, real time PCR training to detect its H5N1-7 subtypes of flu; am I correct on that?

Mr. LEAVITT. Dr. Gerberding would be a better authority on that.

Ms. GERBERDING. We can give you the geographic distribution of the capabilities by laboratory response network laboratory, but in general, that is correct.

Mrs. BLACKBURN. But you have that testing—what I am trying to get at here is this: Do you have a test or a technology that can go in, that is going to be readily available that these individuals can administer and you can quickly divide your population as to who has the flu and who does not have the flu so that you know what universe of patients that you are dealing with? Do you have that technology or that test available, and are people instructed on how to use this and how to follow through?

Ms. GERBERDING. The clinicians and public health workers are including these specific issues in their plans; this is part of the guidance that is included in the department's plan that was put forward. But the short answer is, we do not need to rely on a specific H5 test in order to be able to do it under real live circumstances. Once we know we have H5 in the community, the decisions will be based on other grounds, not on a specific case-contact basis.

Mrs. BLACKBURN. Okay. So you are telling me you do not have a specific test.

Ms. GERBERDING. We do have a specific test, but we would not need to use it on a person-to-person basis.

Mrs. BLACKBURN. Okay. Just in identifying the community where the flu is present.

Ms. GERBERDING. There are many clinical situations where we would want to know specifically what we are dealing with, so it is hard to give you a concise answer. It is a very situational problem.

Mrs. BLACKBURN. Okay. Thank you.

Mr. Leavitt, I want to come back to the affordability of the plan. I know that the budget for HHS this year, your mandatory spending is \$584.4, and you have got \$67.9, and then next year we are approving \$672.5 billion, and your discretionary is \$67.1. In all this money, are you telling me you can't find a way to help divide this expense out and focus on a part of this? Because we have got \$2.8 billion for the cell culture technology, which I agree with you is a good thing to move forward on, but in all of your budget, can you not prioritize? Can your department not look for some savings and some efficiencies this year and next year and come up with this money so that we are not asking the taxpayer for another \$7 billion dollars? Frankly, my constituents have just about had it with the one more thing and the one more thing and the one more thing. I had a constituent say, instead of nickel and diming me to death, I feel like you guys are billion dollaring us to death. So are there savings there? Is there a way that you can afford this within your structure?

Mr. LEAVITT. As you pointed out, the great share of the HHS budget is tied up into programs that involve entitlements. The discretionary portion of our budget, which is around 10 percent of it,

is tied to other priorities that the Congress thought were of sufficient importance that they appropriated them. I recognize the tension that is involved here, particularly when you are moving forward with a substantial supplemental, and we are prepared to—

Mrs. BLACKBURN. So you have nowhere you can find a savings?

Mr. LEAVITT. Well, the President has proposed this as an emergency supplemental because he felt it was an emergency and because he believes, as I do, that it is necessary for us to make very clear to those that we are asking to put up complimentary capital and intellectual property and opportunity, that they have the certainty necessary to move forward.

Mrs. BLACKBURN. Thank you.

I yield back, Mr. Chairman.

Mr. DEAL. I thank the gentlelady.

Ms. Schakowsky is next.

Ms. SCHAKOWSKY. Thank you. Let me just say that my constituents are concerned about expenditures, too, but they ask me about the \$6 billion a month we are spending in Iraq and the \$70 billion in this budget that goes for tax breaks largely for people who don't need it. And just for the record, so you know, they want to be protected from the flu and don't think that these kinds of health care expenditures are out of line.

I have a couple of areas of questioning. I want to just associate myself with some of the concerns that were raised about State and local funding and the expectations for the States and localities and the lack of resources. I don't want to go further than that, just to say that I agree with those concerns.

I wanted to ask about the liability protection. My understanding is that it is—the concern is that there won't be enough—that the shortage in part is because there is not liability protection; just a yes or no, is that—

Mr. LEAVITT. Yes.

Ms. SCHAKOWSKY. Well, I just wanted to say that—just give a couple—Dr. Ornstein, who was for 12 years head of the vaccine programs at Centers for Disease Control said liability was never the issue. I have not seen liability as a major problem with the flu supply to date. The National Vaccine Advisory Committee determined the shortage did not come about because of liability concerns. I don't want to get you in trouble, Dr. Fauci, but there is a quote that says, it is only a very small part of the problem, and even Pharma played down the lawsuit issue for the flu vaccine.

But my understanding is that this bill does not limit its application only to new vaccines used in pandemic context or even a bio-terrorist context. The bill's provision provides that any drug, device or biological product used to, quote, diagnose, mitigate, prevent or treat a potential pandemic may qualify for protection. And then it doesn't stop there. I understand the bill also applies to any existing device, drug or biological product used, quote, to diagnose, mitigate, prevent or treat a side effect of another vaccine. So would that mean, for example, that if Tamiflu qualifies for protection under the bill because it is a potential treatment for the Avian Flu, and an individual takes a pain reliever like, say, Vioxx to treat serious side effects caused by Tamiflu, that both Tamiflu and Vioxx would be protected under the bill?

Mr. LEAVITT. Actually, that is a legal interpretation that I am not prepared to make. But I do think it is important to suggest that your constituent would not want the legal liability issue to stand in the way of being able to have a treatment, and that is what this is about.

Ms. SCHAKOWSKY. But you are suggesting that it would stand in the way of a treatment. And what I wanted to say was that the experts in the field are saying that liability protection is actually a small part and that, in fact, a much larger part has been the low profit margins that vaccines provide, unpredictable demand and complexities of the manufacturing process, all those things which I can understand that we need to deal with. But this is a small part. There were questions before about what happens to first responders, for example, who take the drug. This is a concern, too. And we saw, as Representative Capps said, they didn't want to take the smallpox vaccine, and it is just interesting to me that there was such a rush to protect manufacturers here, and millions of people who could be affected on the other end are not even considered at all, especially when there is so little evidence, it seems to me, that this is the problem that is causing a shortage.

Mr. LEAVITT. The proposal is put forward to provide a capacity to manufacture vaccines. Now I have met with all of the vaccine manufacturers directly and personally. I met with them as a group with the President. And they have made it abundantly clear that they are not able to step forward to do this without protection from liability. And they have reason to feel that way. If you look back over the previous times where we have done this, it is clear that there is risk, if you—

Ms. SCHAKOWSKY. Let me ask one other—I know that is your position, but let me ask one other area that I am very concerned about, and that is the issue of how much we are spending on international surveillance. And the New York Times said only \$251 million, a tiny fraction, would be used to help foreign nations improve their ability to detect and control flu outbreaks.

It does seem like, if we stop there or help to contain it there, before it comes here, that that makes sense, and out of \$7.1 billion, that seems like a small amount. I wonder if you would comment on that.

Mr. LEAVITT. The system needs to be enhanced. We have a substantial presence already, particularly in Southeast Asia. The world is a big place, and there are substantial parts of the world we know nothing about. We know nothing about what is going on in North Korea. Burma is another example where the conditions are similar to what is going on in any one of the Southeast Asian countries. And we have essentially no contact there. So there are limits in our capacity to develop surveillance, even though we do need to enhance it.

Ms. SCHAKOWSKY. I would hope Romania, Indonesia, Vietnam, places we do have relationships with. Thank you.

Mr. DEAL. Ms. Baldwin would be next.

Mr. Secretary, if you are at the point that you need to leave, we will certainly understand. If the other members could stay, perhaps we can complete the hearing with their presence.

Mr. LEAVITT. I will stay as long as I can. I think I have another 5 minutes.

Mr. DEAL. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

A couple of very quick questions, and then a broader question. We had lots of questions that have gotten at this, but I am not sure it has been asked this directly, so let me do so. Is it the operating assumption, Mr. Secretary, that in the event of a pandemic, if we don't manufacture the vaccines or the treatments, the antivirals here in the United States, that those treatments and vaccines will not be available to us?

Mr. LEAVITT. Yes.

Ms. BALDWIN. Okay, I just wanted to get that on the record.

A couple other quick questions.

Does anyone—do you know what the over-the-counter cost for a full dose of Tamiflu would be today? And second, in your negotiations with vendors, what sort of cost savings have you realized in those negotiations?

Mr. LEAVITT. I do not know the so-called rack price. It has fluctuated with supply and demand. We are realizing, in our negotiations with them, substantial savings, and it will depend entirely on the size of the order we ultimately place.

One of the conversations we have had in this hearing and in others is, why are we not ordering large volumes? We have to have an appropriation in our hand under the rules of procurement in order to do that. Now, other nations, who have no more Tamiflu than we do, they have been able to place orders because they don't have that procurement restriction; we do. And that is one of the reasons we are here asking that an appropriation be made so that we can both get our order in and try to advance ourselves in that queue. The bigger the order, the more muscular you can afford to be in terms of how you position yourself in the market.

Ms. BALDWIN. And I appreciate that from your earlier testimony, and I know many are very anxious to have an order placed because, obviously, they are not manufacturing it until we do so.

You had talked earlier under questioning about, I think, the figure of around 50 million doses of Tamiflu. What sort of price would you be able to achieve if that was the order that was placed?

Mr. LEAVITT. Well, I would only be speculating because we are in the process of negotiating, and it would be inappropriate for me to guess.

Ms. BALDWIN. Well, I know the company has been forthcoming about some of those figures—

Mr. LEAVITT. Well, I would be anxious to see that.

Ms. BALDWIN. The broader questions I wanted to pose really deal with the parallel epidemic of fear and panic that typically accompany something like what we are describing. And I would argue that, even today, there is significant public anxiety about the Avian Flu, particularly as we discuss it in a very open manner. It is hard to turn on the television without seeing stories about this. And there have been stories about members of the public beginning to stockpile their own Tamiflu, if you will. I would like to really hear you describe a little bit more about the administration's strategy for dealing with fear, with panic, the sort of steps that we can take

now. And I reflect that lots of irrational behavior occurred around the AIDS epidemic when it began 2 decades ago in the early 1980's; when the Anthrax attacks in our country created a lot of panic, fear and irrational behavior. So I am wondering if you could elaborate on what assumptions you are making about public reaction to news of an outbreak in the U.S., whether you have done any sort of modelling? What other agencies are involved in that type of planning? What is your proactive public education strategy? I know you have launched the pandemicflu.gov website, but what other outreach are you doing with the media, who will probably be some of the first points of contact for average citizens? And also, getting down to the grassroots, your ability to inform and educate nonhealthcare professionals in local organizations, local government.

Mr. LEAVITT. I will comment generally, and I will ask Dr. Raub and Dr. Gerberding to supplement.

The first principle is that it will happen instantly. Once there is news of a person-to-person transmittable event, there will be broad concern.

The second principle is that it needs to be rooted in good information. Mr. Gonzalez read from the book, *The Great Influenza*, and one of the lessons I took from that in my numerous readings was that people just need to know the truth. We need to tell it as it is. We need to tell the truth as we know it, and let people draw conclusions.

Now the whole foundation needs to be a desire to—an aspiration to communicate. We need to inform but not inflame; we need to inspire preparation, not panic. And that comes primarily with good information.

Now Dr. Raub and Dr. Gerberding can talk to you a little bit about the specifics. We are going into great detail, having materials prepared, things ready so that they can be deployed at the moment they are needed and not having to do it in the 2 or 3 days after an event.

Ms. GERBERDING. From the beginning of the preparedness grant investments that followed Anthrax, we have recognized how critical communication was to our success, and CDC has a program called the Emergency Risk Communication Curriculum that is available online to anyone who wants to learn it. It is a beautiful curriculum. And we have trained public information officers all over the country so that they can support their Governors and their mayors.

We are doing the kinds of research that you have recommended with focus groups. Just on my BlackBerry I have something from a Gallup poll that we commissioned just to understand what people are thinking about pandemic flu right now today. What are their fears? What is their knowledge? What are their confusions? And the Secretary said absolutely the most important thing, which is to tell the truth and to get them information out there, what we know, what we don't know, what we are doing about it.

My experience has been, with Anthrax and SARS and a few other public health threats in the last couple of years, that while there are some people who will panic or who will find it difficult to do what we would like them to do, generally people behave re-

markably rationally if they trust the credibility of the communications support that they have.

The single most important and desired communicator about a health threat is not us at this table; it is the clinician that the person already trusts. So we are specifically working on projects with the AMA and other organizations to help the clinician at the local level really be the broker of information and reassurance and advice to people at the front lines of this program.

Mr. DEAL. I better cut it off at that point.

Mr. Inslee, you are next.

Mr. INSLEE. Thank you. I wanted to ask about the preemptive strike we could maybe try to strike against Avian Flu itself, since that is the source potentially of this problem.

There are some new technologies that at least three companies are looking at for an airborne detection system of single viruses to be used to try to detect this so it can be eliminated in these flocks: Research International, they are a Washington company; Miso Systems in New Mexico; Smith Detection. In Maryland, I think Research International actually has a system that can find a single bacteria and believe it is capable of having one ultimately to have a single virus.

Could you comment on those efforts? What we are doing to promote those, whether you think it is a viable strategy and what we can do to advance that?

Mr. LEAVITT. I will ask Dr. Raub to comment; he will be more conversant.

Dr. RAUB. I believe, as Dr. Gerberding indicated before, there is a continuing interest on our part in newer and better and more rapid diagnostic methods, and certainly the ones you are describing fall in that category. In this particular case, there is an equally strong interest in the Department of Agriculture, as with us, because much of the surveillance of the animal stock, especially chickens, would be with the USDA. There is also interest in the Department of the Interior, the Fish and Wildlife Service are the ones that track what happens in the migratory bird populations and the like. So there is a potential significant use of this kind of methodology, and we are interested in seeing it—

Mr. INSLEE. Does the plan have a number attached to it for the development of that technology?

Dr. RAUB. No, sir, it doesn't.

Mr. INSLEE. Shouldn't it?

Dr. RAUB. In this particular case, because of the emergency nature of the supplemental, we focused on the vaccine and the drugs, but the regular appropriation process includes continuing investment in development of diagnostic methods, but it is just not in this particular budget.

Mr. INSLEE. Well, I encourage all of us to try to figure out whatever the fastest procedural way to get that investment made. For a very small investment, it seems to me to be an appropriate thing for us to do about what could be a significant threat. And I hope to work with you in that effort. If it is not in the supplemental, which I would like it in, I hope that you could support an effort ultimately to get it somewhere.

Let me ask you about this issue of what households can do. We have had a little interchange about what you can do individually to protect yourself and the like. And I don't want to belittle the importance for household protection, having 3 days supply of water, food, radio for earthquakes, storms, whatever; all of us need that even if the flu never takes off. But I would suspect and some were arguing that that would sort of replace a very vigorous Federal response to this, both on a proactive and a response mechanism. And by saying that, I want to appreciate the President's trying to alert the Nation to this potential situation and at least proposing one possible response to it because I think this is a very significant threat. And I just want to make sure that we are on the same page, that we are not expecting an individual response to this to diminish in any way what should be our Federal responsibility.

Mr. LEAVITT. I would like to assure you we are not. I will tell you my biggest concern is that all that has been said about the Federal plan will be viewed by State and local communities as we have got it covered. Well, no one has got this covered on their own. This is going to require every element. A virus is a network enemy, and it requires a network response. If we use a mainframe response, to borrow a computer term, to try to compete with a network enemy, we lose. A network trumps a mainframe. And that means Federal—and by that, I mean to imply every department of the Federal Government. It includes State and local governments integrated with the Federal plan. It includes communities. It also—and by that, I mean to imply corporate interests as well as non-profit interests, and it also includes, in my mind, individuals. Now no part of that network can stand alone, and no part of the network can stand without the other part.

Mr. INSLEE. I appreciate that comment, particularly with regard to the county local public health services. I think in my opening comment I noted that they have been substantially degraded over the last several decades. And I hope that you will be alert, as the budget cycle goes through, to ways we can beef up their infrastructure, not just to the flu problem, but some of the others as well.

And I have to tell you, I am very concerned that we are going into this risk with a local infrastructure which has been so oriented toward the real terrorism threat that it has diminished our local response to this potential threat. We looked at sort of an earthquake response in Washington; about 90 percent of the Federal dollars are now to terrorism rather than earthquakes. And I just hope that you are vocal on the need for local infrastructure, the nurses on duty, the communications system on duty, the epidemiologists on duty ready to go, because it will be too late once it happens.

Mr. LEAVITT. Mr. Chairman, I see the light is on, but can I respond to that?

Mr. DEAL. Surely.

Mr. LEAVITT. At some point, we will look back on this period, and H5N1 will have either triggered a pandemic or it will not. What are the chances it will? I don't know. There are clearly warning signs that we are appropriately responding, I believe, to. But there is a pretty good possibility that it won't. At that point, people are going to say, oh, they overreacted or they may say they were out crying wolf. That will not be the case. Because I believe whether

H5N1 is the triggering point for the—the triggering virus for a pandemic or not, through the implementation of this plan, we have an opportunity to become a safer and better prepared nation. We will leave this period with new cell-based technology that will save millions of lives. We will leave this period with the annual flu—with the capacity to manufacture an annual flu virus that will save tens of thousands of lives every year. We will leave this period with improved preparation among State and local governments. We will leave this period having an international surveillance system that will allow us to better identify disease wherever it is in the world. We will leave this period with the piece of mind knowing, whenever a pandemic comes, that we are prepared. So I pray that H5N1 isn't the virus. If it is, we will deal with it in the best way we can according to the preparation we have achieved. If it doesn't, let us all look back on this period as the time we made America a better and safer place.

Mr. INSLEE. And we will leave with an airborne virus detection system. Thanks very much.

Mr. DEAL. Mr. Engel, you are next.

Mr. ENGEL. Thank you, Mr. Chairman.

And Mr. Secretary, and the other witnesses thank you for staying and listening to all our questions.

I just want to make a very brief comment which you don't need to comment on, but I say this a lot because I feel so deeply about it. I know that there is State matching, and some of my colleagues have wondered about how the States are going to be able to do this. The Medicaid program is costly, and the Federal match ranges from 50 to 77 percent, and States are only going to receive a 25 percent match a year. And again, I just want to say that our orientation, the administration's orientation, which I think is very wrong, in stressing tax cuts again and again and again over moneys for programs that are important is really wrong. And while I appreciate that there is a lot of Federal money going into this program and I don't denigrate it at all, I think, again, we are going to be asking the States to incur a greater burden, and that would not have been the case if we weren't robbed of our ability to fund good programs because of the tax cuts for the wealthy. I just think it is a wrong orientation. You don't have to comment on that, but I need to say that.

There are a lot of questions that have been asked, and I want to ask you a question a little bit down the line. I know that, every year, of course, we get our flu shots, and we are told that there is guessing in terms of which shots, what to put into the flu shot. I am wondering if, down the line, since you are saying that the emphasis has to be on the pandemic flu, which I agree, what happens down the line a year or 2 down the line with the regular other vaccines? Are we—because we are concentrating so much on the pandemic flu, what will happen to our concentration on the others? 36,000 Americans die average per year from complications of the other flu, and I am just wondering how you integrate the two.

Mr. LEAVITT. One of the real opportunities for gain in terms of our public health infrastructure is the capacity to have sufficient vaccine manufacturing capability that virtually all Americans would have access to an annual flu vaccine. That will be—I don't

even want to call it a byproduct because it is a fundamental objective of this plan to enhance that capability, and it is a necessary part because if we have the need or the capacity to surge for a pandemic, we have to keep that capacity warm, or in other words, keep it active and maintained. And we will use that capability to substantially improve the number of people in this country who get an annual flu vaccine.

Mr. ENGEL. So what you are saying is that resources, essentially, you don't foresee resources being targeted away from the others as well?

Mr. LEAVITT. In fact, dual purpose. By creating a pandemic capacity, we automatically create the capacity to enrich our delivery ability on annual flu.

Mr. ENGEL. All right. Well, thank you. I know you have been very patient. And let me just comment on something that you mentioned to the previous question; I couldn't agree with you more. If it should come to pass that the epidemic is not as great as it may be and people will say that you and others were crying wolf, I think if we are going to make an error—which wouldn't really be an error—we would err on the side of caution. And I don't think that any American believes that if this doesn't happen, that we expended time or effort and energy on it. And I know you have been working very hard on it, and I want to personally thank you.

Mr. LEAVITT. We should all remember how the parable of the boy who cried wolf turned out; the wolf came.

Mr. ENGEL. Thank you, Mr. Secretary.

Mr. DEAL. Well, thank you.

And Secretary Leavitt, we thank you for your presence here.

And Dr. Gerberding, Dr. Fauci, and Dr. Raub, thank you all for being here and for your patience during this hearing. I think it has been really a very effective hearing and one that exposed a lot of questions and answers that all of us need to have exposure to. Thank you all very much. The hearing is adjourned.

[Whereupon, at 2:18 p.m., the committee was adjourned.]

