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H1N1 PREPAREDNESS: AN OVERVIEW OF VACCINE PRODUCTION AND  
DISTRIBUTION

WEDNESDAY, NOVEMBER 18, 2009

House of Representatives,  
Subcommittee on Health,

Joint with

Subcommittee on Oversight and Investigations,  
Committee on Energy and Commerce  
Washington, D.C.

The subcommittees met, pursuant to call, at 10:07 a.m., in Room 2123, Rayburn House Office Building, Hon. Frank Pallone, Jr., [chairman of the Subcommittee on Health] presiding.

Present: Representatives Waxman, Dingell, Pallone, Eshoo, Stupak, Engel, Green, DeGette, Doyle, Harman, Schakowsky, Gonzalez, Baldwin, Ross, Weiner, Matheson, Barrow, Christensen, Castor, Sarbanes, Murphy of Connecticut, Space, Sutton, Braley, Whitfield, Shimkus, Blunt, Buyer, Pitts, Walden, Sullivan, Murphy of Pennsylvania, Burgess, Blackburn, and Gingrey.

Staff Present: Kristin Amerling, Chief Counsel; Bruce Wolpe, Senior Advisor; Karen Nelson, Deputy Committee Staff Director for Health; Ruth Katz, Chief Public Health Counsel; Sarah Despres, Counsel; Stephen Cha, Professional Staff Member; Allison Corr, Special Assistant; Mike Gordon, Chief Investigative Counsel; Dave Leviss, Chief Oversight Counsel; Erika Smith, Professional Staff Member; Ali Neubauer, Special Assistant; Karen Lightfoot, Communications Director, Senior Policy Advisor; David Kohn, Press Secretary; Jen Berenholz, Deputy Clerk; Matt Eisenberg, Staff Assistant; Alan Slobodin, Minority Chief Counsel, Oversight; Ryan Long, Minority Chief Counsel, Health, Aarti Shah, Minority Counsel, Health; Karen Christian, Minority Counsel, Oversight; and Kevin Kohl, Research Analyst.

Mr. Pallone. The meeting will come to order.

Today we are having a joint hearing of the Health Subcommittee and the Oversight and Investigations Subcommittee, and the hearing is titled H1N1 Preparedness, an Update of Vaccine Production and Distribution.

We are going to begin with opening statements from the members of the subcommittees. The chairman and ranking members of the two subcommittees will be recognized first for a 5 minute opening statement, followed by 5 minute statements by the Chairman and ranking member of the full committee and the Chairman Emeritus. Other members of the subcommittees will then be recognized for 2 minute opening statements. I am going to begin by recognizing myself.

Let me explain that the purpose of this hearing is to get an update from the main stakeholders involved in the manufacturing and distribution of the H1N1 vaccine and to shed some light on where we currently are in the process and what we can expect moving forward.

The most recent estimates from the Centers For Disease Control are truly alarming. Over the past 6 months, it is likely that 22 million people in our country have been infected with the disease and about 98,000 have been hospitalized. To date, it is estimated that 3,900 individuals have lost their lives to H1N1.

Unlike regular flu that affects predominately the elderly

population, the vast majority of H1N1 deaths have occurred in people between the ages of 18 to 64. Even more tragically, the CDC estimates that 540 of these deaths have occurred in children. These numbers are significantly higher than earlier estimates, and as we move further into flu season, we can only expect to see them increase even more.

We now know that this virus and vaccine is unlike flu vaccines that we have produced before in it is extremely difficult to grow. Early estimates on vaccine amounts were based on how vaccines usually behaved in the production phases. Unbeknownst to anyone involved in this process, H1N1 proved to be very different, and though the manufacturers have been able to speed the growth of the vaccine by selecting the fastest growing strains, we still are lagging behind where we originally thought we would be with our production numbers.

Fortunately though, this particular vaccine appears to be highly effective in creating an immune response in individuals, and for adults, one small dose of the vaccine will produce enough of a response to protect from H1N1. But these early delays in production are now rearing their ugly head as our country watches the disease spread and take lives while vaccine is still hard to come by.

To date, nearly 42 million doses are available for distribution, which is about half of what we originally expected to have by this time. It is no wonder therefore that story after

story in the papers and on the news highlights the frustration that the American people are facing in trying to get the vaccine that will protect them from the disease. We hear accounts of individuals waiting in line for hours at clinics, some cannot find clinics in their neighborhood at all, and areas are still waiting to receive even the first doses of the vaccine.

There is a school district in my hometown, for example, that is yet to receive the vaccine, and understandably the parents are irritated. And this frustration is exacerbated by accounts of places in the country that seem to have more than enough vaccine in some areas, where getting this vital production from H1N1 poses no difficulty at all. So we are getting a lot of disparities from one place to the next, and, naturally, people are confused and they are angry.

So that is why myself and Chairman Stupak are holding this hearing today. I personally would like to better understand how the production of vaccine is going; when, for example, we will be able to expect enough vaccine so that all individuals who want it can get it; and will this happen before flu season is over.

I would also like to understand more about the distribution process. I understand that the States make their own distribution plans and do the ordering for their States through the CDC. But how are these plans created and how do States make the determination where to start with vaccine distribution and which distributors to prioritize?

We have a number of very important individuals with us today who have been working around the clock on these issues, and I would like to welcome you all. We appreciate your taking the time to provide us with this update today.

We understand how difficult this process has been. We are not here to beat you up, but we are here to try to get some answers, and particularly where we go from here.

With that, I would like to let me just thank again Bart Stupak, Chairman Stupak, for working with me to put this hearing together.

I guess we are going to go to Mr. Walden at this point for an opening statement.

Mr. Walden. Thank you very much, Mr. Chairman, and thank you for convening this important hearing.

H1N1 has been dominating the news and parents and the general public's concern for the last couple of months, as we all know. I am hopeful this joint subcommittee hearing can help answer questions and discuss solutions to the challenges arising from the first flu pandemic in 40 years.

As many of you, I have firsthand experience with H1N1. I think I was probably the first Member of Congress to go on record as being diagnosed as likely having H1N1. I had not been vaccinated, because, like the majority of my fellow Members of Congress, I don't fall into the CDC's priority groups. And like millions of other people across the country who have had H1N1, I

felt rotten for a few days. It is not something you want and it is not something you want to pass on to others. But I did follow my doctor's advice and the CDC's directions and stayed home here in D.C. to rest for at least 2 days after my fever broke, which is what I was told to do. Luckily, I was fortunate and recovered quickly.

Others have not been so fortunate. Last week, we learned that approximately 4,000 people, 540 of them children, have died from H1N1. The fact that this flu hit young children so hard and the constant news reports about rising pediatric deaths have scared the daylights out of parents.

You see this fear played out in the number of parents lining up with their small children at public vaccination clinics for hours at a time and flooding their pediatricians' offices with phone calls trying to hunt down the vaccine.

From the folks I hear from in my district, they can't find the vaccines. Based on statements made by HHS and CDC, parents had counted on being able to vaccinate their children by October or November. Originally CDC projected 40 million doses would be available by the end of October. Ultimately, only 23 million doses were available. Instead, parents hear reports every day on the news about rising pediatric deaths and vaccine shortages and delays. Some wait in line for hours, only to be told when they get there, there is no vaccine left.

Today, I hope we can get some concrete answers about when the

vaccine will be available. I also want to hear from HHS and the vaccine manufacturers about the reasons for the delay and what can be done now in and in the future.

HHS Secretary Sebelius was before the full Energy and Commerce committee on September 15th, and at that time she testified by mid-October a "large-scale campaign" for vaccinations would be underway. She also stated repeatedly that there would be "enough vaccine for everyone." Secretary Sebelius now says the vaccine manufacturers painted an overly rosy picture of their production. Is that the case, or is the virus seed not performing as expected?

I don't think finger pointing exercises are particularly helpful at a time when we are facing one of the biggest public health issues in recent years and a somewhat panicked public. But there have been repercussions, no doubt about it.

I also want to learn about how HHS has assisted States and local health departments in preparing for this pandemic. For example, in my district, hospitals are implementing their incident command plans due to emergency rooms being hit with waves of patients with flu-like systems. These spikes of patients are coming at a time when doctors, nurses and hospital staff are either homesick with the flu or taking care of their children that are home from school because of the flu.

So we are looking at a situation of increased patient volume and decreased staff capacity. Hospital administrators are

monitoring staff levels and patient volumes in some cases on an hourly bases so if they reach a tipping point, the hospitals can cancel elective surgeries to ensure there is adequate staffing to care for patients in the emergency room and those admitted to the hospital.

When I called the 18 hospitals in my district, each one of them asked, where is the vaccine that we were told was coming? So let's get the facts on the table about the reasons for the delay and when HHS knew about it; if there were production issues, how can they be corrected; and if there are communication issues between the manufacturers and HHS and HHS and the public, how they can be fixed so parents are not unnecessarily confused?

When the administration promised enough vaccine for everyone, the people want to know that it is coming. I am very interested to hear from Dr. Lurie and Dr. Schuchat about what direction HHS and CDC have given hospitals in how to prevent this confusion in the future.

So I hope this isn't the last hearing we have on this issue. This is the first pandemic in 40 years and the first since Congress began providing funding starting in 2006 for pandemic preparedness. At that time, we were deeply concerned about the possibility of a pandemic spreading a bird flu that could be 40 percent in mortality. Fortunately, this one has not proven to be as deadly. I believe Congress has appropriated \$13 billion for this effort. This is an area where we need continued oversight so

we can figure out what worked, what didn't, and what we should do going forward.

So I am particularly interested in the technologies for vaccine production and whether we can do better in the future. I understand that one of the manufacturers, MedImmune, has been able to meet its delivery schedule, in part due to the different kind of technology that company uses to make a live attenuated vaccine. Even though MedImmune grows the virus in chicken eggs, which is uncertain and unpredictable in yielding a sufficient supply, they have received better results.

I know that as part of its pandemic preparedness planning, HHS has awarded contracts to companies to look into cell-based vaccine production, as well as other ways to improve yields and production times. So I would like to know about the status of these efforts and whether we are doing enough to ensure that we are prepared for a pandemic influenza.

I welcome the witnesses and look forward to discussing these important public health issues with them. Thank you for your testimony.

Thank you for the hearing, Mr. Chairman.

Mr. Pallone. Thank you, Mr. Walden.

Chairman Stupak.

Mr. Stupak. Thank you, Mr. Chairman, and thanks for working with me and our O&I staff in putting together this hearing. I look forward to doing this joint hearing today. I think we have a

good hearing lined up. As you said, we are not here to point fingers but try to find out how we can do things better in the future.

Today, we continue our committee's oversight of the 2009 pandemic H1N1 flu by examining more closely the production and distribution of H1N1 vaccine. This will be the third hearing the Energy and Commerce committee held this year on the H1N1 influenza.

According to the Center For Disease Control and Prevention, as of November 13th, 2009, influenza activity was widespread in 46 States, almost all which was likely H1N1 influenza. There have been 22 million infections, 9,800 hospitalizations, and 3,900 deaths from the H1N1 virus, 540 of which have been confirmed pediatric deaths. This is a conservative figure, because not every child who dies from flu-related causes has been diagnosed with the flu. To date, there have been more pediatric deaths from the H1N1 than usually occurs in the entire annual flu season.

In September, Secretary Sebelius testified before the Energy and Commerce Committee indicating that by mid-October, the U.S. Department of Health and Human Services would be up and running with vaccines. In fact, CDC had projected that 40 million doses of H1N1 vaccine would be on hand by October 13th, but not even 13 million doses had arrived by October 22nd.

News reports have indicated that because of shortages in vaccines, doctors were dealing with worried and panicked parents

who wished to have their children vaccinated while State and local health care departments are experiencing long lines that can produce up to 5 hour waits for parents, children, pregnant women and seniors.

There have also been news reports indicating that private businesses, such as J.P. Morgan and Goldman Sachs, have been receiving the vaccines before individuals in the high risk category. And let's not forget about the reports citing military officials saying terrorists subjects being held at Guantanamo Bay would receive the vaccine before most Americans.

Like many districts around the country, my own district in northern Michigan has been affected by the H1N1 in a variety of ways. Since the outbreak began, Michigan has had over 500 schools shut down because 25 percent or more of their student bodies were absent with flu-like symptoms. Since September 1st, 1,226 people have been hospitalized in Michigan with flu-like symptoms, a 35 percent increase over last week, when 801 cases were reported.

The Oversight Investigation Subcommittee, along with the Health Subcommittee, have a responsibility not to merely rely on media accounts, but to get to the bottom of the situation. While we are not here to point fingers at who is to blame for the delay in the production and distribution of vaccines, we do need to shed some light on the process between the government and the manufacturers.

Given the urgency of the circumstances and the need for

expeditious action, cooperation between drug manufacturers and Federal agencies is imperative to ensure that our country is prepared to respond to H1N1 and future pandemics.

When the H1N1 virus initially broke out, we knew very little, including how Americans would react to the vaccine, and if we would need more than one dose per individual. A vaccine didn't even exist. We did not know how different H1N1 vaccines were from the vaccinations for the seasonal flu.

In addition to discussion the specifics of H1N1 vaccine production and distribution, I hope we can shed some light today on our outdated vaccine process. It is my understanding that the manufacturing process for the H1N1 vaccine relies on obsolete egg-based influenza vaccine technologies that are subject to certain inherent uncertainties and delays such as incubation periods.

As a result, we will continue to face similar challenges in responding to future influenza outbreaks, both outbreaks of novel strains, such as the 2009 H1N1 strain and the pandemic or seasonal influenza we face every year. Many experts, including the CDC director Tom Frieden, have said that it is important to develop new technologies such as cell-based vaccine production.

We will hear from four of the five manufacturers that the U.S. Government has contracted with to produce and distribute H1N1 vaccines. These manufacturers will give us an in-depth knowledge of the production challenges that they face and share their

thoughts on how we can improve this process as we move forward. GlaxoSmithKline was not invited to testify at the hearing as their vaccination was just recently approved by the FDA.

Joining the manufacturers is Dr. David Lakey, Commissioner of the Texas Department of State Health Services, who will be the voice of the State health departments across the country, and Dr. Jeffrey Levi, the Executive Director of Trust For America's Health, a nonpartisan organization dedicated to making disease prevention a national priority.

I look forward to hearing from all of our witnesses today and delving deeper into the challenges that both the government and industry are facing with the H1N1 pandemic.

Thank you, Mr. Chairman. I yield back.

Mr. Pallone. Thank you, Chairman Stupak.

The gentleman from Kentucky, Mr. Whitfield.

Mr. Whitfield. Thank you very much, Mr. Chairman. I suspect that every member of this panel has received many phone calls from their district, as I have, complaining about the shortage and wanting some answers and expressing their fear for their children and their family members.

As you said, we have had about three hearings on this subject matter, but today I really want to focus from my perspective on really the relationship and the interaction between the Federal Government, the State government and the manufacturers in the distribution process.

Number two, why have there been production delays specifically? Why? And why has there been difficulty in growing the virus? Is it because of technology? Is it because of process? Is it something else?

Then, third of all, I would like to touch on how does the U.S. compare in getting this vaccine out with other countries and how do our problems compare to those problems?

With that, I yield back the balance of my time.

Mr. Pallone. Thank you.

The full committee chairman, Mr. Waxman.

Mr. Waxman. Thank you very much, Mr. Chairman. I want to thank you and Chairman Stupak for holding this joint subcommittee hearing on the H1N1 virus and how we are responding to it.

The reports on H1N1 are sobering. As of last week, 46 States are now battling the disease. CDC estimates that perhaps 22 million people have been infected with H1N1 and as many as 98,000 have been hospitalized and about 4,000 have died, including 540 children. This is a harsh reminder that we don't need a bio-terror attack or other man-made disaster to threaten our health and make us worry for our children.

In several ways, we have been well-prepared. The Federal and State governments have been preparing for a pandemic for several years. Our surveillance worked and we were able to catch the H1N1 relatively early in its spread. Federal and state governments have developed and exercised pandemic plans. Public education has

been commendable.

There are five safe and effective FDA-approved H1N1 flu vaccines now available, and FDA has the authority for emergency use authorization to allow for unapproved but promising drugs and other products to be used to prevent and treat H1N1 flu. FDA has used this authority to make antivirals, diagnostics and personal protective gear available in the fight against this flu.

But there are clear gaps in our preparedness. We had widespread disease before we had vaccines, and vaccine supplies have been more limited than we had hoped. At the same time, hospitals and other health care providers have been stretched to capacity.

We know that the best way to protect ourselves from the flu, H1N1 or seasonal flu, is to get vaccinated. Because of this, the Obama administration contracted to purchase 195 million doses of H1N1 vaccine. They also picked up the full cost to the States for purchasing the vaccine. The hope was that a robust vaccine supply would arrive before infections began to soar and everyone would as quickly as possible to meet that goal.

These hopes were not met. The past several weeks have reminded us that the process of making flu vaccines is unpredictable and challenging. Millions of chicken eggs have to be injected with virus and then the virus has to grow. Unfortunately, this virus initially grew much more slowly than anticipated, and this lag has caused most of the delay in

producing and delivering needed vaccine supplies.

There is understandable frustration in the face of a growing number of infections and long lines at vaccination clinics. Parents are understandably concerned about getting their children immunized as quickly as possible.

I want to make sure that everyone who needs the vaccine has access to it. At the same time, there have been unprecedented levels of collaboration among Federal agencies, the vaccine manufacturers and the States, and according to experts, the manufacturers' ability to produce a vaccine within 6 months after identifying the virus is impressive.

These efforts, while significant, are not enough for those people who are still seeking immunization. I look forward to today's testimony so we can understand where we are in the epidemic and the vaccine Nation effort. We also need to learn how the process can be improved. Both in the short-term so that people can be protected from this disease as quickly as possible, and in the long term, so that when we face the next flu pandemic, we can be even better prepared than we have been this year.

I thank the witnesses for appearing today. I look forward to their testimony.

Mr. Pallone. Thank you, Chairman Waxman.

Next we have the gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman. I too want to mention our sincere prayers for those who have lost family and loved ones

during this illness. They are throughout the country, and I think a lot of districts have been affected.

Information has been good as far as there is more people washing their hands, there is more people covering their mouths, as Greg Walden mentioned, staying at home, and that is an thing where information has been very, very helpful. Information has also been harmful, and that is this rush and this fear of people lining up for the injections or the mist sprays.

So my concern is we have got to be real about the projection of information to the public, because the public will respond appropriately. I think the rosy expectations have really caused this dilemma that we are in.

The other thing that I think we should focus on is this is something that we have had a year in essence to prepare for. What if, in our first thoughts about a pandemic after September 11th, is there is something we cannot prepare for, we do not know what has hit, and how do we ramp up, get information out, and then respond? I think that is as critical a question in the Homeland Security terrorist debate as responding to something we can prepare for.

So there are a lot of things we can learn about in the hearing today, and I appreciate the first panel and the follow-on panel. I think we will be very attentive to your testimony and I think there will be a lot of good questions offered by members.

I yield back my time, Mr. Chairman. Thank you.

Mr. Pallone. Thank you, Mr. Shimkus.

Chairman Dingell.

Mr. Dingell. Mr. Chairman, I thank you, and I want to commend you and Chairman Stupak for holding this hearing, which is very important.

Since the initial outbreak in March of the H1N1 influenza in Mexico, the Federal Government, State and local public health departments, health providers, vaccine manufacturers and many others who have been working overtime to produce and distribute the H1N1 vaccine and to educate the public on precautions that can be taken to prevent the spread of the influenza.

Since April, 42 people in Michigan have died since contracting any strain of influenza. More than 1,200 hundred have been hospitalized and over 584,000 have reported flu-like symptoms. Across 48 States, there have been 3,900 deaths from H1N1 virus, 9,800 hospitalizations and 22 million infections. The high number of deaths from H1N1, in particular the high number of pediatric deaths has increased the demand for the vaccine, a demand that is unlikely to cease at any time soon.

This vaccine first became available in the beginning of October, and as of November 5, approximately 35 million doses have become available. This is well below the CDC prediction of 40 million doses by the end of October. There is no doubt that manufacturing a vaccine in short order is a difficult task and this country has had difficulties with flu vaccines before.

This task requires scientists to identify the virus correctly, determine the appropriate and most effective method for a vaccine, and then manufacture millions of vaccines to be distributed, all with the pressure of completing the task quickly and, most importantly, safely.

I know that there are many unforeseen roadblocks to manufacturers, whether it be the difficulty in producing the vaccines in an egg-based system, a shortage of appropriate egg supply and equipment, and equipment failures, amongst other things. While this shortfall is a disappointment, I believe we better serve the American people when we focus on producing a safe and effective vaccine and having it made available in a safe and efficient manner.

History has taught us that prioritizing speed over safety is shortsighted when it comes to flu outbreaks. In February of 1976, two recruits at Fort Dix fell sick from the H1N1 flu strand. Congress responded swiftly. That August, the National Influenza Program was produced and one week later was signed into law by President Ford. We were forced to deal with the costly consequences of our actions, which ultimately led to great public mistrust of immunizations as the program was mishandled and lives were lost.

It is appropriate to respond to the national threats, but we need to remember to be deliberate and thoughtful and wise in our response.

The H1N1 outbreak and the distribution of the vaccine provides the Federal Government with an opportunity and the responsibility to closely examine our pandemic response system. For HHS and CDC in particular, this means examining the way in which our government communicates with the public. For FDA, this means examining the methods in which the vaccines are approved.

For many of my colleagues and for many of those testifying today, my goal is to ensure the safety and health of the public, while at the same time looking forward to how we can best prepare for future pandemics and how we can learn from the ongoing events of the day.

This will include examining the national strategic stockpile and whether it is adequately supplied, preparing our scientists and manufacturers with the most effective and efficient technology to create and produce vaccines, as well as looking to whether or not the Congress has provided adequate funding for HHS, CDC and FDA to give them the resources needed to carry out their missions.

Today, I believe this hearing will be helpful in answering these questions and others, and I look forward very much, Mr. Chairman Pallone and Mr. Chairman Stupak, to working with you and hearing what our witnesses have to say today as we seek to mitigate the outbreak of H1N1.

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

Mr. Pallone. Thank you, Chairman Dingell.

Next is the gentleman from Texas, Mr. Burgess.

Dr. Burgess. Thank you, Mr. Chairman.

Like so many the other Members of Congress on a Sunday afternoon in April, a football game was interrupted with a notice of a public health emergency about a new kind of flu. We had a conference call later that day for Members of Congress, I don't know how many were actually on the call, but I remember thinking at that time, our greatest danger here is not anticipating how aggressive this virus could be if we are truly faced with the novel influenza for which most of us do not have preexisting immunity.

And that is sort of where we are today. Fortunately, the story is not nearly as bad as it could have been and many of us feared it might be, but nonetheless, it points up some of the difficulties that have been encountered.

Mr. Chairman, I will say I am grateful we have had three hearings, but it seems to me when we were preparing for a possible avian flu pandemic in 2004, 2005 and 2006, we had many more hearings for just the preparation for that possible pandemic than we have had after we find ourselves in the throes of this illness.

Now, we do have to ask ourselves, how could we have misanticipated the ability to produce vaccine? We saw this coming, we knew it was coming, we had reports over the summer from the southern hemisphere that it wasn't as bad as it could have been, and yet there were some particularly vulnerable populations

which would need perhaps aggressive use of vaccination protocols, and we find ourselves in our districts without being able to provide even the vaccines for those high risk individuals.

In fairness, I do want to say I have had good cooperation from the CDC, the Department of Homeland Security, the Department of Health and Human Services, that came to my district in August and had a roundtable with school districts in my area so they could be better prepared. The Fort Worth Independent School District took a lot of heat last April and May for closing their school district early, but they were frightened of what might happen with not anticipating the severity of this illness.

Then just finally, on a personal note, I want to thank Dr. Lakey for being here from the Texas Department of Health. He has also been good enough to do conference calls with members of the Texas delegation as we worked our way through some of the difficulties with the distributional issues of getting the vaccine where it is needed.

I will also just thank Dr. Hamburg at the Food and Drug Administration, who was kind enough to take my call after the news reports said that Texas was getting expired Tamiflu to protect its citizens. And this was one of the problems we encountered in 2005. We produced a lot of anti-viral, the illness doesn't materialize, and how long is the shelf life? And, indeed, there were tests done to ensure that that shelf life was longer than what was stamped on the box. It was just an unfortunate public

relations aspect that we didn't correct that. But I was very grateful to Dr. Hamburg for calling me and helping me through that particular public relations crisis.

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

Mr. Pallone. Thank you, Mr. Burgess.

The gentlewoman from California, Ms. Eshoo.

Ms. Eshoo. Thank you, Mr. Chairman, for holding this important joint hearing on H1N1 preparedness, production and distribution. I appreciate the witnesses being here today and I look forward to their testimony.

As we have heard from our constituents or experience in our own families, the H1N1 pandemic has proven to be widespread and really highly contagious. Since the vaccine was first slated for distribution in mid-October, I, along with, I am sure probably all of my colleagues, have received countless calls from constituents asking when they can get the vaccine. Lines of patients have been out the door and around the block, and the news has been filled with stories of empty clinics and angry parents.

While I don't think there is one source to point out relative to production and distribution problems, I am interested in looking at the systemic reasons for the somewhat antiquated vaccine process we have today.

For more than half a century, the United States has been using egg-based technology to create vaccines. While it is safe

and effective, it is a slow-moving process. Across Europe, vaccine developers are using the faster process of incorporating mammalian cells to grow vaccine. As we begin to explore cell-based technology, I would pose the question, will there be an adequate FDA approval process for these new vaccines?

I am also interested in hearing from the vaccine manufacturers on how they ramped up production, in some cases to ten times their normal production schedule. We know that production has been delayed for H1N1, a harmful but relatively moderate virus, compared to something more lethal like the Spanish flu. But in the case of a stronger virus with a higher fatality rate, would our country be able to produce enough vaccine for everyone in a short time period?

So I look forward to questioning the witnesses. I welcome them again, and learning more about how we can improve vaccine production in our country. And, again, I thank the chairmen for this joint and important hearing.

I yield back.

Mr. Pallone. Thank you, Ms. Eshoo.

The gentleman from Pennsylvania, Mr. Murphy.

Mr. Murphy of Pennsylvania. Thank you, Mr. Chairman.

As we look at how we are handling this latest crisis in our government, I reflect back on a few years ago when we were faced with the sudden and unanticipated problem of Hurricane Katrina which led to an unfortunate between 1,300 and 1,800 lives lost

from the hurricane and the flood itself. But it also resulted in a flood of Members of Congress repeatedly and bitterly attacking the administration and anybody else in town because of the government's mismanagement of the whole issue.

Now, of course, it begs the question, who do we blame this time for where we are, or should we stop that game and simply get down to the business of understanding we want a painfully candid and brutally honest assessment of what is happening, what has gone right, what has gone wrong, do we have any weaknesses, and what do we need to do about it. I would hope it is this case instead, that we use this hearing as an opportunity to be honest with each other.

We are all deeply concerned of the thousands who have lost lives, the thousands who have been hospitalized, and, quite frankly, the millions who are worried that they might be affected by this latest virus hitting our Nation.

We recognize the incredible scientific achievements, and quite frankly, I would like to compliment the manufacturers for working so hard in trying to develop the vaccines and the nasal systems for sending out these things to help us deal with this virus.

But we still have a long way to go, and we are having this hearing today, quite frankly, because we are concerned. Something is not going right. Was it the goals were set too high, too unrealistic? Was it done somehow to assuage the worries of the

public about something we were not ready to do, or can we really meet those goals?

I am looking forward to hearing from all the witnesses today. We have a very talented panel before us. I am excited to hear what you have to say. But more than anything else, let's use this as an opportunity to be honest, not political, and really work for some solutions.

I yield back my time.

Mr. Pallone. Thank you.

The gentleman from Texas, Mr. Green.

Mr. Green. Thank you, Mr. Chairman. I want to thank you for holding this hearing today and giving us an update on H1N1 vaccine production and distribution.

Texas has ordered its full allocation of 3 million doses of the vaccine, but that order has not been filled due to the slow production and supply of the vaccines. I worry that States like Texas, which is the second largest State, whether they are receiving their fair share of these vaccinations. We are a border State and that comes a great deal of border issues, along with swift transmission of infectious diseases.

I welcome Dr. Lakey, who is the Commissioner of the Texas Department of State Health Services, who will be testifying on our second panel today. He assured me that Texas is receiving its fair share of vaccines and the State is continuing to order of the maximum the amount. The issue is whether the commitments of

production are being met and why they are not.

I would like to highlight a piece of legislation I sponsored along with our colleague Representative Tim Murphy, H.R. 2596, the No Child Left Unimmunized Against Influenza Act. The bill would allow HHS to perform a voluntary multistate demonstration project to test the feasibility of using the Nation's elementary schools and secondary schools as influenza vaccination centers in coordination with school nurses, school health programs, local health departments, community health care providers, State insurance agencies and private insurers.

I am pleased the bill was included in H.R. 3962, the Affordable Health Care For America Act, that was passed out of the House. Schools are logical places to vaccinate our children. Parents can opt into the program and not have to take time off from work to get their child vaccinated, which in a blue collar district like ours is hard to do.

Again, the issue is why haven't the production goals been met? Did we fill the requests from the various States?

I thank our witnesses who are here today. It appears we will know what problems have occurred with H1N1 vaccination production and distribution and how we can fix it, and I hope we will learn from the mistakes and hopefully make it much better.

I yield back my time.

Mr. Pallone. Thank you.

The gentleman from Missouri, Mr. Blunt.

Mr. Blunt. Thank you, Mr. Chairman, and thank you Chairman Stupak for holding this hearing.

This is an important topic, obviously, and one we ought to be concerned about. I have been concerned about both the vaccine distribution process and, frankly, the misleading overestimates of vaccine availability. I believe Mr. Waxman, the Chairman of the full committee, said in his statement that the administration's hopes were not met. Well, apparently hope does not get the job done here.

In addition to their hopes not being met, I think it is outrageous that suspected terrorists at Guantanamo Bay and Wall Street people, people who work on Wall Street, were apparently slated for access to the vaccine ahead of the people that health care professionals said were in danger.

Since October, 43 million vaccines have been made available, but that falls far short of the 159 million people considered to be at high risk because of these complications. It also falls short of the government's original projection that 120 million vaccines would be available by mid-October.

In fact, just last week, the government was still estimating that 8 million vaccines were going to be shipped, when only 5 million were released. I don't know how we could be this far into this process and still be 40 percent off in our one week estimate. So will be interested to hear the answers to those questions.

In Missouri alone, there have been 60 school closings this

year since the beginning of the year. Last year, during the same period, there were none. Since October 4th, approximately 21,700 people in Missouri have possible cases of H1N1 flu. During the first 6 months of last year's flu season, there were 28 cases of all kinds of flu. Sadly, last week in Missouri, the eighth person died from complications with H1N1.

I want to know and the people I work for want to know where this problem came about, the failure to understand the problem, to recognize the problem, to move forward with the problem; and with vaccine delivery, how long ago did we know that the vaccines were not going to be available and what could we have done about it.

Mr. Chairman, I expect some of those questions to be answered today, and I am grateful to you for holding this hearing.

Mr. Pallone. Thank you, Mr. Blunt.

The gentleman from Pennsylvania, Mr. Doyle.

Mr. Doyle. Thank you, Mr. Chairman. I want to thank you for holding this hearing on the issue of H1N1 preparedness at such a relevant time.

As the Centers for Disease Control have recently reported, the H1N1 strain has now claimed over 4,000 lives since April of this year. Of those, over 500 were children. I am very sad to report that just this past week, a newborn baby died at Children's Hospital of Pittsburgh located in my district of suspected H1N1 influenza. If confirmed as being an H1N1 death, this will be the first reported infant death.

In the State of Pennsylvania alone, 9,600 cases have been reported. Nearly 1,800 of them have been in my Congressional District. This is indeed a very serious problem.

This pandemic is different than what we are used to dealing with every fall as the target is an unlikely and unusual population. This strain is mostly affecting younger people, with more than 70 percent of the reported cases in Pennsylvania involving people under the age of 25. Antivirals are playing an increasingly important role in fighting this epidemic, and I am happy that the FDA has recognized this by issuing emergency use authorization for intravenous administration of these potentially lifesaving drugs.

I do have serious concerns about the reports of the difficulty doctors have had in obtaining enough vaccines for their patients, and I am anxious to hear our witnesses testify to this. This year's distribution plan for the vaccine was unprecedented, and I am extremely interested in the opinions of our panel of its effectiveness. I think that this hearing will serve as an important venue to hear from all sides of this issue and help us all work together so that in the future, we know what works and we know what must be improved upon.

I look forward to hearing from our witnesses, and I want to thank you all for your testimony today. Again, I want to thank the committee for holding this important briefing.

I yield back.

Mr. Pallone. Thank you.

The gentlewoman from Tennessee, Ms. Blackburn.

Ms. Blackburn. Thank you, Mr. Chairman, and I want to say thank you to each of you for taking your time to prepare and to come and to be in front of us. We do appreciate it.

I join other members on this panel in extending our sympathies to those who have lost life or who have found a serious complication to their health through this process.

I bring a perspective of being a grandmother and also a good friend to lots of school teachers that have kept me informed of what is happening on this. As a grandmom, I have a daughter who has an 18 month old and a 5 month old, and I know the "mommy blogs" have just been filled with the frustration of young mothers trying to get to this vaccine. It has been like playing "Where's Waldo" trying to find who has it.

We have done a disservice to these young mothers because you all knew this was coming, appropriate preparations were not made, and these are some of the questions we are going to want to get to today.

I want to talk with you about the delays and what you think has caused those, the communications processes, and where the breakdowns have been between you all and HHS, because we had different messages that were coming out. That is confusing to the public. I think also the processes that were in place for approval, for distribution, and then certainly looking at the

diagnosis-confirmation portion of that.

Then let's talk about lessons learned and how we moved forward. Dr. Schuchat, I pulled a Reuters article, a comment you made in here where you say "I think the key barrier to our immunization effort is really the fragility of the public health infrastructure."

I would love to explore that comment with you. Thank you all. Thank you, Mr. Chairman. I yield back.

Mr. Pallone. Thank you.

The gentlewoman from California, Ms. Harman.

Ms. Harman. Thank you, Mr. Chairman. So far, there have been 3,900 deaths in the U.S. from the H1N1 flu, with 266 deaths in California. This compares favorably, it is less than annual deaths that are expected from the seasonal flu. I suppose that is good news. But I agree with Chairman Waxman that this is our rehearsal for a major terror attack from some sort of biological weapon, and I think our grades are very mixed.

In terms of preparing the public, I think we have done very well, and I commend the panel and I commend others in our Federal Government for making the case calmly and providing lots of details for what the public is supposed to do. I would give that an A.

In terms of preparing the vaccine, we have had a lot of mixed results, and I suppose that could be a B-minus.

But in terms of distributing the vaccine, I would give us a

D-minus. A lot of that is the lack of preparation to States and localities for exactly what they should do with scarce resources.

I was personally scared because I have a pregnant daughter-in-law who had to spend weeks in New York City finding a doctor who had the vaccine. She did get vaccinated.

But in my district, the Beach City Health District, one of the first providers able to offer the vaccine, had a drive-in event recently. People drove more than 100 miles from as far as Santa Barbara and San Diego, turning what was supposed to be a local event into a regional scramble. The line of cars leading to the clinic backed up for miles, police were deployed to manage the unexpected crowds, and all this mayhem was just for 3,000 doses of vaccine. It was a disaster and now other areas are not doing the same thing.

As my time expires, the distribution piece was a failure, and I hope our witnesses have learned from this and they will move forward much more effectively.

Thank you, Mr. Chairman.

Mr. Pallone. Thank you, Ms. Harman.

The gentleman from Georgia, Mr. Gingrey.

Dr. Gingrey. Thank you, Mr. Chairman. Today, the Subcommittee on Health and the Subcommittee on Oversight and Investigations will have an important opportunity to shed some light on our government at work and what is a matter of life and death, and hopefully we will be able to gain a few answers to the

many questions our constituents have asked us about H1N1 preparedness and the Obama administration's response.

Mr. Chairman, from fiscal year 2004 to 2009, this Congress appropriated almost \$7 billion for pandemic flu preparation. Congress also provided an additional \$6.4 billion in the fiscal year 2009 supplemental, bringing the total since fiscal year 2004 for pandemic flu preparation to almost \$13.4 billion.

Without question, the promotion of the public health and safeguarding the lives of all Americans is an important national priority. But we also have a solemn duty to thoroughly scrutinize every dime we appropriate, because every single dime is one more IOU that will be thrown upon the backs of our children and grandchildren, likely for decades to come. Both the American people's physical health and fiscal health have to be priorities for this Congress.

Mr. Chairman, I make this point because I have concerns about this government's response to H1N1, and I believe that it may be a microcosm of what is in store if the health care legislation this House passed 10 days ago becomes law. When this government prioritizes KSM, Khalid Sheikh Mohammed to receive a vaccine, when this government has enough vaccine for Guantanamo Bay but not for Grandma Kay, we have a big problem. Is this what the American people expected? Is this what the American people deserve? At the same time, this Congress continues to put them and their children further and further into debt.

Mr. Chairman, I think not. I hope that today we will be able to pull back the curtain for the American people so they can see how the government attempts to manage their health and their collective pocketbook.

I yield back.

Mr. Pallone. Thank you.

The gentleman from Arkansas, Mr. Ross.

Mr. Ross. Thank you, Mr. Chairman. I would like to thank the Chairman and ranking member for having the Energy and Commerce Committee hold today's hearing on H1N1 preparedness.

Over the course of this year, we have seen the strain of influenza spread to a global proportion and lead to a declaration of national emergency. According to the CDC, as of November 13, 2009, influenza activity was widespread in 48 States, almost all of which is likely H1N1 influenza. Furthermore, there have been 9,800 hospitalizations, 22 million infections and 3,900 deaths from the H1N1 virus, 540 of which have been confirmed pediatric deaths.

Both public and private sectors have attempted to work together in an expedited effort to ensure adequate vaccine production and delivery to patients. Unfortunately, such efforts have fallen short and we have seen major delays in access to this much-needed vaccine. As a result, we have thousands of individuals, including those in high-risk categories, still waiting for the vaccine as we fight this pandemic.

I am also deeply concerned about the impact of H1N1 on our children and our schools. During seasonal flu outbreaks, 95 percent of deaths are usually among those older than 65, but for the swine flu, 95 percent of the deaths are occurring in those younger than 65, and typically among those far younger than that. My concern is that every parent who wants to get their child vaccinated should have the opportunity to do so. The delays in getting the vaccine to the American people must be addressed and fixed now.

Clearly there are problems with the current process in place that could have been prevented. The public deserves answers as to why there is such a shortage in supply of a vaccine when H1N1 has posed such a serious health threat for months.

I look forward to hearing answers to these and other related questions.

With that, Mr. Chairman, I yield back.

Mr. Pallone. Thank you.

The gentleman from Pennsylvania, Mr. Pitts.

Mr. Pitts. Thank you, Mr. Chairman, and thank you Chairman Stupak for convening this joint hearing.

I am sure that all of us have received phone calls and e-mails from anxious parents wondering if they will be able to obtain the H1N1 vaccine for their children. I am sure we have all been stopped by constituents back home wondering when the vaccine will be available in their area and worried that there is a

shortage.

Today we will hear from the government departments and agencies tasked with responding to the H1N1 pandemic and from the manufacturers of the vaccine itself to determine how much vaccine has been produced and how much more is on the way and how it is being distributed and allocated. I also anticipate that we will suggestions for how production and distribution could occur more smoothly in the future.

On our second panel, I would like to specifically welcome Phil Hosbach, Associate Vice President of Immunization Policy and Government Relations, the head of the Sanofi Pasteur global influenza pandemic crisis team. The U.S. headquarters for Sanofi Pasteur is in my home State of Pennsylvania. The Pennsylvania site is also the only domestic manufacturing sight of injectable flu vaccine, and the employees there have been working around the clock to produce both seasonal and H1N1 influenza vaccines.

I would also like to welcome Paul Perreault, President of CSL Biotherapies, which has its headquarters in King of Prussia, Pennsylvania, right outside my district.

Mr. Chairman, again, I thank you. I look forward to hearing the testimony of all of our witnesses, and I yield back my time.

Mr. Pallone. Thank you.

The gentlewoman from Wisconsin, Ms. Baldwin.

Ms. Baldwin. Thank you, Mr. Chairman, for holding this very important hearing.

I want to highlight three issues that I hope our witnesses will address according to their expertise during our hearing this morning.

Clearly a thorough response to any public health emergency such as a flu epidemic requires a partnership between local, State and Federal public health agencies and labs, and I am concerned about resource shortages at the State and local level, particularly with regard to personnel and modern information technology and communications. I have a bill on that matter and would like to hear your insights on how those resource shortages have affected our response to this flu, H1N1.

Secondly, I would like an update on the State of innovations and improvements that many of my colleagues have referenced that will help us do a better job next time. Cell-based manufacturing technologies, the use of adjuvants and alternative methods of vaccine delivery beyond injection or nasal sprays.

Lastly, and I think most importantly to me, I would like the witnesses' comments on our lack of domestic manufacturing of H1N1 and seasonal flu vaccine. This is of great concern to me, and I asked this of our Secretary of Health and Human Services when she last appeared before the committee. It appears that we have five contracts with five manufacturers for H1N1 vaccine. Only one does its bulk manufacturing in the United States, in the State of Pennsylvania.

I think that if we were to ever face much greater flu that

presents much greater virulence, it would be a question mark whether we would be able to get supplies of vaccine from production sites in other countries. Any country that hosts vaccine manufacturers would want to assure that their own population was protected first before permitting the export. So I am very concerned about the lack of domestic manufacturing presence and would like your comments on that.

I yield back.

Mr. Pallone. Thank you.

The gentleman from Oklahoma, Mr. Sullivan.

Mr. Sullivan. Thank you, Mr. Chairman. Thank you for holding this joint hearing today on the national H1N1 swine flu preparations, especially on the current status of the vaccine production and distribution. I am interested today in examining the lessons learned from both the administration and vaccine manufacturers in terms of responding to this national public health emergency.

To date, manufacturers have delivered 48.5 million doses of H1N1 vaccine, and the Department of Health and Human Services had hoped to have as many as 120 million doses by now. Obviously there is a large gap between what the administration promised and what they were able to coordinate and deliver. I am concerned that the administration's plan was overly optimistic and that this has led to confusion with the American public.

Since September 1, 890 Oklahomans have been hospitalized due

to complications from influenza and 27 persons have died. Ninety percent of the H1N1 related deaths have been persons less than 65 years old.

Health officials in my State announced yesterday that all Oklahomans who wants to reduce the risk of H1N1 infection are now eligible to receive H1N1 influenza vaccine. While vaccine supplies are limited, demand from priority groups has dipped to a point where all Oklahomans can begin to receive vaccine. H1N1 influenza activity has been widespread in Oklahoma since early September, and even though statewide monitoring has recently shown a decline in influenza linked to hospitalizations, this virus is expected to circulate throughout the winter months. The possibility also exists that another surge of H1N1 flu may follow the current one and we need to be prepared for this contingency.

RPTS MERCHANT

DCMN BURRELL

[11:00 a.m.]

Mr. Sullivan. I look forward to hearing the testimony of our witnesses today and examining how we can continue responding to this public health emergency, and I yield back the balance of my time.

Mr. Pallone. Thank you. The gentlewoman from Florida, Ms. Castor.

Ms. Castor. Well, thank you, Chairman Pallone, and good morning to our witnesses. The CDC and Secretary Sebelius and all of you have done exceptionally well in your public health outreach. You have kept Americans informed about the risk in basic prevention methods to combat the spread of the virus such as hand washing and the use of alcohol-based sanitizers. And I appreciate Secretary Sebelius' visit to Florida last week. She visited the East Manatee Family Health Care Center in Bradenton, Florida. And we met personally with representatives from the health department, community health centers, and other providers throughout the area to review local distribution of the vaccine, particularly to people in the high risk categories like pregnant women and young children and others with asthma and diabetes.

My greatest concern right now is the spread of misinformation, especially on the Internet. Just over the past weekend I was talking with a doctor who I know who is also -- who

works in Tampa General Hospital. He is married to an OB/GYN. And they were explaining to me that they are running into the problem of pregnant women and others in high risk categories that have read something on the Internet that has discouraged them from receiving the vaccine. And after talking with them I went on-line to see what is out there, and they are right, there is a lot of misinformation on the Internet.

One Web site calls it a complete load of nonsense, that mainstream media and American public health officials state that the benefits of H1N1 vaccine far outweigh the risks. They are frightening pregnant women who are at high risk to think that they might miscarry if they are vaccinated. This Web site reports that the vaccine is responsible for death, paralysis, seizures and other ailments.

So we have got our work cut out for us. But it doesn't stop there. In September a major cable news network did a segment with a so-called infectious disease expert advising parents not to vaccinate their children and declared that he would not vaccinate his own children, claiming that the vaccine and others are not safe and they cause more serious devastating conditions.

So in your testimony would you please address how we can effectively combat the spread of misinformation and continue to empower communities with accurate information and continue to encourage those, especially in the high risk categories, to receive the vaccination.

Thank you. I yield back.

Mr. Pallone. Thank you. The gentlewoman from Illinois, Ms. Schakowsky.

Ms. Schakowsky. Thank you, Chairmen Pallone and Stupak.

I wanted to put on the record the effective manner in which my State of Illinois is handling the H1N1 flu vaccine and administration. The Illinois Department of Public Health has an H1N1 specific Web site that contains a wealth of information about vaccine availability and prevention information.

The City of Chicago set up six free clinics to administer H1N1 vaccines at city colleges. Chicago vaccinated nearly 51,000 people in the 7 days following the opening of the free clinics.

There are a number of issues surrounding the infection and death rates in Illinois that lack sufficient explanation. Maybe you have these answers. Why is the highest number of H1N1 deaths among adults age 25 to 29? These numbers defy all the things that we previously knew about flu viruses. Do we have the correct distribution system? Is giving the vaccine to banks and companies likes Goldman Sachs and NBC the best way to distribute the vaccine?

Our current lack of research data limits our ability to draw concrete conclusions, and if we are unable to draw conclusions there is no way we could construct an adequate or effective response plan which only increases all of our risk.

So I hope to hear about the public health plans and research

efforts under way to help us better understand the disease and innovation prevention and treatment methods that are emerging.

I thank all of the witnesses for being here today to help shed more light on the situation, particularly as we are learning new information every day, and I look forward to your testimony.

I will yield back.

Mr. Pallone. Thank you. The gentleman from Utah, Mr. Matheson.

Mr. Matheson. Well, I want to thank both Chairmen Stupak and Pallone for holding this hearing today. My State is not unlike my colleagues here on the committee. We have had our outbreaks of H1N1 in schools and communities. We have seen over 623 hospitalizations due to the influenza this year as well as 14 deaths. Our State has worked with the Federal Government and manufacturers to make as many vaccines available as possible to our residents, and I am looking forward to hearing how we can better improve our strategy and coordination for responding to this public health crisis.

To date my State of Utah has received a total of just over 296,000 doses, and providers have reported having administered just over 176,000 doses of the vaccine as of November 7th. While our State supply of vaccine continues to arrive in weekly shipments, the vaccine is still in limited supply.

I represent the State with the youngest population in the country. So I continue to be worried about making sure our

children get access to this vaccine in a timely fashion. I am also concerned by several recent reports in the uptick of counterfeit medications.

The U.S. Food and Drug Administration has issued warnings to consumers to use extreme care when purchasing products over the Internet that claim to diagnose, prevent, treat, or cure the H1N1 influenza virus. The agency issued this warning after the FDA recently purchased and analyzed several products represented on-line as Tamiflu.

The FDA notes on its Web site that one of the orders which arrived in an unmarked envelope with a postmark from India consisted of unlabeled white tablets taped between two pieces of paper. When analyzed by the FDA the tablets were found to contain talc and acetaminophen but none of the active ingredient.

I am working on legislation to proactively address the rise in counterfeit medications with my colleague, Mr. Buyer. Counterfeiting is a lucrative business, and I hope that my colleagues will proactively work with me to address this issue with any drug safety legislation to come before this committee.

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

The Chairman. Thank you. The gentleman from Ohio, Mr. Space.

Mr. Space. Thank you, Mr. Chairman, for conducting this important hearing. We have heard today already a couple of

allusions to Guantanamo Bay and I think one to even Katrina. And I am as concerned as anybody about the specter of Khalid Sheikh Mohammed getting this vaccine before my son. And I guess I would like your assessment as to whether that is in fact happening.

But more importantly, I think it is important that we understand what we can do as a legislative body at this point to enhance our ability to manufacture and distribute the vaccine in a better way. We have obviously seen far too many deaths across the country. Certainly Ohio and my congressional district has been no exception to that.

But I am also interested in hearing your opinions concerning other ways that we can combat this H1N1 pandemic apart from administering the vaccine. My colleague from Florida referenced the misinformation campaign that seems to be occurring out there. I am curious as to the educational component that we can promote in simple things like hand washing and things that our constituents can do to put themselves in a better position.

And finally your assessment as to those who are most likely to get sick and die if they contract the virus, what they can do. In particular, diabetes. I understand that the obese have a particular risk factor. And how we can again from a legislative perspective at this point in time do everything we can to maximize our ability to combat this troubling epidemic.

Thank you, and I yield back my time.

Mr. Pallone. Thank you. The gentlelady from Ohio, Ms.

Sutton.

Ms. Sutton. Thank you, Mr. Chairman, and I appreciate you holding this hearing today. So much has changed since this committee held its first hearing on H1N1 back in April. At that time the H1N1 flu was just breaking and there were only 91 confirmed cases in the U.S., including a young boy in my district. There was also no vaccine and the government was just beginning to formulate a Federal response to the growing pandemic.

So we have traveled some distance since then. Now nearly 8 months later over 22 million Americans have had the H1N1 flu, and there is a vaccine in production, as we all know, and it is being distributed free of charge to the American people. However, there have been challenges along the way, and we have heard that discussed here today, with manufacturing and distribution of the vaccine. And because of the slow rate of vaccine production, demand has outpaced supply and the vaccine remains difficult for people to obtain. It is difficult even for those in high risk populations sometimes.

So it is very important that we have this hearing and we figure out ways to address these challenges that we are facing currently and the ones that may be ahead. We have seen moms with young children and pregnant women and the elderly standing in lines hoping to get the vaccine, and we want them to get it. We have heard the reports of Wall Street employees having access to the vaccine. And it certainly undercuts the public's confidence

in the distribution process, which is important. And it is important that we correct the record so that people understand what is and isn't happening.

But it is also just critically important that we do everything we can to effectively deal with H1N1 from this point forward, and frankly this won't be the last flu challenge that we have, so that we can formulate the proper way to respond to these kinds of challenges in the future.

I yield back.

Mr. Pallone. Thank you. The gentleman from Indiana, Mr. Buyer.

Mr. Buyer. I pass.

Mr. Pallone. The gentlewoman from Colorado, Ms. DeGette.

Ms. DeGette. Thank you very much, Mr. Chairman. I want to thank both of our chairmen for having this hearing today. I will submit my statement for the record because I am sure every single thing I had in there has been said by other members of the committee. But let me just say this.

The Oversight and Investigations Committee has had a number of hearings over the years on flu pandemics. The good news about what has happened with this pandemic is our public campaign, our awareness has been terrific, as Congresswoman Harman said. The problem is we still do not have an alternative to the egg-based vaccines, and we were assured at the September 15th hearing that we had that, we were ramping up production, we knew H1N1 was

coming and those vaccines would be readily available very, very soon.

That obviously has been the big problem with our response to this pandemic. Now, it is not so bad because as it has turned out this particular strain, while fatal and we feel badly about the fatalities that we have had, is not as virulent as say the avian flu. But I will tell you what, if this had been a virulent flu strain like the avian flu we would have millions of casualties already.

Now, my own daughter, who is a Type I diabetic, spent weeks going around Denver trying to get a vaccine only to finally get it last week. And I have got to say over the 13 years I have been on this committee we have got to fix this problem. We can't wait until we have the next pandemic to say that we have got to get an alternative to egg-based vaccines.

And so again to both of our chairman I want to thank you for having this hearing. And I want to say that at least this Member of Congress intends to keep pushing even when this is out of the headlines to make sure we find these alternatives, because if we don't it will be on our shoulders the next time we have a pandemic and it is a virulent pandemic that causes millions of deaths.

So I intend to do everything I can to make sure that that will not happen the next time.

Mr. Pallone. I thank the gentlewoman. Next is the gentleman from Connecticut, Mr. Murphy.

Mr. Murphy of Connecticut. Thank you very much, Mr. Chairman. To Chairman Pallone and Stupak, I appreciate this hearing today. I appreciate it especially as a parent of a current 15-month-old H1N1 patient at home. He is doing fine, but I am looking forward to the testimony today. For a number of reasons. One, I think that this conversation about how our Federal Government is interacting with State governments is important, and I know you are going to spend some time talking about how you turn your recommendations for distribution systems into best practices.

But I would also like to hear about your interactions with States regarding preventative measures. We have had a number of long-term school closures in Connecticut due to outbreaks, and I think one of the difficult things for local school districts has been an inability to really get the best information regarding how they should approach small or larger size outbreaks in school systems, in day care settings, and so I think a lot of us would be interested in hearing about how you are disseminating those recommendations down to school districts and to other settings in which you have a lot of kids.

And second, just to partner and build on the remarks of Representative Baldwin and Representative DeGette, I think a lot of us are very interested in the progress we are making this season, but also for next season, on alternative processes. I know that HHS has already given out some fairly large research

grants to companies, one actually located in my district, Protein Sciences, to start building some nonegg-based processes that have I think some real potential, and I am interested in whether you think any of those processes might come online this season or whether we are looking out into the next outbreak or to the next season for some of these alternative processes.

But again I think there are a lot of questions but I think that you have answered many of them so far. I think you have done a great job in disseminating information and getting information out to the public, and I think that this hearing can just help you build on that.

I yield back.

Mr. Pallone. The gentlewoman from the Virgin Islands, Mrs. Christensen.

Mrs. Christensen. Thank you, Mr. Chairman, and I thank all of the Chairs and the ranking members for having this hearing. As a physician and a former public health administrator, you can imagine this issue is of great concern. And as someone who has managed emergencies in the past, I know how important communication is and managing them and controlling panic and controlling the spread of the disease in this case.

Since the spring, when we were first made aware of the H1N1, it is now widespread I think in 48 States and at least two Territories. As of the last report there are 80 cases in the Virgin Islands, I am sure there are more now, and one death. And

444 cases and 34 deaths in Puerto Rico. And I am very concerned that half of the children that died from H1N1 between April and August were African American and Hispanic children, which is considerably more than the percentage that both groups represent in the population. So I would like to hear something of what is being done to outreach to those communities, as I have asked before.

I want to say that several years ago I introduced the Rapid Cures Act, which would increase research to shorten the time from bug to drug and vaccine. I didn't introduce it in this Congress because I was assured that the research was being done and I thought we would be further along. But the shortage shows that we are probably not, and I am hoping also that the limitations that we have faced in providing adequate vaccine will allow real valuable lessons going forward, and I look forward to the testimony of our witnesses.

Mr. Pallone. Thank you. Mr. Weiner.

Mr. Weiner. Thank you, Mr. Chairman. Mr. Chairman, I want to thank the members of the panel both for their work and for being here today. I represent the community around Saint Francis Prep, which represents I guess the closest thing to the American Ground Zero for this virus. You know frankly we have -- this is the problem with trying to deal with a complicated health thing in the context of 24-hour news. And a lot of people who look at this through the lens of their own experience, we have swung wildly

from poll to poll between this as an enormous problem that is going to smite us all to this is not that big a deal. We have the very same people who have been traveling the country saying get government out of our health care are now saying how come government isn't doing a better job with our health care.

I certainly hope that you have had a strong and stern talking to to those viruses that refuse to grow fast enough. I hope that any of those viruses that haven't been performing have been summarily dismissed. And I look forward to an oversight report by the GAO about how it is that we are recruiting a virus that does such a poor job of growing in chicken eggs when we ask it to.

But the bottom line of all of this is to some degree we have all participated in a small way to dealing with this notion of frenzy around this. Even the Vice President of the United States I think probably regrets saying he would recommend his family members not get on a subway in New York City, where you can catch things, but I am not sure swine flu is going to be at the top of your list.

The point is that we to some degree in government, we too exaggerate our ability sometimes to be able to be a fulcrum against Mother Nature and the laws of medicine and to some degree chemistry and physics and the like. And I think that you should be commended for trying to keep a level conversation tone here even in the face of many different cross currents. We should try to learn each time we have one of these instances what we can do

better. And I think to some degree a lot of what you have done now is based on lessons that have been learned.

But I think that it is also important that we as the legislative branch empower you all to do the jobs you can and then do our best to give you the elbow room to try to make smart medical decisions in what is an environment that is often hypertense, hypersensitive, and often polluted with a lot of misinformation.

So I appreciate your being here to help us do that.

Mr. Pallone. Thank you. The gentleman from Georgia, Mr. Barrow.

Mr. Barrow. I thank the chairman, and with my thanks to the witnesses for their participation, their work and their testimony, I will waive an opening.

Mr. Pallone. The gentleman from Iowa, Mr. Braley.

Mr. Braley. Thank you, Mr. Chairman. It has been a long time since the word "smite" has been uttered in this hearing room. And unlike my youthful colleague from Connecticut, my three children are in another high risk category, college students. But I am very concerned about the delay in productions of vaccine and the shortages of both the H1N1 and the seasonable flu vaccine and the process of vaccine distribution. There have been severe shortages in my State of Iowa which, by the way, is the number one egg production State in the country, and I would like to speak out on behalf of all eggs who have been criticized.

Vaccine shortages that led to the cancelation of flu shot clinics in my State left thousands of Iowans without access to the flu vaccine and left them vulnerable to the virus. And as of last Friday the Iowa Department of Public Health had confirmed 19 H1N1-related deaths in Iowa, including one child and 18 adults. And those victims include people from Dubuque and Black Hawk Counties, both of which are in my district, and more than 500 Iowans have been hospitalized with the H1N1 virus.

That is why you can imagine how outraged I was to learn a couple of weeks ago that some of the biggest companies in New York, my apologies, Mr. Weiner, including Goldman Sachs, Citigroup, JPMorganChase, and Time Warner, were receiving large doses of this vaccine for their employees. I don't think that it is appropriate or fair that big Wall Street firms be given priority access to the vaccine while thousands of Iowans are going without it.

I sent a letter on November 5th to Secretary Sebelius expressing my serious concerns about the distribution process and urging her to ensure that the vaccine is distributed based on risk and need, not based on wealth or profession or zip code. I haven't received a response to my letter. So I hope that you folks today can shed some light on this process, what additional corrective measures, if any, have been taken and explain to me and my constituents why these companies were receiving the vaccine when so many of my constituents were forced to go without. And I

am talking about seniors, immunocompromised individuals and children.

I look forward to hearing the testimony of the witnesses today and learning when the Iowans that I represent who would like to receive these vaccines and would like to receive them soon will receive access and what is being done to promote expansion of the availability of the virus.

So thank you.

Mr. Pallone. The gentleman from Maryland, Mr. Sarbanes.

Mr. Sarbanes. Thank you, Mr. Chairman. I will be very brief. We are looking forward to your testimony. I will be curious to hear you describe where things have gone compared to where you thought they would be the last time we had a hearing, so that at the beginning of this process you made projections, you talked about certain contingencies, and I would be interested to know how the advance of the disease has panned out against those original projections because it helps us make judgments as you project further. And that would be both with respect to advance of the disease and with respect to the way we are responding to it.

And I just want to echo what Congressman Braley just said, and that is if there are going to be delays in the distribution and if what has been manufactured is less than what we hoped to have at our disposal at this point in time it becomes even more critical -- I mean it is always critical that the distribution be

done in a fair way, but it becomes even more critical that it be done fairly because the larger context is that there are shortages and it makes people, I think, much more resentful, and rightly so, when they see an unequal distribution and one that is not occurring according to the criteria that you have laid out.

So I think there is probably a lot of interest in having you address that in your testimony. And I yield back my time.

Mr. Pallone. Thank you, Mr. Sarbanes.

Mr. Engel.

Mr. Engel. Thank you very much, Mr. Chairman. And I too will be brief. I am delighted that we are holding this hearing this morning, and I look forward to listening to the witnesses. Obviously what has gone on with the swine flu is something that Americans are asking lots and lots of questions. And we are hearing that this is something that is easily spread and yet we were told several months ago that there would be adequate vaccines and there aren't. And I know people have been contacting my office to find out where they can get vaccines. And I think what happened here is that people's expectations were rising when the government announced that there would be no problem and people would have enough vaccines for use. I think if that had not been stated or said perhaps people's expectations wouldn't be so high. But the double whammy of not having enough vaccines, plus the announcement that there would be enough for people has made people, have made people think that something is terribly wrong.

I have had some discussions with some of the people testifying today, and they have helped me to understand what has happened, but I think that we really need to ensure that something like this really never happens again. I know that people in my district have been wondering. My Staff Director had his two little boys just last week both come down with swine flu. And people have been calling my office and wanting to know where they can get vaccinated, and we have been trying to help them the best we can. But people are confused and angry at the same time.

So I look forward to the testimony and to hear what the witnesses have to say. And I thank you, Mr. Chairman, for holding this very important hearing, and I yield back.

Mr. Pallone. Thank you, Mr. Engel. I believe we have concluded our opening statements. So we will now proceed to the witnesses. Let me call or introduce the first panel. Starting with my left is Dr. Anne Schuchat, I hope I am pronouncing it right, who is Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. And then we have Dr. Nicole Lurie, who is the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. And finally, Dr. Jesse Goodman who is Chief Scientist and Deputy Commissioner for Science and Public Health for the Food and Drug Administration.

Now, in accordance with the policy of the Oversight and Investigations Subcommittee, I have not done this before but

because of the policy of the Oversight and Investigations Subcommittee all testimony at today's hearing will be taken under oath. And I am to advise you that you have a right under the rules of the House to be advised by counsel during your testimony. And I have to ask you initially if you wish to be represented by counsel and, if so, you would have to State your counsel's name.

Dr. Schuchat.

Dr. Schuchat. No, thank you.

Mr. Pallone. No. Dr. Lurie.

Dr. Lurie. No, thank you.

Mr. Pallone. You said no. And Dr. Goodman.

Dr. Goodman. Thank you, no.

Mr. Pallone. No. Okay. So then we are going to stand.

Each of you should stand. We are going to take an oath. Or you are going to take an oath I should say. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. Thank you.

[Witnesses sworn.]

Mr. Pallone. And we will start with a 5-minute opening statement from Dr. Schuchat. I think you all know that you can submit a longer statement for inclusion in the record, but we would like you try to stick to the 5. Thank you.

**STATEMENTS OF DR. ANNE SCHUCHAT, DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL**

AND PREVENTION; DR. NICOLE LURIE, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DR. JESSE GOODMAN, ACTING CHIEF SCIENTIST, DEPUTY COMMISSIONER FOR SCIENTIFIC AND MEDICAL PROGRAMS, FOOD AND DRUG ADMINISTRATION

**STATEMENT OF DR. ANNE SCHUCHAT**

Dr. Schuchat. Thank you, Chairmen Pallone and Stupak, Ranking Member Walden, and members of the subcommittee. I am really pleased to be back to talk with the committee about our comprehensive response to the H1N1 pandemic and to answer your questions.

A brief update on the situation. As you've heard, we released new estimates for the toll the virus has taken in the first 6 months of the pandemic: 22 million infected or ill, 98,000 hospitalized and, sadly, almost 4,000 deaths. The virus is spreading in -- considered widespread in 46 States. In many areas it is beginning to decrease, the burden of illness, but in some it is still on the upswing. There has been no change in the illness pattern, still disproportionately a younger person's disease, many people with underlying conditions or pregnancy disproportionately affected with severe complications.

So far no change in the virus. It hasn't become more virulent or changed genetically. We still think the vaccine is an excellent match with this virus that is circulating.

But unfortunately, the trajectory that the virus will have is unpredictable. We do not know how long this wave will last, whether there will be multiple waves. We know that flu season can last until May usually. We don't know how much seasonable flu

strains we will have, many unknowns. And that makes it even more important that we strengthen our response.

Without the investments of Congress in preparedness and strengthening our ability to cope with a pandemic we would be in much worse shape than we are today. I will go through CDC's response, and others will talk more broadly.

We rapidly identified and characterized the virus, we developed candidate vaccine strains, we carried out epidemiologic and laboratory surveillance in the U.S. and abroad to understand what was going on and direct our interventions. Our aggressive response has been science based. We have rapidly deployed lifesaving anti-viral medicines and other material from our strategic national stockpile. Laboratory kits were prepared in record time and disseminated to all of the public health labs here in the U.S. and to 150 other countries. We deployed field teams to support the State and local response and continue to support the State and locals in what's very much an implementation effort at the front lines.

We have issued science-based guidelines on prevention and mitigation. We expected disease to increase this fall before vaccine was available, so we worked very actively with other sectors to make the best use of antiviral medicines in high risk people or in severe illness, to work with education on ways to better intervene in schools without as disruptive effects as we saw last spring. We focused on businesses and health care

workers, and so forth. Communication has been a priority for all of us and we have done outreach with new media and old media and many partners.

Of course the heart of our response is the vaccination effort right now. It's been unprecedented in the speed with which we've gotten this vaccine. But of course like everyone I am disappointed in the initial production and we've been held captive really to this slow growing virus.

However, today I can announce that there are 49.9 million doses of H1N1 vaccine that are available for the States to order. It's not as much as we wanted to have by now or frankly what we needed to have by now, but every dose that's coming out is being rapidly moved to places where it can go into people and help protect them.

At CDC we work to develop recommendations to prioritize the use of scarce vaccine for those at highest risk of disease or most likely to spread. We have a distribution system that gives each State a pro rata population based share of the vaccine trying to have as fair a process as possible. The States and local health authorities are the implementers. They are deciding where that vaccine gets shipped. They are working very closely with the provider community, the local health departments, hospitals, with community health centers, with others, schools for instance, where vaccination efforts can go forward rapidly.

Thirty-four States so far have initiated school located

vaccination efforts to really reach large numbers of children promptly. Not as many have been able to be completed because of the supply but more are happening every day, and we know that the State of Maine expects to finish their school located program by the end of this week.

We've done all this mindful that the environment we live in makes communication and emphasis on the safety of vaccines the forefront for many. And so we've done this without cutting any corners on safety and have strengthened our safety monitoring system to address any unanticipated problems.

We are working hard with partners across government and in particular with the State, local, and tribal authorities who are directing the program where they are. They have been working tirelessly to make this succeed, and I'm happy to detail some of the efforts they've been making in the comment period.

When we have the opportunity to look back on this public health challenge, we'll have time to reflect on the remarkable scientific accomplishments that made it possible to rapidly detect and track a previously unseen virus and get a vaccine developed in record time. We'll have time to more systematically search for lessons in production and delivery that we can apply in a future pandemic and to rebuild the public health system that we all rely on. But today we need to quickly adapt from our recent experience and maintain our focus on the days, weeks and months just ahead.

We'll have more vaccine to put in the path of this virus.

And it's our commitment to continue to work closely with our State and local public health partners to ensure that it's as effectively delivered to those who need it most.

I will look forward to answering your questions.

[The prepared statement of Dr. Schuchat follows:]

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Mr. Pallone. Thank you, Dr. Schuchat.

Dr. Lurie.

#### STATEMENT OF DR. NICOLE LURIE

Dr. Lurie. Thank you. I, too, am very pleased to be able to talk to you today about our pandemic response.

Mr. Pallone. Maybe put that mic a little closer to you there.

Dr. Lurie. Is that better?

Mr. Pallone. Yeah. Talk into it directly if you can.

Dr. Lurie. Thank you for your foresight in helping to rebuild our country's vaccine infrastructure. As a result, when we decided to pursue vaccine for H1N1 this spring we had preexisting contracts with manufacturers already licensed in the U.S. to get us out of the block quickly to contract for manufacturing vaccine and preparedness efforts have helped hospitals and health care systems also be ready.

My office has a four-fold response related to this pandemic: First, to coordinate across department response and work with the interagency; secondly, to stimulate the development of and contract with for vaccines and antivirals; third, to monitor and ensure that we can backstop States and communities if they get overwhelmed and request our help; and finally, to stay prepared

for any other emergency, not to take our eye off the ball.

This whole response has been a public-private partnership from the get-go. Starting with vaccines, as you know, we developed a new vaccine with unprecedented speed. And this was really made possible by investments in basic and clinical science, manufacturing regulatory processes, and would not have been possible at all without our partnerships with industry. And while modest amounts of vaccine came ahead of schedule, as the graphic over here details on the left, a combination of poor production yields, late completion of seasonable vaccine, problems with new filling lines, decisions in the home country of one manufacturer, cost delays in the availability of vaccine, not just for the U.S. but around the world. And while the number of doses that's been produced and distributed and administered continue to grow we remain vigilant.

To ensure a steady supply of vaccines we talk with manufacturers almost every single day. We constantly monitor the progress of every lot produced, working to make up ground wherever possible. And right now we have full time staff in the facilities of two of the manufacturers.

In addition, Secretary Sebelius and I have spoken directly with CEOs actually on several occasions seeking to identify opportunities to work together to be sure that there are no arcane kinds of obstacles in the way. And while these delays are really frustrating to everyone, we do need to remember that the virus is

the real enemy here. And the way forward, as we've been talking about this morning, is to improve our country's domestic manufacturing capacity, using newer, faster and more predictable technology so that the virus of the future does not defeat us.

Antivirals have been another critical aspect of our response, and I just want to point out that we supported the development of new antivirals, issuing the first emergency use authorization for an intravenous antiviral, and we have procured over 30,000 doses across three types of antiviral drugs.

We are also focused on ensuring the health care system and communities throughout the country remains able to care for those who need it. CMS can now grant 1135 waivers to decompress hospitals and other facilities when they are getting overburdened, letting them use those emergency plans. And we stand ready to deploy Federal assets when necessary, including vaccination teams, clinical and laboratory staff, and temporary medical facilities. And our first ever vaccination team is headed to Delaware to do just that.

We have also partnered closely with the private sector health care system, including health insurers, pharmacists, big box stores, AMA, and the public health community to find ways to pay for vaccine administration so cost is not a barrier to people who want to be vaccinated.

Let me shift for a minute to lessons learned. Clearly the support of Congress in the past few years have been critical in

enabling us to respond so quickly to this pandemic. And yet it is clear the chronic underinvestment in public health, whether at the Federal, State or local levels or on the manufacturing infrastructure, has real world consequences, and we cannot afford to let this happen again ever.

While we have made vaccine in record time without cutting any corners, in retrospect our original projections were based on the collective experience with seasonable flu and with H5N1 vaccine manufacturing, and we are optimistic in the face of what's proved to be a daunting challenge provided by Mother Nature, and despite the best efforts of Federal Government and our partners in the private sector.

Congress and the public have rightfully asked for projections about numbers of doses, and we want to be transparent, but at the same time provide all of the caveats about the uncertain nature of these projections.

This has been a real challenge, especially as measures are captured with shorter and shorter sound bites that omit detail about such caveats, and this has led to frustration for everyone involved, especially the public.

As an important part of this transparency and part of our public-private partnership we will start releasing this week, together with all five vaccine manufacturers, the number of projected doses by manufacturer for successive 2-week periods.

In this past week storm-related delays nearly derailed

shipment of vaccine to many States from Maine to Alabama. And I want to credit the hard work of CDC and ASPR staff who worked all weekend to be sure the vaccine could be ordered and shipped so the clinics could go on as planned.

But we are far from done with the science of advanced development related to vaccines and with building manufacturing capacity in the United States. We are excited that the first cell based facility will open or have its ribbon cutting next week in North Carolina.

But my fear frankly is when this is over we will decide we don't need to worry about a pandemic for the next 30 years. Nothing could be more dangerous. Despite these challenges, I think that much of what we have learned and frankly continue to learn through this pandemic and in the investments we have made to address it will serve us well in confronting future public health emergencies as well as for day-to-day public health for years to come.

I, too, look forward to your questions.

[The prepared statement of Dr. Lurie follows:]

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Mr. Pallone. Thank you, Dr. Lurie.

Dr. Goodman.

#### STATEMENT OF DR. JESSE GOODMAN

Dr. Goodman. Chairman Stupak, Chairman Pallone, and members of the subcommittee, I really appreciate the opportunity to be here today to describe FDA's activities in this response.

First, when this influenza virus emerged in the spring we said this can't be business as usual and we immediately set up an incident command system response with several teams, for example, in antivirals and vaccines. And this enabled us to mount a very flexible and rapid response with our partners inside and outside of government.

In vaccines, our vaccine team acted immediately along with CDC to begin the steps to produce a vaccine even before there was a decision or knowledge that we were going to need one.

As you heard, in record time vaccine was produced and became available, and I can assure you everyone in this effort, government and industry, has done everything possible to get as much vaccine to as many people as quickly as possible without cutting corners. And I know this committee is concerned that a vaccine be safe.

A very important perspective here is that the entire world is

struggling with the biology of this virus, the challenge of reduced manufacturing yields, and frankly the entire world is struggling with inadequate vaccine manufacturing infrastructure.

Yet despite these challenges we face in the United States and the frustration we have been talking about, this country is one of the first to mount an effective large scale immunization campaign.

Now, many people have asked us at the FDA how can we be confident in a vaccine produced so quickly. We have this paradoxical situation where many people really want vaccine and many people don't trust it.

Well, I would like to say that the answer is straightforward and to reassure the American people. The vaccines we've approved are made with methods that are tried and true. Every year FDA and vaccine manufacturers follow a series of very specific careful steps to produce new influenza vaccines every single year, and these steps have produced safe vaccines year after year, adding up to hundreds of millions of doses manufactured and used in the United States. And we followed this exact same scientific and regulatory approach for this 2009 H1N1 vaccine.

In response to some of the disinformation that was mentioned, I think by Congresswoman Castor, one of the things we have done, for example, is my Commissioner, Dr. Hamburg, with our working together, sent a letter to every physician in the United States to explain about the vaccine, how it was produced, and to provide a balanced review of the benefits and risks of the vaccine. But

clearly we have a lot more work to do there.

You heard from the others that your investments in pandemic preparedness have been critically important. With respect to domestic capacity, I want to say that in May FDA in an accelerated manner licensed an additional facility at Sanofi-Pasteur in Swiftwater that the company has said has dramatically increased its ability to produce vaccine and that is helping us now so that's important. But clearly we have much, much more to do.

I would also say during this response we have worked with HHS to bring on-line multiple additional filling lines to help make sure we can get the vaccine that's produced out there as quickly as possible.

Now, on September 15th we licensed four vaccines against the influenza virus, a fifth last week, and I also wanted to point out that again in a very collaborative effort with the CSL manufacturer who submitted data to us we were able to extend the approval of CSL's vaccine to include children down to 6 months of age who we are very concerned with.

Now, while we expect these vaccines to have the same excellent safety record as seasonal vaccine every year, we are taking nothing for granted. The same intensive oversight of these facilities, the enhanced safety monitoring Dr. Schuchat mentioned, and I want to point out that every single lot of vaccine must be evaluated, tested, and then released by both FDA and the manufacturer before it is used in people.

Now, because of the limited time I won't go into the work we have done on antivirals and diagnostics. I do want to say that we have prevented, for example, through emergency use authorizations discarding of antivirals that we scientifically know is safe to use, and that has helped avoid shortages. Diagnostics have been fielded in record time, within weeks of the new disease, thanks to CDC's effort and our work with them collaborating to evaluate those.

You've heard about protecting the public from fraudulent and counterfeit products. We almost immediately put a team in place to surf the Internet, to deal with consumer complaints. My favorite is the magic wand that can protect against everything, including anthrax and H1N1. But you also heard there are issues of counterfeit and unapproved medications. We are continuing to be very vigilant in this respect, and we have actually put a widget out there so others can spread the word with the list of counterfeit products.

Now, looking ahead, I really do feel much has been accomplished in a very short time, and it is because of these strong collaborative efforts that the people you are seeing here and many more are talking every single day. We are talking with the States, we are talking with the manufacturers, and this has been going on from day one. But we need to ask ourselves, and we are asking ourselves, what do we need to do more both right now for this epidemic and moving forward.

Clearly you've heard about we need more capacity, we need cell-based manufacturing, and we at FDA are very committed to make that happen. We recently last year or the year before provided guidance so we could get cell-based vaccines, but we also want those to be safe. We are supporting with HHS development of recombinant and newer technologies that can help us respond even faster. And I think, as I heard from one member, this is important not just about flu, this is important about other emerging infectious diseases. If we had SARS, if we had a bioterrorist attack, we need a strong technologically advanced vaccine infrastructure.

Now, due to time I think I will stop there, but just to say that we at FDA are very committed to working with our partners and you to protect the health of the American people. We've moved forward with a very flexible rapid response while taking our responsibility about the safety of these products very seriously. We really want to encourage strengthening our infrastructure here.

I also want to mention again that this is a global issue, and we in the United States can work with global partners to strengthen the global response. None of us are safe and well protected from infectious diseases until we all are.

So I thank you for your support for public health, your support for the FDA, and your interest in this issue. Thank you very much.

[The prepared statement of Dr. Goodman follows:]

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Mr. Pallone. Thank you, Dr. Goodman, and thank you to all of you. The way we proceed now is we have a 5-minute period of questions from members going back and forth, Democrat, Republican. For members who passed on their opening they get 7 minutes. They get to add their opening to the 5. I'm going to start with myself. And I want to start with Dr. Schuchat.

The big concern -- the biggest concern that I hear from my constituents is about the distribution. And I know that the CDC has guidelines for distribution, but basically leaves the distribution up to the States as long as they meet those guidelines. My concern is whether that's a good way to go about it. I mean I suppose you assume that the States and the localities, since they are closer to people, would have a better -- would be the best way to distribute, but that's been seriously questioned in the last few months or so. And of course being from New Jersey the biggest issue has been the Wall Street companies; Goldman Sachs, Citigroup. I literally, being from New Jersey, hear about this constantly.

Why is it that New York, I guess you know, gave Goldman Sachs and Wall Street firms the opportunity to do this? I'm told that employer-based distribution is one of -- meets your guidelines. And perhaps it was assumed that they would do well since they have health clinics and have a good distribution amongst their employees.

But I guess the concern would be, you know, if you leave the distribution to those who do it best and the ones that do it best happen to be, you know, high-powered Wall Street firms, then there are two concerns. One would be does that make sense given that maybe a hospital or a school might not do as well a job at distributing but there is a greater need.

And then the second thing is whether or not some of these firms would only give it to high risk people as opposed to maybe their CEOs or somebody else. So I mean that's the concern. I mean, my question really would be why does the CDC leave it up to the States to create the plan for distribution and wouldn't it perhaps be better to have some other Federal mechanism rather than doing it this way? And what, you know what prevents somebody like Goldman Sachs getting it when it maybe should be going to a clinic and monitoring how they go about it?

Dr. Schuchat. Thank you. The CDC issues national standards about the populations at greatest risk for disease that are recommended to receive vaccine when there is a scarce situation. So we issue that as a national level setting. We leave it to the States or the large cities like New York City to find the best ways to put vaccine in the path of the priority populations to identify the venues.

New York City actually put hospitals and doctors' offices first. They put employer clinics in a lower tier and small numbers of doses went to some employers --

Mr. Pallone. But the problem that I'm hearing, you know, I don't have a lot of time, is that in some of those cases, I don't remember which Wall Street firm it was, they actually had excess and didn't need it. So you know you could argue that maybe they are getting fewer dosages but you know it may very well be that maybe all or most of what they got should have gone to the hospitals because there is a greater high risk pool there. How do we prevent that?

Dr. Schuchat. I think that issue was of concern to all of us. Dr. Freiden sent a letter out to all of the health officers reminding people about our priority groups and how critical it is for all of us to adhere to them. Every provider or venue that gets vaccine signs an agreement that they are going to follow the recommended target populations.

Mr. Pallone. And I understand that -- I'm not suggesting, although some have, that Goldman or others are giving it to people other than the high risk, although some are concerned about that. But it is just that have you thought about the fact that if you do it that way or if the States do it that way it may be giving it to people that have a better distribution network within their employers but they may not have as great a need? It is sort of like when there is a grant program and the guy that does the best, has the best grant application person gets the grant whereas maybe there is a greater need for the person who doesn't have an expert to do it, you know.

Dr. Schuchat. We have had a major commitment to vulnerable populations and to the underserved and to make sure that we are not leaving behind those without good access. Most of the States have carried out these larger mass clinics to get people who do not have doctors offices to go to.

Mr. Pallone. If you can just -- I don't know if you have it, but I would like to see, maybe get back to me at some point to talk about why this kind of distribution is better as opposed to maybe looking at some kind of a Federal alternative. I don't know to the extent that you've looked at that, but if you could get back to us at some point.

Dr. Schuchat. Thank you.

[The information follows:]

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Mr. Pallone. And then the other thing I wanted to ask Dr. Lurie is that when Secretary Sebelius testified before the committee on September 15th I mean basically she left us with the feeling that we are on track in terms of adequate supplies of vaccine. I know that turned out not to be the case, some of you explained why and I'm sure we will get more questions from the other panel. But you did mention underfunding, and I don't remember her saying anything about lack of funding. You said that underfunding or chronic underfunding was one of the contributing factors. That's the first time I have heard that, and I was a little disturbed because I don't remember her mentioning it.

RPTS COCHRAN

DCMN ROSEN

[12:00 p.m.]

Dr. Lurie. Let me try to clarify here. I think the chronic underfunding has been in the vaccine infrastructure overall, as opposed to the response. So it would have been wonderful if we had had more manufacturing capacity in the United States by this point, if we had had cell-based or recombinant technologies that could surge and really produce large amounts of vaccine.

But, you know, while we have invested in that over the past few years, we need to continue to make a much-more robust investment. So that is the kind of chronic underfunding for the vaccine manufacturing capacities.

I think we all know that the chronic underfunding in State and local public health has been a different kind of problem. But Congress has been extraordinarily responsive to the very acute needs that we have had to deal with this pandemic, and what I would like to see us in the situation of is that we can sort of apply prevention in that sense too and really get ahead of this for the next pandemic.

Mr. Pallone. Again, as I said, I don't want to beat you guys up today, but when it is something like that that Congress can make a difference, it really is important that if the Department or anybody feels that there is a need for more funding, to detail

that to us.

Again, I would ask you maybe to get back and give us more information about this chronic underfunding in writing, because a lot of things that come up here, we can't do anything about. But that is certainly something we could.

Dr. Lurie. We look forward to working with you on that.

Mr. Pallone. Thank you.

Mr. Walden.

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

Dr. Lurie, thank you, and thank you all for your testimony.

I note Secretary Sebelius did state in retrospect that the vaccine manufacturers had painted a "rosy" picture. Now, some of you have indicated you have been in contact almost on a daily basis with these same manufacturers. My understanding is the seed that they used to produce this vaccine was made available to them on June 23rd. We had testimony September 15th from Secretary Sebelius saying everything seemed to be on track and fine.

So explain, did the manufacturers, weren't they straight with you? What is this rosy picture piece? Is that blaming the manufacturers?

Dr. Lurie. I don't think there is anybody to blame here. I don't think that there is a smoking gun, and I want to make that really clear. It is a very complicated process.

What we have tried to do is put together a little graphic here that shows you all of the different points where things can

break down. So I think in the very beginning when we had that seed strain and started making vaccine, everybody was very optimistic. Nobody anticipated how hard it was going to be to get this thing to grow. Manufacturers got a new seed, they started having increases in their yields.

Mr. Walden. I don't mean to cut you off, but they only give us 5 minutes here to solve the whole vaccination issue.

When did you first learn vaccine production was going to be delayed?

Dr. Lurie. Well, what I should say is we learned at several points along the way. We learned over the summer that there were problems with this vaccine growing. We learned in the fall that there were problems --

Mr. Walden. My understanding on that is that regular vaccine or the traditional flu vaccine would produce about 3 doses per egg, and this was producing like a tenth of a dose or something?

Dr. Lurie. Somewhere between .2 to .5 or something. So that was very challenging. What I will say is at every step along the way when we got information that things were not going as quickly as possible, we actually downgraded our estimates and we got that information out to the American public as quickly as possible.

Mr. Walden. I guess what we are trying to get at here is I was here for that hearing on September 15th, and I walked away thinking, wow, that is a pretty strong statement, to say we are going to have vaccine for everybody on schedule on time and 20

million doses in October, or whatever the number was, and then we got people waiting in line for hours. I mean, people are really frustrated.

Dr. Lurie. I think we are all really frustrated. I don't have any doubt about that.

Mr. Walden. But did the Secretary know when she testified in September of these delays?

Dr. Lurie. When she testified in September, those initial getting-the-virus-to-grow problems had been largely cleared out of the way. Then, you know, as happens, other problems happened. Problems in getting production lines up and running, for example, just took longer than they could have, so it actually took longer to get from the big vats of vaccine into vials that you could actually ship out to States, just as another kind of example. And at every step along the way. Even now we still have problems. You know, if a dose gets shipped here and a temperature sensor goes off, or like the storm, things happen.

So at every step of the way things happened. When the Secretary testified, she was using the best available information she had at the time.

Mr. Walden. Let me move on to a different topic then, because one of my colleagues who had to leave wanted me to ask if we could have for the committee the contracts you entered into with the manufacturers, if we could? Is that something you can provide?

Dr. Lurie. Absolutely.

Mr. Walden. And one of the questions that has come up is in the contracts, did the manufacturers or did you request knowledge as to whether or not these offshore manufacturers, which is all but one, I understand, that their countries, like we have the authority, can say, produce the drugs for us first and then you can ship to the U.S.?

Was that discussed with each of these manufacturers, and did HHS know ahead of time kind of where we might get a manufacturer that is required by their in-country law to provide the vaccine there first, and we might have been relying on that shipment here? Did that pose problems that we know?

Dr. Lurie. Let me say first that these contracts are all structured so that manufacturers don't get paid until they produce vaccine. I just want to make that clear, because I think that there has been a lot of confusion about that. We have worked very hard to be responsible stewards of society's resources in that respect.

Yes, almost every country has what this country has --

Mr. Walden. So you knew going in.

Dr. Lurie. Going in, or early on into this, we did know that other countries had this.

I also want to just say that despite the problem in Australia, CSL has worked very, very hard to get us vaccine as soon as it got freed up.

Mr. Walden. I understand. The final question, because it is, I believe, in your testimony, is your reference to this vaccination team that has been sent to Delaware. What is that about and why Delaware, other than maybe the Vice President's home?

Dr. Lurie. Because they requested it. So one of the things that we did in working with our colleagues at CDC and State and local health departments is we said we want to do everything we can to help everybody be successful and get vaccinators out there. So if, within your State, you don't think you can mobilize the resources to get populations vaccinated, we actually through the National Disaster Medical System have trained about 15 teams now that on request could go out and help gets those vaccines into arms and noses. There is one out there, I think next week, to help college kids.

Mr. Walden. Are there other States requesting that, and how do they do that?

Dr. Schuchat. Just to add that CDC has also received requests and we have adapted. So Dr. Lurie is describing one mechanism. CDC has got other mechanisms. But everybody's shared goal is to support the States in succeeding.

Mr. Walden. That is terrific. So those vaccination teams are available through HHS, limited numbers, and States can apply, and you are communicating, I assume, with our governors on you how they can do that?

Dr. Lurie. Yes, we are.

Mr. Walden. Thanks for your indulgence, Mr. Chairman.

Mr. Pallone. Chairman Stupak.

Mr. Stupak. Thank you, Chairman Pallone.

Let me ask a couple of questions because I am a little confused on a couple of things. What I have heard everyone say, or Dr. Schuchat, you said next time we will have more time, we will have more vaccines, we have learned.

Dr. Lurie, you said we have gathered data from around the world and the H1N1 has not mutated significantly since the spring and we are doing what other countries do. And Dr. Goodman, you said the entire world is struggling with the biology of this virus and that you worked with foreign governments and the World Health Organization.

Can you show Exhibit 4 for me.

When I was looking at this, HHS has put out a timeline, the 2009 H1N1 activity timeline, and I noticed the antivirals was very important, the page I looked at. On the antivirals here, I saw here on April 28th HHS released its 11 million treatment courses, 25 percent of the Federal antiviral stockpile held in the Strategic National Stockpile to States in anticipation of State influenza efforts. The Secretary approves a procurement of 13 million treatment courses to replenish those to the States and Mexico.

We know it heart started in Mexico, at least on this side of

North America, and this was in the spring. Mexico was having trouble. We sent them 13 million treatments. April 30th, HHS provides 400 treatment courses, one percent of the Nation's stockpile to Mexico to help spread the virus. And I have no problem with doing that.

But what did we learn from all these countries? Because it seems like the problems, and we had supply to help out Mexico, that, number one, there was a shortfall. Number two, we are trying to come up with vaccine formulary. Number three, does only one dose work or do we need two doses? And four, what about the young people, especially the pediatric deaths seen in this county? Didn't we see that, all the same things in Mexico? Go ahead.

Dr. Schuchat. I can probably begin and let others finish. We have worked very closely with the global community to learn as much as possible about the behavior of the virus in people everywhere, particularly with --

Mr. Stupak. How about these questions? Did we realize there would be a shortfall from at looking at Mexico, did we find a vaccine formulary, did we realize only one dose would work, and the young people being injured. Didn't we learn that from Mexico and working with the other countries?

Dr. Schuchat. One dose seems to work in children 10 and adults.

Mr. Stupak. My question is, did we learn this in April from working with other countries?

Dr. Schuchat. No, there was no vaccine in April.

Mr. Stupak. Why did you ship it to Mexico then if there is no vaccine?

Dr. Schuchat. No, we shipped antivirals to help them, because they had people dying in hospitals.

Mr. Stupak. Yes, they had people dying in Mexico. So what did we learn from that?

Dr. Schuchat. We learned that the clinical severity in Mexico is very similar to here. Their initial reports of very severe disease were because they hadn't actual looked broader in the community. They found a lot more mild disease once they started looking. So we learned that the clinical picture in Mexico turned out just the same as what we have had, the same in Australia, the same really around the world.

Mr. Stupak. So then it still took us 6 months after shipping to Mexico and everything else to learn, number one, we are going to have a shortfall; number two, that we didn't release the license to these manufacturers until September 15th; we didn't realize we needed only one dose, according to your timeline until September 11th; and that young people were going to die.

Dr. Schuchat. Right. The vaccine clinical trials were carried out during the summer, and so decisions on licensure were based on product submissions to the FDA.

Mr. Stupak. Let me go to this question then. If we are having all these problems, we know there is these shortfalls, all

this is going on, and you have your emergency use authorization, then this adjuvant, are we the only country that doesn't require an adjuvant, that we said no adjuvant? If we are learning from all the rest of the countries, other countries aren't using adjuvant, why are we insisting -- we are non-use, right?

Dr. Schuchat. We are not using adjuvant.

Mr. Stupak. Other countries are using adjuvant, right?

Dr. Schuchat. Some are using adjuvant.

Mr. Stupak. Why aren't we? Especially when our suppliers are telling us we can quadruple the amount of vaccines available if we would have used it when we realized we have all these short supplies, and you have an emergency authorization, emergency use authorization, and the President issued a national disaster declaration on October 24th. So you are looking at the rest of the world, Novartis and some of the other manufacturers tell us, look, we can quadruple your supply just by using the adjuvant, and we say no, we are not going to do it.

Dr. Lurie. Let me see if I can sneak in, and maybe Dr. Goodman would also like to comment. Adjuvants haven't been licensed in the United States. We haven't had a lot of experience with them.

Mr. Stupak. Correct, but the rest of the world has.

Dr. Lurie. Their safety profile was not known, and so we got all of our top scientists together and we made a decision that if the situation got a lot worse, then we would use adjuvants.

Mr. Stupak. How much worse does it have to be before we use adjuvants?

Dr. Lurie. We also thought since the unadjuvanted vaccine also worked quite well, that that was a better alternative.

Mr. Stupak. But we receive 25 percent less than what we could have if we used the adjuvant. What is the problem with the adjuvant, other than we haven't done the tests here in this country?

Dr. Lurie. Well, as you know, the public's confidence in our vaccine system and in vaccines in this country is very, very fragile. We made a commitment not to cut corners and to use vaccine that had been demonstrated to be safe and effective.

Mr. Stupak. But it seems like we rely upon data from the rest of the world when it is our convenience, but then yet when we look at the track record of the rest of the world and this adjuvant, whether or not we add or not, suddenly we decide to go different. The M-59 adjuvant that Novartis talks about says look. The rest of the world, they had to change because the United States told them to change the formulary. So were we taking into concerns the needs of other people, or just our own people based upon our own interests? Then we could have had more supply out there if we would have looked at what Novartis and others say works.

Dr. Schuchat. You know, one thing you may not be aware of is that the demand for the vaccine is actually much higher here than

it is in Europe, and there quite a bit of skepticism in Europe. So I think we have a very complex environment.

Mr. Stupak. I agree. We hit it a little quicker than Europe. Europe may hit it here pretty quick, right?

Dr. Schuchat. Absolutely. But I think the other point is, as Dr. Lurie says, at several steps since last spring, the government has reevaluated the adjuvant decision. We have looked to our external advisory groups. We have considered is this a scenario where it makes sense? And we don't feel that we have reached that point, given where we are with production.

Mr. Stupak. Okay.

Dr. Goodman. Chairman Stupak, maybe I can add one thing that may be helpful to you. One is that we are working very hard with the manufacturers. In fact, we have asked NIH and the manufacturers to study these adjuvants, including with H1N1, to give us more data.

The other point I wanted to make is that the vaccine you mentioned, that is marketed in Europe, so there is one previously approved adjuvanted flu vaccine in Europe. However, that was only previously approved for the elderly. So in terms of the kind of broad experience with millions of people, that is only in the elderly, who were not a focus population for this vaccine.

Finally, I do want to point out that it is not those identical vaccines that would be available here for our citizens, but vaccines where the vaccine material itself is manufactured in

other facilities and then combined with those adjuvants, and there is much less information about that combination. And, again, that is why it is important for NIH and the manufacturers who have been very cooperative to provide this information.

So we don't have enough data about those at this point or at the beginning of the pandemic for them to meet the standard of FDA licensure. However, we have said all along, and the senior scientists at every agency at a scientific level are meeting periodically and reassessing this decision. In fact, a decision was made to go ahead and stockpile adjuvants and have them ready if they are needed. The good news has been that the normal doses of non-adjuvanted vaccine have induced an excellent response, just like every year.

Mr. Stupak. But if you are stockpiling to determine if they are going to be needed what is the breaking point when you determine they are needed, if you already stockpiled it and it can give you four times more vaccine?

Dr. Goodman. Yes. I think that initially, for example, exactly what you are asking, a break, a breaking point would have been if a normal dose didn't give a good response. Another breaking point would be if the virus changed dramatically and it looked like an adjuvanted vaccine could provide better protection.

But I think we are very open to this, and we have really tried to walk a line based on the science. It is very complex science, and we look forward to getting more information, and we

are committed to continuing to assess it going forward.

Dr. Lurie. Let me just add that --

Mr. Stupak. One minute. He has been generous with the time. I am way over. And the next panel is coming up I am going to ask them the same questions.

I still think we could have quadrupled our supply and taken care of our supply if we weren't so shortsighted in this.

Mr. Pallone. Thank you.

We have 8 minutes left. We have three votes. Mr. Shimkus says he would like to go next before we break and then after him, we will break and come back.

Mr. Shimkus. Thank you, Mr. Chairman. I am just going to be pretty short. But I appreciate Bart's focus, because in my opening statement, I hope that we do an after-action review on this process to help us be prepared, because the questions that he is raising are really the questions that I would have under a terrorist attack, biological or weapons of mass destruction. And it really keys in to what Bart has said.

We have to have a way to streamline the process and get approvals quickly, and that would be the debate on egg versus cell and how quickly -- I understand the FDA's responsibility. But if you have a massive possible pandemic, we better have a way to subvert the regular order for the needs of the whole and move rapidly.

Just like Bart's comments on the adjuvant. I hope there is a

process in place, and if there is not one, I am former military and after every training exercise you do an after-action review. Will that be done, Dr. Schuchat?

Dr. Schuchat. What I can say is we have actually had several in-process reviews already, and we are committed to after-action reviews as part of our routine procedures.

Mr. Shimkus. Dr. Lurie?

Dr. Lurie. I would add to that, and I would also add that there are processes in place now through emergency use authorizations so that if this pandemic were to become much more severe, et cetera, we would be able to shift to other products under an emergency use authorization, and that has been part of our pandemic planning since 2005.

Mr. Shimkus. Because if something hits that we don't even know about and we are looking at this timeline, then I guess we just identify it and then isolate people until we can roll out, you know, some --

Dr. Schuchat. There are several mitigation steps, and one of the things we did this summer was update guidance for mitigation, what to do with the current level of severity and what we might do if the virus mutated and was much more severe. So no automatic school closures in this setting, but if things changed substantially, we would go to much more disruptive interventions. So we do have things that were available to us, knowing that vaccine supply might not come soon enough.

Dr. Goodman. I really appreciate your comments, and we want to have a very agile public health response, especially in an emergency. I do want to mention that in that respect, it took us about a day or two when there was a need for antiviral, not approved for children under 1-year old, but to treat children under 1-year old, to work with our colleagues at NIH and CDC and issue an emergency use authorization. Full transparency to the public. Not the kind of data required for approval, but appropriate risk-benefit weighing and a public health response.

This is a tool you in Congress have given us, and we are ready to use it when there is the right emergency. And as recently as the last couple of weeks with respect to the adjuvant question, the senior scientists of every agency have sat together and revisited that decision and decided, do we want at this point to switch to adjuvants? It is a very complex discussion. But that is being revisited in action and we are committed to continuing to revisit it after action.

The biggest improvements we can make are strengthening this infrastructure and getting new technologies ready ahead of time. We are better prepared than we were a few years ago, thanks to your investment, but we have a long way to go.

Mr. Shimkus. And I will just end by saying I think education is a key. The positive aspect is the public is really better stewards of everybody else's public health by better health practices, and that will be the key thing before we can roll into

this.

Thank you, Mr. Chairman, for letting me get this in.

Mr. Pallone. Thank you, sir. We have three votes and we will come right back after that. The subcommittee is in recess.

[Recess.]

Mr. Pallone. The subcommittee will reconvene.

Our next member is the gentlewoman from Wisconsin, Ms. Baldwin.

Ms. Baldwin. Thank you, Mr. Chairman.

I mentioned in my opening statement three topics that I hoped to hear more on. I know that I won't get a chance to exhaust those three topics in Q and A, but let me start with Dr. Lurie on the issue generally of domestic production of vaccine.

You had been asked a question by Mr. Walden that I think time didn't permit you to finish answering regarding the policies in other countries where vaccine is manufactured, and I wondered if you could basically generalize those policies, but also tell us specifically what happened in the case in Australia?

Dr. Lurie. Sure. I think many countries, including the United States, in the United States we have the Defense Production Act, and basically what that tells us is that if we need material for the safety and security of this country, that we can prioritize that. And I think many countries have that kind of situation that they need to prioritize for their home country.

That is why it is so important for us to get to domestic

manufacturing capacity in the United States. It is actually something that we learned and realized during our pandemic planning early on, and in fact, even earlier than that when we realized several years ago that we were down to just one licensed flu manufacturer in the United States. And I think people have worked very hard to get to the point that we are today, and now we need to get to the point where we have much more domestic manufacturing capacity.

I think in the case of CSL, they are based in Australia and they have a similar kind of arrangement and requirement with the Australian government. You remember that the southern hemisphere has its outbreak at a different time, so Australia was experiencing a pretty severe outbreak and decided that it needed vaccine first for its home country.

Now, when that happened, CSL let us know that right away. We immediately were able to downgrade our projected numbers of doses of vaccines and at the same time we worked very closely with the manufacturer so that as soon as they met their requirement for their home country, they were able to start making and shipping doses to us.

In addition, I think as you heard, they have also submitted additional data recently so that their vaccine can be used down to a lower age in children. That was really recently licensed.

Ms. Baldwin. I, also in my opening statement, talked a little bit about using this pandemic, this seasonal flu as well as

the H1N1, to learn and to innovate, and I am wondering what your thoughts are in three particular areas. One is faster manufacturing processes, whether it is cell-based or other opportunities there; use of adjuvants; and alternative methods of vaccine delivery, something other than injection and nasal spray.

If we were to have a very virulent influenza next year, where would be in a year that we aren't today? What is your sort of time horizon for when these innovations are going to be generally more available?

Dr. Lurie. I think that is really a great question. I think, again, BRTA is in, right now, year three of a five-year strategic plan to really try to move us toward more modern manufacturing technologies and manufacturing capacity in the United States.

As I said, the first cell-based facility has its ribbon cutting next week in North Carolina, but it actually I don't think it is going to be able to make flu vaccine for another year. But when all is said and done, that ought to get us to the point where they will be able to make I think 150 million doses. So that is still far short of the capacity, the surge capacity, we would need in a public health emergency.

In addition, cell-based vaccines still require the virus to grow in cells, so we need to move toward recombinant technologies and other kinds of technologies. We have invested in some of those. I think there is a lot of promise in a number of the new

methodologies. I can't yet predict when they are going to come on line.

But I also want to say that it is great to be able to do those things, but once you do them, we can't forget that we have to manufacture to scale with whatever those are. So we have to be thinking now about, you know, how those new technologies and manufacturing capacity meet one another, so not everything is done one after another. So that is I think another real challenge that we have.

With regard to adjuvants, I think we all know and believe that adjuvants have a lot of promise. And just to reiterate, adjuvants really are used for two reasons. One is so you need less vaccine. The other is if you don't get a good immune response to that vaccine, they help you get a better immune response. It is a substance that you mix with the vaccine.

There is a lot of work going on right as we speak to understand the experience with adjuvants, trials being done by the manufacturers, as well as by NIH mixing one company's adjuvant with another company's vaccine to make sure those things are safe and effective. Depending on the outcome of those trials, I would expect that if they are promising, that the manufacturers will submit applications to the FDA. But we are not there yet.

Then in terms of the alternative methods, people are working on things like patches, a transdermal method. Some people are work on vaccines that you can eat. There is a lot of very

exciting breakthroughs in the science that I think are going to move us far forward. Some are more ready than others. But it would be great if you could use a patch instead of a shot, for example.

Mr. Baldwin. It is my understanding some of that technology also may have an impact on increasing the effectiveness of the vaccine. For example, skin micro-needle application versus injection.

Dr. Lurie. Right. And I think we are continuing to learn more about those. But I think a lot of these new technologies are very promising in terms of also being able to get a better immune response. It is really the immune response and it is sort of how it gets into the body to make that immune response that is the difference in some of these technologies.

I don't know, Dr. Goodman might want to amplify on that.

Dr. Goodman. I would want to add one thing, which is there is a lot of amazing innovation incredibly promising technologies.

We have licensed cell-based vaccines in this country, just not for influenza. That has been a real challenge. We have licensed recombinant vaccines in this country, just not yet for influenza. And I think those things are making some real technological progress, and those are things we are going to see progress in very soon.

But one thing I wanted to say is we see, even in the most sophisticated manufacturing technologies, there are still

challenges producing large amounts of things consistently and of high quality. So even with some of the most advanced biotechnology products out there today, this is complex, challenging manufacturing, and it is not like just -- I mean, the egg has been amazingly efficient and for some of the problems relatively reliable. Clearly it is an old technology. It has many disadvantages.

But I am just pointing out that some of the newer technologies are going to need the same kind of care, and that what works in a mouse or works in a very small production is not always the same and sometimes takes some time to get it to industrial scale and be sure it is going to be safe and high quality for people.

But we are all working together to accelerate that, because our goal should be for an emerging infectious disease threat, to have vaccines much, much faster, much, much faster, and there is promising technology that can help us do that.

Mr. Pallone. Thank you.

I want to thank all of you for your comments today. I know that we did have some questions that I and others asked if you could get back to us in writing. The process is that members can submit additional questions in writing to you and usually they are supposed to be submitted within the next 10 days. So you may get some additional written questions to respond to as well.

But thank you very much really for such an important issue

and that you are so involved in.

You had some comment?

Dr. Lurie. I wonder if it might be okay if I responded to something I heard in a couple of comments earlier.

Mr. Pallone. Of course.

Dr. Lurie. I was very concerned and we haven't really had a chance to I think correct some misunderstandings here, and that has to do with vaccines going to Guantanamo or vaccines going to terrorists.

There is no vaccine on its way to Guantanamo. There is no plan to vaccinate terrorists or Khalid Sheikh Mohammed ahead of anybody else right now. That is a program that is handled by DOD. But I think it is one of those things that gets out there in a sound bite and it sort of travels virally and there is a lot of misinformation out there. There is no vaccine on its way there.

Mr. Pallone. All right. Thank you very much.

Did you not -- I am sorry, Mr. Gingrey is here. He hasn't had a chance to ask questions. So, go ahead. The gentleman from Georgia is recognized.

Dr. Gingrey. Mr. Chairman, thank you. I am pleased that the first panel is still here.

You know, I have some concerns. In the interest of full disclosure, I have been a bit of a doubting Thomas as a physician-member about our response to this crisis, this pandemic as it is now, and, of course, my great concern was us creating a

pandemic of fear. I think we have certainly done that, and we also have since 2006 when we were dealing with avian flu probably in the aggregate have appropriated something like \$12 billion or \$13 billion. Feel free to correct me if I am wrong on my numbers, but a lot of money.

And, of course, as we track this and the concern was whether or not to develop and spend billions of dollars in the process and develop a vaccine specific to H1N1, different, of course, from the regular vaccine that we will be producing for seasonal flu. I think the decision was going to be made, I guess was made, on the basis of how virulent this strain became and what kind of changes might occur, was it getting worse. And I think you have said in your testimony, maybe all three of you, that the strain really hasn't gotten worse and the virulence has not increased.

But one thing that I did notice here lately was that all of a sudden we went from 1,000 deaths in the United States literally overnight to 4,000, and that is, I find, a little disingenuous. But there has been this explanation that, oh, well, we originally were basing cases of H1N1 on laboratory evidence, but now we are using a mathematical formula that we kind of extrapolate or estimate. Some people maybe in the CDC ought to go to work for the Census Bureau with those kind of calculations.

I have real concerns about that. In fact, I brought along with me a blank death certificate where it says "cause of death" and "contributing factors" and that sort of thing. I would be

really curious to know how many of those 4,000 cases does the death certificate say the cause of death is H1N1 viral influenza.

Dr. Schuchat. Thanks for those comments. Communication is really important to all of us and being clear and not confusing. We did not overnight go from 1,000 deaths to 4,000 deaths. All along we have been talking about using a variety of surveillance systems appropriate to the period of the pandemic and the efficiency of data collection, and we have said that reported cases underestimate the true burden of disease.

With seasonal influenza, when we talk about how many deaths or how many hospitalizations there are, that is not based on individual reporting by doctors and health departments and so forth. It is based on looking at a lot of different data sources and modeling those data.

What we did last week was release estimates that took information from a couple very good surveillance systems: Hospitalization data from our emerging infections program network in 10 different States; information from 30 or 35 States, depending on the week, about laboratory confirmed hospitalizations and laboratory confirmed deaths. We use those two as a ratio to understand from hospitalizations how many deaths might there be.

We looked at the influenza-like illness surveillance system, our sentinel providers, to divide up States into high, medium and low at any one time in terms of how common the transmission was. And then we used correction factors based on community surveys

done to really understand how many illnesses are in the community, based on household telephone surveys, for everyone who actually goes and sees a doctor, how many people that see a doctor get a lab test.

Dr. Gingrey. Dr. Schuchat, with all due respect, because my time is limited, I want to make one other point. I appreciate your explanation. I hope all of the panelists, all three doctors understand my concern.

The State University of West Georgia is in my district in Carrollton, Georgia, and they weren't having a problem getting access to the vaccine. I know that has been the main theme of this hearing, why we didn't develop, I don't know, millions, literally 50 million vaccines by a date certain in October, and it was only 15 million or whatever.

But the State University of West Georgia had no problem. They had plenty of vaccines. They have 11,500 students, and only 141 were willing to be vaccinated. A lot of them are very concerned. Let me give you a quick quote.

"Most students are saying that they haven't gotten the swine flu yet, so they believe that they are not going to get it at all," said Shandra Jones, a student, who is from Franklin, Georgia. There are also people telling students not to get the shot. There are some who are afraid of the side effects of the shot, and they've read about 1976 and Guillain-Barré Syndrome. They believe that the government did not test the shot enough."

Mr. Chairman, I know I have extended beyond my time. If the panel, if you would allow them as a courtesy to respond to this, because I think this is a huge issue. I don't care, if we have got 100 million vaccines and 10 percent of the population is willing to take the vaccine, even those that are high risk, what have we really accomplished here?

Mr. Pallone. I am going to let you answer Mr. Gingrey's question, but also I have to be careful here, Dr. Lurie, because you opened it up to the Guantanamo thing. Chairman Stupak wants to say something too. So we will do those two and then be done -- no, we are not done. Mr. Green is here. I give up.

All right, Mr. Gingrey. Respond to Mr. Gingrey.

Dr. Schuchat. Sure. You raised one of the most challenging aspects of this pandemic. At the very same time people are waiting in line, driving hours to find vaccine, we have supply way in excess of demand in some communities. We have huge information needs to fill, and I think we are really committed to break the myths about the safety of this vaccine, what we do know and what we don't know.

There is a Web site, [flu.gov](http://flu.gov), that has a lot of information about myths and facts that might help some of the college students understand what is the case. We have actually planned for some more outreach for youth, such as college students, to try to reach them and have them understand what is the threat to them, what are the risks or not about the vaccine.

But we have this very exquisitely challenging time where do we risk raising demand in some communities like that, at the same time we have so much extra demand versus our supply elsewhere. And that is one the reasons why we have really focused on State and local support, because in your community, your public health experts understand on the ground, you know, we got a supply-demand mismatch the other way at West Georgia College, whereas in the national level, we may not really understand the community supply and demand.

So really one of our reasons to focus on State and local distribution or direction of where the vaccine goes is because of that trust of the community and that awareness of what is going on with your local community. So I think, if you want to get back to Gitmo -- okay.

Mr. Pallone. Are you done with Mr. Gingrey's response?

Mr. Green, let me just explain what happened is it looked like we were done and there was nobody here, so Dr. Lurie asked to take some time to talk about terrorists in Guantanamo, and Mr. Stupak just wanted to clarify and ask a question about that. Then we will go to you.

Mr. Stupak. Dr. Lurie, you don't have anything to do with the military and getting the control of the drug to the military, do you?

Dr. Lurie. No, this whole program is run by the Department of Defense.

Mr. Stupak. Right. Some you don't know if people at Guantanamo have received it. If anyone at Guantanamo has got it. You don't know if the 218 international terrorists we hold in U.S. jails has received it. You don't know that, because that is handled by a different party?

Dr. Lurie. Well, what I can tell you is like all militarily installations run by the Department of Defense, and they have pretty strict criteria, just like we prioritize vaccine going to U.S. forces, deployed health care workers, civilians and contractors, civilians, et cetera.

Mr. Stupak. The point is under oath you said they did not receive it. You don't know that. When Major Diana R. Haynie says they will be receiving it on November 2nd, they could already have the vaccines down in Guantanamo. This was November 2nd and it is now, what, the 18th. Sixteen days ago. They could have it there. You don't really have any personal knowledge of it?

Dr. Lurie. No, I am sorry. What I was trying to do was correct a misconception about how the vaccine was distributed. I do not have personal knowledge of that.

Mr. Stupak. Correct. I realize uniformed personal first are required to do it, and even these detainees will have a right to accept it or refuse it. But the point being, this was released at November 2nd at the time of the height of the shortages, and the American people are upset about it.

I have no problem. I just say you are under oath. Don't be

testifying to things you don't have any personal knowledge of.

Dr. Lurie. Fair enough.

Mr. Pallone. All right. Mr. Green.

Mr. Green. Thank you, Mr. Chairman. I appreciate the patience of our witnesses. You have been here a long time, plus you had to listen to our opening statement. But that is just the way it works here some times.

I appreciate your being here. I guess the frustration is because we have had, both the Health Subcommittee and I benefit, I am on both the Health Subcommittee and the Oversight, and we have had a number of hearings since the spring, and the most recent one in September, and it seems like the best plans that we had just didn't pan out. And it is not necessarily with the delivery system. We will hear from that at the next panel. We have the Commissioner, but we will also have on the manufacturing side the next panel.

But there has been talk for many years about what we need to do for pandemics, and yet here we have what relatively can be major. A month ago we had a Homeland Security hearing in Houston, Texas, and we had 1,000 people died. Now it is up to 4,000. If it had been something much worse than H1N1, we would be sitting here and saying why are we having tens of thousands of people dying from avian flu?

What do we need to do, or the agencies, all your agencies and even Congress, need to do to live up to the plans and expectations

that we had from the earlier hearings where we were going to have enough vaccine, the distribution system was there. Right now we don't know if the distribution system is there simply because we don't have enough vaccines, all we know something is working because people are lining up all over the country to receive it.

The other question I have is my concern that the lack of regular flu vaccine, or at least the participation, and the one thing we know now is hopefully next year or the next flu season we will have H1N1 in with the seasonal flu, but that we need to make a national effort to increase the seasonal flu vaccinations. That comes from all of us. We have seen a little up-tick because of the fear of H1N1, but I want to see what we can do to -- the cheapest thing we can do for the business community is a flu shot for their employees.

So with that, and the time I have, 2-1/2 minutes for all three of you.

Dr. Schuchat. I think there are several things we could do to strengthen our response for seasonal flu as well as for a future pandemic, which I do believe we will have. We have a public health infrastructure that is weak right now. It has suffered many job losses, many furloughs, and it leaves us a little bit of a weakened core to respond to this kind of thing.

We do not sufficiently use information technology that could help connect the electronic health records in the private health care system with public health needs. We could do much better

targeting of priority groups if we had better information systems. Some States have immunization registries that work pretty well, but they don't often reach to adults. We don't have a strong adult immunization program in the U.S. Adult providers haven't yet really stepped up the way pediatricians have to use prevention at the forefront.

Mr. Green. I appreciate that, and we are going to run out of time, but we are talking about pediatricians, and we have a really robust vaccination system for children. We know H1N1 targets children and young adults. I had my 62nd birthday three weeks ago, and for the first time I said I am glad I am 62, because H1N1 doesn't hit us that much. But we have that system now. The problem is we don't have the vaccinations.

Dr. Schuchat. Right. I think there is two things though. We certainly need a more robust vaccine production with the new technology, broader manufacturing capacity. But with children, if you look at this pandemic, it is really disproportionately affecting school age children, and they don't go to the pediatricians very often and they don't get vaccinated very often compared to younger children, 1-year-olds and 2-year-olds. So there is a tremendous opportunity to strengthen immunization for school age children.

Many States are having great experiences with school-located vaccinations for H1N1. Those could be models for seasonal flu, for instance, in the future. But there is a lot of work to do

before we would realize the very efficient delivery system that we would like to have.

Dr. Lurie. Certainly. And I would really second Dr. Schuchat's comments about really strengthening the public health infrastructure at all levels. In addition, as we have talked about some already this morning, we do need to get to much more robust manufacturing technologies.

We talked about the fact that there are some promising new developments, and we need to continue to invest in pulling those kinds of technologies along so that they can make vaccines faster and more reliably. And then those new developments have to somehow meet the large scale safe manufacturing capacity so that were we to have another emerging infectious disease, another kind of pandemic, that would be able to get vaccine out in very large quantities much faster and not be reliant on the vagaries that we have now.

Mr. Green. Mr. Chairman, I know I have run out of time, but those of us who are from the sugar cube generation that dealt with polio, I know we use that example many times in our hearings, I think our agencies need to look at that and say how do we deal with this. Because next time it won't just make us sick for a few days, it may be killing a lot more people than just 4,000, because we lose 36,000 people every year from regular seasonal flu. But I am worried about the pandemic on something much more serious.

Thank you, Mr. Chairman.

Mr. Pallone. Thank you.

I guess I am going to say thank you again. I won't repeat what I said again though. Thank you so much, and again get back to us with any written comments. We would appreciate it.

Now we will call the second panel.

Mr. Stupak. [Presiding.] We will call our second panel up. This panel includes Mr. Paul Perreault, the President of CSL Biotherapies, Incorporated; Dr. Vas Narasimham, President of Novartis Vaccines USA; Dr. Ben Machielse is Executive Vice President of operations for MedImmune; Dr. Phillip Hosbach is Vice President of Immunization Policy and Government Relations for Sanofi Pasteur; Dr. Lakey is Commissioner of the Texas Department of State Health Services; and Dr. Jeffrey Levi is Executive Director of Trust For America's Health.

TESTIMONIES OF PAUL PERREULT, PRESIDENT, CSL BIOTHERAPIES, INCORPORATED; DR. VAS NARASIMHAM, PRESIDENT, NOVARTIS VACCINES USA; BEN MACHIELSE, EXECUTIVE VICE PRESIDENT OF OPERATIONS, MEDIMMUNE; PHILLIP HOSBACH, VICE PRESIDENT, IMMUNIZATION POLICY AND GOVERNMENT RELATIONS, SANOFI PASTEUR; DR. DAVID LAKEY, COMMISSIONER, TEXAS DEPARTMENT OF STATE HEALTH SERVICES; AND DR. JEFFREY LEVI, EXECUTIVE DIRECTOR OF TRUST FOR AMERICA'S HEALTH

Mr. Stupak. I welcome all of our witnesses to testify here today. In accordance with the policy of the Oversight and Investigations Subcommittee, witness testimony will be taken under oath. Please be advised that under the rules of the House, you have the right to be advised by counsel during your testimony.

Do any of you wish to be represented by counsel?

Everyone is shaking their head no, so I will take that as a no. Therefore I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn].

Mr. Stupak. Let the record reflect the witnesses have replied in the affirmative. You are now under oath.

We will now hear a 5-minute opening statement from each of our witnesses. You may submit a longer statement for inclusion in the hearing record.

Mr. Perreault, we will start with you, for 5 minutes, please,

sir, your opening statement.

#### TESTIMONY OF PAUL PERREAULT

Mr. Perreault. Thank you, and good afternoon, Chairman Stupak and Chairman Pallone and members of the committee. I am Paul Perreault, President of CSL Biotherapies, Incorporated, the U.S. distributor of influenza vaccines manufactured by our parent company CSL Limited, located in Melbourne, Australia.

I am pleased to be here today to discuss our experience in manufacturing the H1N1 vaccine specifically for the United States. CSL Biotherapies believes that it is important to understand how the government and industry can best work together to help assure vaccine availability for influenza pandemics.

I want to assure this committee that CSL Biotherapies is committed to providing the entire amount of both the H1N1 bulk antigen and the finished vaccine doses that we have agreed to in our contract with the Department of Health and Human Services. We take the H1N1 pandemic very seriously and have been a leader in developing and delivering to combat this virus.

CSL has manufactured vaccine since its founding in 1916. Our world class influenza vaccine production facilities have the capacity to produce up to 80 million doses of trivalent seasonal influenza vaccine annually. Our seasonal flu vaccine Afluria was launched in the United States in October 2007 and indicated for

ages 18 and above. And as you heard Dr. Goodman state, last week Afluria and our H1N1 vaccines received FDA approval for administration to individuals 6 months through 17 years of age as well. Afluria and our H1N1 vaccine come in multi-dose vials and thimerosal-free pre-filled syringes.

CSL initiated the western world's first human first human trials with the 2009 H1N1 vaccine and published our research findings in the New England Journal of Medicine demonstrating the efficacy of a single 15 microgram dose. These data, along with the rules of clinical trials in infants and children, were communicated rapidly to regulatory and public health authorities in the United States and globally, recognizing their value to public health decisionmaking.

In May 2009, HHS and BARDA approached CSL Biotherapies to inquire whether we might be able to provide an H1N1 vaccine for the United States. CSL Biotherapies entered into a one-year special contract initiated on May 28th, 2009, to provide 36 million dose equivalents of H1N1 bulk antigen to the United States Government. CSL Biotherapies did not have a previous pandemic contract with the United States Government.

As part of the agreement signed in May, CSL Biotherapies made it clear that the company had a preexisting contractual obligation with the Australian government to provide vaccine to that nation first, should WHO declare a pandemic. I want to stress this had no impact on fulfilling our schedule submitted to BARDA.

On June 1, 2009, CSL received the first H1N1 virus vaccine seed from the New York Medical College. The yields from this lot were approximately one-third to one-half of the average H1N1 seasonal influenza yield. As a result of these low yields, CSL formally communicated to BARDA a delay to the overall timing of the H1N1 bulk antigen delivery.

On the 18th of August, CSL received a new vaccine virus seed that was introduced into the manufacturing process. Yield improvements in excess of 80 percent compared to the previous seed were observed. A revised supply schedule was sent to HHS on September 14th incorporating production on this seed lot.

CSL remains committed to maximizing the yield and availability of H1N1 vaccine. CSL has invested in fill-and-finish capabilities in Europe and Kankakee, Illinois, to improve the availability of influenza vaccine. The Kankakee facility has achieved licensing of its new state-of-the-art syringe fill-and-finish line this past September.

I would like to recommend measures to help assure availability of pandemic vaccine. First I would recommend there be a focus on producing a greater assortment of influenza seed lots earlier that can be utilized in the creation of future pandemic influenza vaccines. The poor yields resulting from the first available seed lot had a significant effect on reducing the amount of available H1N1 vaccine. If the 10-week gap in identifying the second higher yielding seed lot could have been

avoided, higher output could have occurred sooner.

Second, new adjuvants can help to enhance the immune response and reduce required dosing, which would make more antigen available for additional vaccinations. Supportive environment for development of new adjuvants with influenza vaccine could facilitate in this advancement.

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Mr. Perreault. Finally, more education about the benefit of influenza vaccination and the achievement of higher vaccination rates closer to CDC recommendations would help to prevent influenza and support readiness.

Our passion at CSL Biotherapies is to help save and improve lives, and we wish to do our part in protecting the United States population from H1N1 and seasonable influenza. We'll continue to work with the government collaboratively.

Thank you for the opportunity to speak before the committee, and I welcome the opportunity to answer any questions.

[The prepared statement of Mr. Perreault follows:]

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Mr. Stupak. Thank you.

Doctor, would you like to testify? Pull that up and turn that mic on please.

#### TESTIMONY OF VAS NARASIMHAM

Dr. Narasimham. Good afternoon.

I want to thank Chairman Stupak, Chairman Pallone, Ranking Member Walden, and the distinguished members of the committee for the opportunity to speak with you today.

Novartis Vaccines and Diagnostics is a leading global vaccine manufacturer headquartered in Cambridge, Massachusetts. Along with our predecessor companies, we have been a leader in the development and supply of influenza vaccines to the United States for over 25 years.

Today, I would like to highlight to the committee Novartis Vaccines' commitment to U.S. influenza pandemic preparedness in our dedication to prevent every possible illness and death from influenza. We commend HHS for its global leadership in pandemic preparedness over the last 5 years. We have had a broad and successful partnership with HHS, including active collaborations on cell culture vaccines, adjuvants, stockpiles and new production facilities.

Novartis Vaccines has committed approximately \$1 billion in

influenza vaccine development and production since 2006.

Importantly, with HHS support we are constructing the first flu cell culture manufacturing facility in the United States located in Holly Springs, North Carolina, with its ribbon cutting later this month. This facility will help ensure the rapid availability of pandemic vaccine for the American people in the future.

For this pandemic, we have continued our commitment to U.S. pandemic response and public health. First, in May, we voluntarily dedicated the entire vaccine output from our manufacturing facility in Liverpool, England, to the United States. This facility represents over half of our global egg-based manufacturing capacity. We did this because of our long partnership with HHS, foregoing the potential opportunity to quadruple the output of this facility using our MF59 adjuvant.

Second, our entire organization has worked around the clock to support U.S. vaccine production. We've made large new investments, added 300 additional staff, accelerated new production lines, and have been operating our production facility with a high level of quality and efficiency.

Third, we rapidly started and enrolled a broad range of clinical trials in more than 9,000 children and adults in less than 3 months. Our data showed in early September a single dose, as opposed to two, is adequate for adolescents and adults; and we recently showed that a half dose might be sufficient.

Fourth, we have prepared for HHS to use our MF59 adjuvant

that is currently licensed and being used exclusively in our products outside the U.S. for H1N1. We have demonstrated in recent U.S. pivotal clinical trials that our adjuvant could significantly increase U.S. H1N1 vaccine supply.

Fifth, we successfully supplied 27 million doses of seasonable flu vaccine to the U.S. by early October.

Now, most importantly, in partnership with the U.S. Government, we have overcome tremendous challenges to produce a safe and effective pandemic vaccine in less than 3 months. These challenges have included low yields, multiple production uncertainties and compressed timelines. Despite these challenges, as of today, Novartis Vaccines has shipped over 18 million unadjuvanted doses to the U.S. Government; and we are fully on track with our production, a tremendous joint accomplishment.

We also believe, based on the experience this year, there are important opportunities to improve pandemic preparedness in the future. These opportunities include the need to move manufacturing into the 21st century for influenza vaccines using new technology such as our cell-culture-based technology now being used -- licensed for seasonable pandemic use in Europe.

There is a need to accelerate regulatory pathways for novel influenza adjuvants and pandemic vaccines. We need to develop new testing methodologies to speed up vaccine formulation and quality release, which can often slow down vaccine availability. We need to maintain the strategic national stockpile for rapid deployment

in the case of a severe pandemic. And, finally, as noted by other members, we must support reasonable influenza vaccination demand to ensure that suppliers are not forced out of the market, as has happened in the past.

Novartis Vaccines continues to do everything possible to maximize the rapid supply of a safe and effective vaccine in close collaboration with HHS. We believe that when taken into full context the productive public-private partnership to produce, test, and deliver a safe and effective H1N1 vaccine to the U.S. has been a remarkable success. We are fully committed together with HHS now and in the future to ensure we achieve our shared goal of preventing every influenza case in the United States.

Thank you. I welcome your questions.

[The prepared statement of Dr. Narasimham follows:]

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Mr. Stupak. Thank you Doctor.

Dr. Machielse, your testimony please. Turn that green light on and pull it forward. Thank you.

#### TESTIMONY OF BEN MACHIELSE

Mr. Machielse. Chairmen Stupak and Pallone, Ranking Members Walden and Deal, members of the committee, thank you for the opportunity to address you today.

My name is Ben Machielse. I'm the Executive Vice President of Operations for MedImmune, and I'm also chairing the MedImmune's H1N1 preparedness committee.

MedImmune has changed the landscape of influenza vaccination when we launched FluMist in 2003, representing the first innovative development in flu vaccines in over 60 years. This year, MedImmune has contracted with BARDA to deliver nearly 42 million doses of intranasal vaccine based on our FluMist technology. Between September, 2009, and February, 2010, we plan to deliver those doses.

The 42 million doses of H1N1 vaccine, along with fulfilling our commitment of 10 million doses of seasonal vaccine, represent an increase of 700 percent in MedImmune's vaccines production compared to last season. Importantly, MedImmune's manufacturing for H1N1 had no impact on our commitment to deliver 10 million

doses of seasonal vaccine. In fact, we were able to accelerate seasonal delivery and we delivered the first H1N1 vaccine this season to BARDA.

Due to manufacturing efficiencies and high vaccine yields unique to our technology, the intranasal vaccine was the first available and remains a significant proportion of the vaccine available to date. We have finished the manufacturing of all 42 million bulk doses of vaccine, all of which is now on U.S. soil. We are now in the process of filling the vaccine in the specialized single-dose nasal sprayers. As of Friday, November 13th, we have shipped approximately 13.2 million doses and are over 96 percent on track with delivering the orders BARDA has placed.

MedImmune's unique technology provided the significant search capacity for both vaccines. This success validates MedImmune's technology as a strategic asset in pandemic preparedness.

As a result of MedImmune's excess bulk vaccine we have submitted a proposal to BARDA regarding an alternative delivery device in order to further contribute to public health effort.

The development and manufacturing process for our intranasal vaccine differs from that of the shot in several important ways. We develop our own unique master virus seed to grow the vaccine, while most of other manufacturers rely on CDC or other reference labs to generate the master virus seed.

Critical to pandemic preparedness efforts is that we use a

patented technology known as reverse genetics to rapidly create multiple strains and then we can select one that grows well in eggs and has the other necessary properties, too. Like the shot, our vaccine is also produced in eggs. However, unlike the shot, we generate between 60 and 100 doses of vaccine per egg.

Longer term, replacing egg-based technology cell culture manufacturing would be a key advancement for influenza vaccines. In fact, we believe that cell culture technology used to manufacture intranasal vaccine will have similar yield advantages as to the one I mentioned in the egg-based technology.

MedImmune has an R&D program focused on the development of the cell-culture-based vaccine. However, FDA requirements have increased the cost and duration of the development program by several years, and this program is now on hold while MedImmune and HHS evaluate the appropriate path forward.

Now is the time to collectively evaluate what we have accomplished and what we can do better. It is critical that the U.S. government continue to encourage a high level of seasonable vaccination as well invest in public education campaigns that increase awareness of the benefits and options in influenza vaccination.

Additionally, it's key that government agencies and industry jointly develop a blueprint for processes and requirements across a number of key areas, including, for example, clinical development, regulatory requirements, and distribution, to avoid

any roadblocks that could delay delivery of vaccine in the future.

In the few years that BARDA has been in existence, we believe they have done a remarkable job. MedImmune is pleased to be delivering intranasal vaccine in line with BARDA's expectations, and we look forward to building up our successful relationship in collaboration with the U.S. Government.

I will be pleased to answer any questions.

[The prepared statement of Mr. Machielse follows:]

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Mr. Stupak. Thank you, Doctor.

Mr. Hosbach, your testimony please.

#### TESTIMONY OF PHILLIP HOSBACH

Mr. Hosbach. Good afternoon, Mr. Chairman. Thank you for the opportunity to testify before the subcommittees regarding H1N1 influenza pandemic production development and delivery.

My name is Phil Hosbach. I am the Vice President of Immunization Policy and Government Relations for Sanofi Pasteur, and I am currently responsible for coordinating the company's worldwide and U.S. pandemic response teams.

Sanofi Pasteur is the largest manufacturer of influenza vaccine globally and in the United States, producing about 45 percent of the U.S. annual influenza vaccine supply. We are the only manufacturer of an activated flu vaccine on U.S. soil, and all of our seasonable and H1N1 vaccines for the U.S. market are produced in Swiftwater, Pennsylvania. This site, which includes two state-of-the-art influenza vaccine manufacturing facilities, and one of those was just licensed this year, as you heard from Dr. Goodman, they are operating 24 hours a day, 7 days a week, with more than 2,000 dedicated people involved in some way in getting the vaccine out the door. Many of these people have made great personal sacrifices to ensure that we produce the

largest number of H1N1 vaccine doses in the shortest amount of time while ensuring vaccine safety and regulatory compliance.

I would like to start my remarks today by focusing on what a remarkable achievement the U.S. response to this pandemic really is. Thanks to the close collaboration of industry with HHS, FDA, and CDC, we are better prepared for this pandemic than we would have been at any other time in history.

The virus was identified in late April. Manufacturers received the seed strains from CDC in late May. Less than 4 weeks later, large-scale manufacturing was initiated; and by late October there was an FDA-approved vaccine being administered.

It truly is a success story. Nevertheless, we certainly understand the committee's interest in this process, as there are always opportunities to improve.

Sanofi Pasteur began shipping H1N1 vaccine on September 29th, which was earlier than anticipated. We have received orders from HHS for 75.3 million doses of bulk antigen to be delivered by the end of the year. We will meet this commitment.

While Sanofi Pasteur represents only 75 million doses of the 250 million doses purchased by HHS, I am proud to say we represent almost 50 percent of what has been delivered to CDC to date. Sanofi Pasteur has largely succeeded in producing the H1N1 vaccine as initially projected. However, there were some factors that impacted even our considerable abilities and extensive preparation.

The most significant factor initially was the lower-than-expected production yield for the seed strain. It is an unfortunate fact of Mother Nature, but we sometimes see lower-yielding strains even for seasonal flu. However, the initial yields for H1N1 were exceptionally low. Utilizing our expertise, we have been able to optimize the productivity of the seed virus. Our current H1N1 yield should not be a significant factor going forward.

Since April 30th, we have participated in weekly phone calls with HHS agencies, including BARDA, CDC, FDA, and NIH, during which we provided ongoing updates. We have always been transparent about our progress. We now project that we'll not only catch up completely but we may even be ahead of schedule in the coming weeks.

The media coverage regarding H1N1 vaccine shortages have spurred some to question whether the egg-based manufacturing technology might be outdated. The egg-based vaccine production method we currently used has seen many technological advancements and is a very sophisticated process that has proven adaptable to emergency situations like the current pandemic. In fact, this year provides us with an opportunity to directly prepare the availability of flue vaccines prepared with egg-based technology and those produced in Europe using cell culture. In the end, each of the methods used produce clinical lots within similar time frames; and large-scale production was initiated at nearly the

same time.

Contrary to popular perception, cell culture is not a new vaccine production process. It's been around about 25 years and does not save substantial time when it comes to producing influenza vaccine. It does not produce a safer or more effective vaccine and does not necessarily increase yields, which was a critical variable this year.

The production of an influenza vaccine involves many steps, many of which are the same regardless of the technology or medium used. For example, growing antigen or any medium can only begin after the seed virus is isolated and is sent to manufacturers by CDC. Following no matter which production method is used, all vaccines must undergo rigorous quality control and safety testing. This testing accounts for approximately 85 percent -- and I repeat -- 85 percent of the production time.

This year, Sanofi Pasteur faced the unprecedented and complex challenge of producing two influenza vaccines simultaneously. I am proud of the work of our people, that our people have done in ensuring that Sanofi Pasteur will not only meet its commitment to deliver 75 million H1N1 doses to HHS but also meet its promise to deliver all 50 million doses of seasonal vaccine to its customers before the peak of the annual flu season. It is important to note that we still have a very long flu season ahead of us.

Again, it is a credit to all involved that we have been able to respond as well as we have to this pandemic. While it is

important and appropriate to discuss where improvements can be made, I believe it is equally important to recognize the accomplishments.

Mr. Chairman, thank you again for allowing me the opportunity to testify; and I look forward to any questions.

[The prepared statement of Mr. Hosbach follows:]

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Mr. Stupak. Thank you.

Dr. Lakey.

#### TESTIMONY OF DAVID L. LAKEY

Dr. Lakey. Chairman Stupak, Chairman Pallone, and Ranking Member Walden, my name is David Lakey. I'm the Commissioner of the Texas Department of Health Services, and it is an honor to be here today.

I've been in this position for 3 years and had the opportunity to serve in multiple public health events, including Hurricanes Dolly, Ike, and Gustav. My background is that I'm an infectious disease physician trained in both pediatric and adult infectious disease; and, like members that have testified earlier, I have been affected by this. I was the first State health officer to be infected, and my family was also infected.

History has taught us that pandemics occur. The challenges, the timing, and severity of the next pandemic, with the last one being 40 years ago, State and Federal governments have planned and exercised their plans over many years.

The challenge in 2009 was that this pandemic was significantly different than the high-severity pandemic that many of us had planned for. And it also occurred in our continent and, therefore, we were having to respond as we were also figuring out

this disease and defining the severity.

Because of these differences, our State and Nation as a whole had to rapidly flex our plans to match this situation. This ability to adjust your plans according to what you see is a critical component to any successful response. This flexing of our plans included modifying our plans related to the distribution of the novel H1N1 vaccine.

Previous pandemic plans had anticipated a high-level, high-severity pandemic; and many of those had focused on mass vaccination clinics. However, mass vaccination clinics have many challenges, as I have listed in the information that I have given you.

We have also looked at school-based clinics; and they have their own challenges, like I've listed in the information that I have provided. And so both of those strategies have significant challenges.

In light of our real-world experience, Texas and many other States decided that we needed to adjust these plans related to the severity of this pandemic. We decided to use the private sector and the public health providers, the local health departments, the SUHCs that are in our State as much as possible to direct to provide the vaccine to the patients that they usually care for. This method allows us to target the vaccine to those priority populations. We've also worked with pharmacies to figure out how we can provide vaccines to pharmacies so they can provide it in

that private sector.

Now, different States are using alternative strategies based on their experience, their public health infrastructure. Public health is structured in many different ways across the United States in the resources and the capabilities that each State had.

In order to facilitate this, Texas had to develop new resources, new tools in order for us to register providers and to pre-identify individuals within each priority population; and we made that Web-based application and linked it to our primary flu information source at [www.TexasFlu.org](http://www.TexasFlu.org).

Currently, we have 12,600 health care providers in Texas that are part of this distribution system. They have registered to receive vaccine. And, of those, we have been able to apportion vaccine to 7,000 providers in our State. In order to complement the system, we have worked with 211 in order to address concerns from health care providers or from the general public in order to steer them to where we can find vaccine.

Due to the limited supply that has been discussed today, States have had to further adjust these plans to help ensure the most vulnerable individuals are protected. For example, Texas so far has been allocated 3.7 million doses. Of that, we've been able to order 3.3 million doses. However, that's the amount of vaccine that we were told that we would have available back a month ago in mid-October. Because of the limited supplies, we've had to target our populations based on risk and the type of

vaccine that was available and then gradually expand those groups as additional vaccine became available to us.

I've outlined the system for the distribution of vaccine to providers in the State of Texas in the information that I've provided you.

I note that once the FDA approves and releases a lot the CDC informs the States about the amount and the type of vaccine that is available and then a lot of additional work has to take place. We have to match the providers that we know that want vaccine with the vaccine that is available, ensure that they still want that vaccine, and make sure that they're ready to accept that vaccine. It is a challenge to match the current priority groups and to the providers that these populations serve, and we also have to ensure that we have good geographic distribution across a large State like Texas. This can be a complicated and a tedious process.

We have been adjusting our plans as we have gone through this event and recently adjusted our plans to ensure that 20 percent of all the allocation that came to our State went to the local health department so they could fill in the gaps that that private provider base was not supplying.

I would like to finish my time by mentioning several of the challenges that we in State public health have faced as part of this pandemic.

Note this pandemic only occurred 7 months ago; and, as has been noted here, a lot of work has taken place across the United

States in that relatively short amount of time. Furthermore, all this work was accomplished in a background of significant reductions in public health across the United States. We estimate approximately 15,000 public health positions have been eliminated over the last year across the United States.

Now, despite the success, there is a national perception that we are falling short, partly because I believe we set expectations too high about the amount of vaccine that would be available initially and the national supply hasn't been adequate to meet the public demand that was created. Additionally, we created the perception that vaccine would be available to all priority groups immediately. These priority groups account for almost half of the U.S. population, and because of the supply limitations we as a State then had to narrow down those priority groups in order to get the best use of that limited resource.

There's also confusion about that process of how vaccines are allocated, ordered, and shipped and the steps that go in to ensuring it gets to the individuals that need it. And there's differences between how the States manage that because of the different structures within public health and their State. These misperceptions have led to false impressions that States are either not pulling down their full allotment or, second, that they're not being allotted the amount that should be according to their population. And both of those impressions are false.

There is also a challenge in developing tools to link

individuals that are seeking vaccine with the providers that have the vaccine. Various tools have been developed, including Web-based tools, but there's challenges with those tools. That the providers that we're shipping doses to may only receive a small amount of vaccine. If we put their name on a Web page we may steer a lot of individuals to those sites and give another false impression that vaccine would be available, and I think that would compound the current challenges that we are having.

Instead of doing that, we in the State of Texas have worked with 211 and provided them a list of the providers and have steered individuals to 211; and then we can give individual guidance on where they can seek a vaccine in their community. And we've also, as I noted earlier, sent additional vaccine to the local health providers.

Mr. Stupak. Please summarize.

Dr. Lakey. Okay. I think we also have a challenge related to the public health that has been funded, and that's been alluded to earlier today, the intermittent nature in which some of the funds have come down, one-time funding, and that has been difficult.

But I would like to say thank you for the funds that have been made available to the public health emergency response funds this last year. Those have been very important.

And, finally, I would like to say that we really appreciate the commitment of the CDC and the Office of the Assistant

Secretary for Preparedness and Response for how they've engaged local and State public health. We have continuous dialogue with them in order to work out issues and figure out how we can best serve the population of the United States.

Thank you.

[The prepared statement of Dr. Lakey follows:]

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Mr. Stupak. Thank you Doctor.

Dr. Levi, your testimony.

#### TESTIMONY OF JEFFREY LEVI

Dr. Levi. Thank you Chairman Stupak, Chairman Pallone, and Ranking Members Walden and Mr. Green. Thank you for this opportunity to speak to you today about our preparation and response to the 2009 H1N1 pandemic. I'm here on behalf of Trust for America's Health, a nonprofit, nonpartisan advocacy organization dedicated to saving lives by making disease prevention a national priority.

While I understand that today's hearing is a result of considerable frustration with the current H1N1 vaccination program, I wanted to emphasize four critical points:

First, the public health system at all levels of government has moved with remarkable speed in approving an H1N1 vaccine and getting vaccines to as many Americans as supply has permitted. We've moved as fast as or faster than any other country in the world.

Second, the vaccine is well matched to the circulating virus. It has been proven to be safe and effective in clinical trials and offers the best possible protection against the disease.

Third, whatever our concerns with production capacity are

today, had the Federal Government not made the multi-billion dollar investments in enhanced vaccine production capacity since 2005 we would be in far worse shape. The limits on supply we are experiencing are the limits imposed by the science and technology. The decision to use a central purchasing and distribution approach has assured that as supply has become available it has been equitably distributed across the Nation.

And, finally, the Federal Government has been remarkably transparent with the American people about this pandemic since it began last spring. Public health officials have leveled with the American people, making appropriate adjustments and recommendations as our understanding of the nature of the pandemic has evolved and as supply issues have arisen.

The response to this pandemic has mobilized all levels of government. While the Federal Government has assumed responsibility for distributing vaccines to State and local health departments, each locality is then responsible for developing its own policies and systems for administration of the vaccine. This has posed a number of challenges, particularly in a context of vaccine shortages.

First, local health officials received constantly shifting information about how much vaccine would be available and when. This is clearly an issue that has not only created confusion among the American people, it has also made the job of local health officials far more difficult.

Second, the largest mass vaccination campaign in U.S. history is taking place when State and local health departments are experiencing devastating losses because of the recession. While the Federal Government has rapidly pumped almost \$1.5 billion into State and local health departments for pandemic response, this does not address the underlying decline in the core capacity of health departments.

And, third, public confusion may well have been exacerbated by the fact that each State and locality has determined how to distribute its supply once received from the Federal Government. Although each health department based their plans on a larger supply of vaccine, HHS may want to revisit this issue and consider some standardization in future emergencies.

It is our hope that this hearing will contribute to the public's understanding of the complexities of the current pandemic influenza vaccine campaign. Among the key initiatives TFAH maintains are critical to the success of the response to this and future epidemics are, first, an education campaign is needed to assure the American people about the safety and effectiveness of influenza vaccines and all vaccines in general. It is important to remind Americans that even with the delays in vaccine availability they should get vaccinated as soon as they can. We have not seen the end of this pandemic.

FDA should move forward in assessing new technologies that are already in use in other countries, including the use of

adjuvants and cell-based vaccines. However, to have moved forward on an expedited basis without the standardized review would probably have undermined an already fragile confidence in the vaccine system.

Congress and the administration should also come to a consensus on what is an appropriate level of investment in new technologies. This pandemic has demonstrated the Nation still has a long way to go, not just in vaccine technology but with regard to diagnostics and antiviral treatments as well as personal protection equipment. The Biological Advance Research and Development Agency has been chronically underfunded since its inception. Its support is critical to moving promising developmental technologies into mass production. Professional estimates suggest that BARDA needs an annual appropriation of \$1.7 billion, rather than the current \$275 million to achieve its mission.

We need to provide ongoing support to State and local health departments in building capacity to respond to public health emergencies. Just as we don't fund fire departments at the moment the fire breaks out, we must move away from emergency funding mechanisms to respond to public health emergencies. This is one reason TFAH supports the mandatory funding for core public health functions that is part of the House health reform bill.

Finally, Congress and the administration should assure replenishment of the Strategic National Stockpile for supplies

that have been distributed to States such as N95 respirators, surgical masks, and antivirals. We do not know what demand the future wave of this pandemic strain will require of the SNS, nor can we forget the potential for other pandemic strains emerging, such as the H5N1 bird flu that was a primary concern until last spring.

This pandemic has shown our government at its best and highlighted many of the ongoing weaknesses in our public health system. As we continue to ramp up our response to this pandemic, we must also take steps necessary to assure that when the next public health crisis occurs a stronger system is in place and capable of responding quickly, effectively, and nimbly.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Levi follows:]

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Mr. Stupak. Thank you, and thank you all for your testimony.

Dr. Narasimham, how do you say your last name?

Dr. Narasimham. Narasimham.

Mr. Stupak. Narasimham. Let me ask you about November 3rd. You signed a letter back to us, to the committee. We asked a number of questions of all the companies -- the four or (c) companies here, and one that had caught my eye was found on page 3, point number 5.

You said, while the government ordered bulk doses of our proprietary adjuvant MF59 which enhances the potency of the flu vaccine, it, based on recently available data, could have quadrupled the number of doses supplied. The government ultimately determined that the use of adjuvant was not warranted to combat the pandemic and elected not to license or use the emergency use authorization.

These are a number of the questions I asked the previous panel:

It's my understanding -- and correct me if I'm wrong -- do other countries use your MF59 doses with the adjuvant in it?

Dr. Narasimham. That's correct. We have two H1N1 vaccines licensed in Europe and in other parts of the world with MF59, and we're exclusively providing adjuvanted vaccines outside the United States.

Mr. Stupak. Is there a safety issue with that? I think the

FDA said they had not approved it. And if my memory serves me correctly you've been trying to get this approved in the U.S. since 2007.

Dr. Narasimham. The MF59 is not approved in the U.S., but we have licensed it in Europe in 1997. We have a pretty broad range of clinical studies now, up to 200,000 subjects in noncontrolled trials and about 40,000 subjects in controlled clinical studies. To date, we have not seen any significant safety signal, so we've continued to provide that data to FDA on an ongoing basis.

Mr. Stupak. In my 15 years here, I have always been on drug companies to make sure these things are safe. You said it's been licensed since 1997 in the rest of the world?

Dr. Narasimham. That's correct, in the elderly. And for the H1N1 now we have it licensed down to 6 months of age. So for the H1N1 the adjuvanted vaccines overseas are licensed from 6 months through the elderly.

Mr. Stupak. I thought I heard Dr. Goodman on the last panel indicate that they've ordered a stockpile of this MF59 from your company.

Dr. Narasimham. That is correct. We are maintaining a stockpile in Louisville, Kentucky.

Mr. Stupak. And I asked him, then when were they going to use it? When do we get to the point, whether it's adjuvanted or not, we're going to use it? Because the pandemic is so great here in the United States. Have they ever discussed that with you?

Dr. Narasimham. We had a discussion with them in early May as to how to proceed. And the decision at that point was to only use licensed platforms, U.S.-licensed platforms moving forward. Through the summer and into September, we've maintained the capability to always use the adjuvant in case the data suggested that was needed. We continue to stand ready to do that, but to date -- and we also have prepared the EUA application in collaboration with HHS. We have not been asked to date to move forward with that.

Mr. Stupak. I think in your testimony you said that you started discussing this in 2007 -- whether you should use adjuvant or not with the FDA in 2007. You applied for a license in 2008, is that correct?

Dr. Narasimham. We applied for a new drug application, an IND, an investigational new drug, in 2008; and we've been going back and forth with the FDA since then.

Mr. Stupak. Do you see this -- the adjuvant issue, that just won't be with H1N1 but really any kind of a vaccine. Is that because you can quadruple it, at least in this case at least quadruple your doses?

Dr. Narasimham. That's correct. There are a number of benefits from the adjuvant.

One is you improve the immunogenicity so that if you have children or the elderly who do not respond you can actually make them respond to the vaccine. You can increase the number of

doses.

Another valuable thing of the adjuvant, which was not as relevant in this case, is if the virus changes -- so in the spring, if the virus changes, there might be the need to revaccinate everyone in the U.S. Whereas with the adjuvant you can cover a certain amount of variation in the virus we've seen in our clinical studies. Now, we haven't looked at that yet in this case, but it would at least provide you that flexibility.

Mr. Stupak. Dr. Levi, is it fair to ask you -- is it fair to say that this is something we ought to look at as a country? I mean, the FDA hasn't licensed it. I know you mentioned in your testimony about making sure drugs are safe and approved, and that's my concern and I'm sure everyone's concern on this panel. Are we missing something here? Is there something we should look at closer?

Dr. Levi. It's definitely something we should look at closely. I believe the FDA is doing this in a good-faith manner. I think when you think about who we are targeting for this vaccine, the bulk of the data for using the adjuvanted vaccine occurs with the elderly. That's not who's targeted in this vaccine, and so we're just beginning to get the kind of data that would be associated with kids.

But I think the larger question is we have so much vaccine hesitancy in this country, so much inaccurate knowledge about whether vaccines are safe and particularly whether this flu

vaccine is safe, to add on through an emergency use application a new element that may indeed be safe could well have undermined the efficacy of this campaign.

Mr. Stupak. So this one has been around for, as I have said, I think 1997 or so and then approved. Would it be prudent to maybe leave the decision to the parent whether or not they wanted their child to be vaccinated with an H1N1 vaccine that's juvenated as opposed to not.

Dr. Levi. It is sometimes hard to understand why there is so much hesitancy around vaccines in general and this particular vaccine. I think we had a real public health question as to whether people would accept a vaccine that had a new product in it.

Now, if things had been worse and this had been a much more severe pandemic, we may have needed to go that way anyway, because whatever risk around hesitancy might have been overcome by fear of the virus itself. But I don't think that's where we are. I do believe that we need to move expeditiously in preparation for any future pandemic to be able to better address these questions about adjuvants and other technologies.

Mr. Stupak. My time is up.

Mr. Walden, for questions please.

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

For those of us who don't spend our lives in the world you're in, can somebody give me like a 20-second explanation of an

adjuvant? Doctor.

Dr. Narasimham. Sure. Adjuvants have actually been used in vaccines in the United States since the 1920s. There's one called alum that's been used extensively. Adjuvants are actually additives that we put in the vaccine that actually boost the immune response. So, in this case, what we would do is we would make the vaccine as we normally would make it, add in the adjuvant, and then see how the vaccine performs. And typically a lot less vaccine is needed and the immune response is higher.

Mr. Walden. And in your clinical trials overseas did I hear you say correctly that you haven't seen any adverse response -- well, maybe not any adverse response. You always have some. But nothing out of the band you would look at.

Dr. Narasimham. In our clinical trials -- I also just wanted to correct, we have now 25,000 subjects that are nonelderly. So it's not that we don't have data on elderly. We have quite a robust data set in the nonelderly population. We only see -- we see reactions comparable to seasonal vaccine for adverse events.

Mr. Walden. And when in 2008 did you apply to FDA for approval?

Dr. Narasimham. We did not apply -- just to clarify, we did not apply for approval.

The first step is to file an IND, which would then allow us to take the steps to file for the approval. Our intention has been to use our European data to try to move forward. The

question always has been how much data needs to be repeated in the U.S. that was done in Europe.

Mr. Walden. And when in 2008 did you do the first application?

Dr. Narasimham. I can get back to you on the exact date. I think it was mid-2008.

[The information follows:]

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Mr. Walden. And what else do you hear from FDA that you need to supply that you haven't?

Dr. Narasimham. I think they would like to see adequately controlled, randomized studies under FDA oversight that demonstrate the safety and benefit of the vaccine. We have a lot of data. A lot of it -- most of it has been generated not under FDA oversight, with EMEA European oversight. And the question for us as a company is how much of this can we realistically be expected to repeat. And, of course, with flu vaccines being as profitable -- or not as profitable as they are -- or as profitable as they are, which is to say they're not.

Mr. Walden. Okay. So going back then -- well, let me run this -- if this were the feared Avian flu that we had hearings on and the potential of four out of every ten dying because of it, I guess we would declare some sort of emergency and take whatever risk there is. But if you're using this MF59 in Europe and you're not seeing any real problems, I just wonder what it would take here to get going on that. What does FDA -- we should ask FDA.

Dr. Narasimham. I can't speak for the agency. My understanding is, if the severity was such or if the unadjuvanted vaccines had not worked, they would have looked at this much more seriously. With H1N1, it's very difficult to get the unadjuvanted vaccines to work. So, hence, the MF59 becomes -- adjuvants in general become much more important.

In this case, because they had an unadjuvanted vaccine that worked, I think they were more reluctant to move with the adjuvant. I would say that HHS and BARDA has funded a lot of our work with adjuvants so that the U.S. Government has supported a lot of the work that we've done.

Mr. Walden. But looking at it from where you are today with the FDA, what kind of time line do you think you and the FDA are on? And I realize they are your regulator and approver and you have to be really nice here. I don't mean to put you on the spot. Just for my sake and the public's sake, what kind of time line?

Dr. Narasimham. The way we look at this is we have an H1N1 adjuvant, we have a seasonable adjuvant, and we have an H5N1 adjuvant. Our goal is to get ideally all of these licensed as soon as possible. We would be willing, of course, to file as soon as we can find a pathway with FDA that makes sense. But I think we would be unwilling to repeat large clinical studies and incur all the costs again, if that's what's ultimately going to be required, unless the government helped us.

Mr. Walden. Are we the only country that doesn't allow the adjuvant in our vaccine?

Dr. Narasimham. At least for Novartis the only country that we do not supply adjuvanted vaccines to is the United States.

Mr. Perreault. If I could just comment. CSL has a unique adjuvant as well that we developed in Australia, and we did put it into the H5N1 that we supplied to Australia during that time frame

a few years ago.

Mr. Walden. And H5N1 is what?

Mr. Perreault. That's the bird flu, Avian flu.

We also have multiple research programs going on with partner companies who are developing vaccines utilizing our adjuvant, and this adjuvant is being manufactured in Kankakee, Illinois.

Mr. Walden. It's manufactured here. We just can't use it here.

Mr. Perreault. It's being used in clinical trials with new vaccines that are being developed by other companies that we partner with.

Mr. Walden. And as you've used it in other countries, if I understood you correctly.

Mr. Perreault. We've done the studies for H5N1 in Australia.

Mr. Walden. And did you find any outlier effect?

Mr. Perreault. It was safe and efficacious.

Dr. Narasimham. And we're also able to produce MF59 in the Holly Springs facility; and we expect the MF59 suite in Holly Springs, North Carolina, to be operational in December.

Mr. Walden. All right. My time is expired. I know we have other members here who want to ask questions. Thank you, Mr. Chairman. Thank you of the panel.

The Chairman. Chairman Pallone.

Mr. Pallone. Thank you.

I was going to use my time with Dr. Lakey here because you're

the State guy. And I don't know if you were here when I asked the first panel, but all my questions were about distribution and also about funding, because Dr. Lurie brought it up.

Basically, you know that CDC has left it up to the States to decide how to distribute the vaccine. So I wanted to know how a State decides which entities will distribute vaccine, you know, how many doses they receive; and, essentially, do you agree with the CDC that these decisions should be left to the States or should they be dictated by the Federal Government maybe a little bit more strictly?

I know they have guidelines, but -- I don't know if you were here before, but I've been getting all these criticisms in New Jersey about the Wall Street firms getting the vaccine because they can distribute it better than some other places. And we're hearing in my own State of New Jersey and in New York about major disparities, one school district versus another that gets it, one gets it, the other doesn't. I just want your response. I know you're a State official, so you probably think States are great, but I would just like your response.

Dr. Lahey. Let me provide some background related to how we do this.

We have the ACIP guidelines, the high-risk groups. And then those were further prioritized into a group taking it from 159 million to about 49 million. And so the challenge for us has been the changing landscape of how much vaccine is going to be

available. Because your strategy to deliver a vaccine changes depending on how much vaccine you have. You can't run a mass vaccination clinic if you only have 100 doses, and you can't provide a school-based clinic if you're not immunizing healthy young kids.

And so States looked at those priority groups; and I think most States looked at health care workers, pregnant women, and very young kids as those top individuals that we needed to start our immunization program with. The challenge was that the first vaccine that was available was the nasal spray, and so we couldn't immunize pregnant women with the nasal spray.

Mr. Pallone. Just to interrupt you, I've had that phenomenon, too, where one of my school districts has the nasal spray but doesn't have the vaccine and they want the vaccine instead of the nasal spray.

Dr. Lakey. And so it's a matching of the vaccine you have available with your priority groups and your distribution system, what systems do you have available. And so a lot of us State health officials tried to move from large vaccination clinics to using the private sector.

Mr. Pallone. So you use employers as well the way New York does?

Dr. Lakey. Well, we're providing it to the physicians, the health care systems --

Mr. Pallone. So you don't actually -- I know I'm

interrupting, but I'm running out of time. You don't actually do like what New York has done or maybe New York City has done, where they would go to large employers like Citigroup or Goldman Sax that have health clinics and have them do the distribution.

Dr. Lakey. I have 13,000 registered providers on our system, and it's a combination of many of those. There may be some occupational health, but they're the minority. Most of these are pediatricians, ObGyn, family practitioners in the State.

Mr. Pallone. Do you think that -- I mean, I'm asking you to criticize another State, but, I mean, would you -- New York obviously uses some of these large employers. Do you think that makes sense?

Dr. Lakey. Well, I don't know the details of New York. From what I have gathered is that they have been trying to meet the priority groups and trying to reach pregnant women in different ways that they can do it, but I cannot speak for the State health officers.

Mr. Pallone. Let me you ask you this. You did mention the challenges of intermittent public health funding. And Dr. Lurie brought up funding challenges. I was a little critical because I don't remember the Secretary mentioning that when she was here. And, of course, if you need money, this is the place to come, for the most part, these days. Talk to me a little bit about that. I mean, to what extent the lack of funding or intermittent nature of it has been a problem.

Dr. Lakey. Sure. I think there is a couple of issues here.

One is, the Federal funds that have been made available, you know, after 9/11, a lot of funds were made available, it peaked, and then it gradually declined. And so we receive now about half of what we were receiving earlier on.

We also had in 2006 one-time funding related to pandemic flu. And so that money was utilized to put together plans. But you can't hire people for long term on one-time funding, and so that funding went away. Those plans were made. But you can't continue that process after those funds have went away.

Mr. Pallone. But you obviously feel that it makes sense for the States to have a lot of discretion here. In other words, you wouldn't suggest that the Federal guidelines be strengthened or made more detailed at this point. You believe the States should have the leeway to pretty much do what they want pursuant to the existing guidelines.

Dr. Lakey. I guess, for clarification, that's for the folks that are being vaccinated right now --

Mr. Pallone. In terms of the distribution.

Dr. Lakey. The distribution system?

I think where we are right now folks are titrating up those groups. I think they base that on their capacity as a State. What were the resources? What was their history with delivering vaccine? And then they use those systems.

And so you have -- public health is structured many different

ways across the United States. And they use that uniqueness of their system, who they could reach the quickest, in order to determine their priority groups, using the same basic philosophy trying to get pregnant women, young kids, health care workers from the beginning, but then how they message that and adjusted that was dependent on what that State system was.

Mr. Pallone. All right. Thank you. Thank you, Mr. Chairman.

Mr. Stupak. Mr. Shimkus for questions, please.

Mr. Shimkus. Thank you, Mr. Chairman; and thank you to the panelists for being here.

We have spent a lot of time on adjuvant and how it boosts this. But I want to focus a little bit on the nasal spray. And so, Dr. Machielse, I know in your written and opening statements you mentioned the -- I guess it's intranasal technology and the ability to get 80 to 100 versus 1 through 7 doses. Can you explain that to us and why that's -- I mean, if we're talking about needing a lot of doses, from the layman's point of view it sounds like a good thing to be focusing on.

Mr. Machielse. I can explain it. I think there are two reasons for that.

One is, I think we at MedImmune, we develop our own seed strain; and using the reverse genetics we can quickly screen multiple variants of the vaccine and select for growth properties immunogenicity. So, for instance, for the H1N1 vaccine, we

basically screened 23 variants and did not lose any time; and we were in commercial production at scale on July 3rd.

I think the other important factor is -- so we were able to actually immediately create an H1N1 strain which produces as much as we have seen in the past.

And then the other advantage of the live attenuated technologies is it is actually sprayed in the nose. The virus replicates there and creates an immunoresponse. So if you compare it to the inactivated vaccine you need a very, very small dose. Maybe if you compare it from -- let's call it quantitative burst -- a factor of 50 or lower. So I think that is a very important attribute, to actually consider this technology as part of pandemic preparedness. And I could tell you we have manufactured over 100 million bulk doses, and we could easily have gone up to 200 million doses by -- bulk doses by the end of this year.

Mr. Shimkus. And what piqued my interest was also some of the comments when Chairman Pallone got into the discussion a little bit in the nasal spray issue is not for pregnant women. But there's a lot of other -- I mean, the other two groups, there would be no prohibition for them, is that true?

Mr. Machielse. That's correct.

Mr. Shimkus. I think he mentioned a school that didn't want to do nasal spray.

Mr. Machielse. I think that we are not -- you know, we do not have pregnant women in our label and we cannot administer the

intranasal spray to that population. But the majority of the risk population is covered by the intranasal vaccine. So I think what's also very important is that there is enough education to actually objectively make people aware of the choices available in the flu vaccination technology. Because maybe people now react on the intranasal vaccine, but it may be the same fear factor for the adjuvanted vaccine. And I think those assumptions in the public could be avoided by a targeted education campaign where it is emphasized that the safety and efficacy of the general vaccines available in the U.S. is good.

Mr. Shimkus. Thank you.

Dr. Lakey, the title of the hearing is An Update on Vaccine Production and Distribution; and when I initially read that I always think distribution is can a drug get from point A to point B. I think what a better title for this would have been in the decision-making matrix of who gets it. Not -- for me -- there is no distribution problem as far as you see when this is produced to delivery to an end point user, is there?

Dr. Lakey. For the most part, no. There is -- so that is in the private sector. It is manufactured, we order it, and it is shipped. That system seems to work for the most part. There have been weather events, et cetera, that have slowed that down, but for the most part that distribution system has worked.

Mr. Shimkus. What else do you think we need to do? Because you probably listened to the opening statements. My concern is,

if we can't get this right, how do we do something? What do we need to do to prepare ourselves better for H5 or something that could -- may turn out to be a bigger problem?

Dr. Lakey. Well, I guess I've learned through other events, such as hurricanes, et cetera, that you have to take time afterwards to critically look at what went well and what you could have done better and just learning from your experiences.

I think there's been good discussion today of what we can do to improve the availability of vaccine. I think making sure that we communicate effectively to individuals' real expectations and not set artificially high expectations. Because I think the general public will respond when we give them the right expectations.

Mr. Shimkus. And I agree.

My time is expired. Thank you, Mr. Chairman. Thank you, panel.

Mr. Stupak. Thank you, Mr. Shimkus.

Mr. Green for questions, please.

Mr. Green. Thank you, Mr. Chairman.

And, Dr. Lakey, I appreciate you being here and glad we got to meet earlier and appreciate what you've done for 3 years as the Commissioner of Health in Texas.

And I guess one of my interests is on the delivery system. Although our big issue here is why we don't have enough vaccines, obviously. And I know you experience it every day in Texas like a

lot of us hear from our offices. But one of the challenges you mentioned is associated with school-based clinics and vaccinations. And I notice in today's Houston Chronicle some of my school districts in the Houston area are actually doing it -- Alief, Humble. And I was wondering are you having any resistance from schools, particularly schools that have school-based clinics, to providing the H1N1 for their students?

Dr. Lakey. I think what you are seeing in Texas is a mosaic of different strategies working together to get individuals immunized. I think some schools -- there are school systems that have a lot of experience with school-based clinics, and those seem to work. There are other school systems that haven't done that well, haven't done it in the past.

There are some challenges, making sure that you get parental consent so you don't immunize a child that hasn't provided consent, the parents haven't provided consent, and other just logistical challenges.

There are folks that you have to have there to provide immunizations, et cetera. We are using some of the funds that were provided by Congress to be able to hire individuals to allocate that.

But all those things have to come together. So that's one part of our system. We're able to do that now in Texas because as we've titrated up the number of groups we've been reaching the high-risk individuals, you know, the children with asthma, et

cetera. And so we're now able to expand out to some of the healthy kids in our State.

Mr. Green. Can you tell us how public health emergency funds help you and other State public health departments set up and operate the H1N1 program?

Dr. Lakey. Excuse me again, sir?

Mr. Green. How the public health emergency funds that you receive help with that.

Dr. Lakey. The public health emergency funds came in three components, and they've been critical to our ability to respond.

The first part had to do with getting surveillance systems. Again, public health has been cut and so having feet on the ground in order to investigate cases, figure out whether it is H1 or not, that's been critical to hire those individuals.

We've been able to improve our laboratory capacity. Having the individuals in the laboratory to process samples, that has been a critical component of our system. We've been able to develop the vaccine ordering system in order to make sure that we have that technology in order to accomplish this.

About 81 percent of the funds that came in public health emergency response three we sent out to the local health departments so that they could hire the individuals to be able to respond.

Again there's been significant cuts at the local level in public health. A lot of those public health departments are

shrinking and can't provide that investigation, the delivery of vaccine, all those different manpower components without the funds that were allocated in order to hire those individuals.

RPTS COCHRAN

DCMN ROSEN

[2:45 p.m.]

Mr. Green. Dr. Levi, I know you released a report coauthored with the American Academy of Pediatrics that states that school age children are the population most responsible for transmission of influenza and has the highest rate of attack. That report also sites in 2005 a school-based pilot program in the State of Maryland where FluMist was administered to children in several Maryland secondary and elementary schools and the results were that the program showed significant reduction in respiratory illnesses within households of children who received these vaccines versus schools that do not participate.

It seems like that report, and I am sure there is other proof that shows school-based facilities, of course, with the parents' permission, but that making it available to parents is a successful way to deliver that.

Mr. Levi. Absolutely. And certainly using school-based facilities for both immunizations and the other types of health care are critically important. That is why there is some major provisions in the health care legislation that would expand that capacity. This is a tremendous opportunity to reach kids.

A lot of our pandemic planning assumed that kids would not be -- it would be more like seasonal flu and the elderly would be most vulnerable. As it turned out, young kids were the most

vulnerable. So if we had a strengthened school-based clinic and immunization program, we would certainly be in better shape today.

Mr. Green. Mr. Chairman, my last question actually is for the reason we are here, and it is to ask our producers of the vaccination, I know there has been a lot of discussion regarding benefits of new technologies to produce flu vaccines and the cell culture is the newest one. But I understand there is no difference, we wouldn't be producing faster vaccines using cell as compared to the eggs. And if each of you, as brief as you could, could respond to that, is there something we could do to make it quicker, whether it is eggs or the cell?

Mr. Hosbach. Cell culture is not a game changer, and I think I will steal that phrase from Tony Fauci. The game changer probably is something along the lines of a universal flu vaccine, which you could stockpile that covers all different variants of flu strains over the course of seasons. However, that is a long ways away.

In terms of saving time, whether it is cells or eggs, you are, again, dealing with Mother Nature. You have to adapt the virus to the system that you are utilizing. And perhaps with cells make you save 2 or 3 weeks. But in terms of capacity and overall production capacity, I don't think it is really a game changer. You get vaccine out there about the same time.

In fact, the two facilities we have based in the U.S., they have the potential to produce 150 million trivalent seasonal

doses. If you convert that to a monovalent, that is 450 million doses of an H1N1 type vaccine. So there is plenty of capacity right here on U.S. soil with the one new facility and our existing facility.

What we really need to look at why aren't we immunizing as many people as we should be immunizing on a season basis, when 36,000 people die every year and 200,000 people are hospitalized. We have recommendations from the ACIP that 275 million people should be immunized on an annual basis. We are lucky to immunize 100 million people.

If you want to sustain influenza immunization, production, development of new technologies, we really need to make sure we get more people immunized for the benefit of public health and for sustaining our manufacturing capabilities.

Mr. Green. Okay. So the capacity is here, whether it is production in the United States, and I know we have one production in Australia, which is fine. But we have the capacity to produce 400 million vaccines?

Dr. Narasimham. I think there is an important dynamic here for this vaccine. What we saw with the avian influenza is that an unadjuvanted 15 microgram dose was not sufficient. In fact, many manufacturers thought it took 90 micrograms, right, which is six times as much, which means that the supply collapses.

So as the only manufacturer here that actually produces cell-culture-based vaccines, we actually have two licensed cell

culture vaccines now in Europe. We are producing it for Europe, unadjuvanted and adjuvanted, seasonal and pandemic. And what our belief is with cell culture, you get some speed gain. Our expectation is a little different view is that it is on the order of 6 to 8 weeks, but it is not massive. I mean, it is going to be on that range as to the gain you get with cell culture.

But as Dr. Machielse also mentioned, with reverse genetics and using some new technologies, cell culture allows you to actually meet the need of many of the changing viruses that are out there. The worst case scenario for the American public is you rely on a single technology, that technology doesn't work when it is a different influence a strain, and then suddenly you have a real crisis on your hand.

So I think it is a wise strategy to invest in multiple different technologies, simply because we don't know how anyone virus will behave.

Mr. Stupak. Quickly, because we have to get to Mr. Burgess. We have votes here soon.

Dr. Machielse. For us, you know, the eggs are working well. But I think if you can have the cell culture technology also available, it derisks the supply. In effect, if you have a really bad avian flu going around, it may affect the supply of eggs and those kind of things.

I think the scalability of cell technology is very critical, and I think especially if you think about the live attenuated flu

technology. We have a facility in Frederick, Maryland, with two 2,500 liter bio-reactors. With the cell culture inter-nasal technology, we could manufacture half a billion doses in that facility. If you think about the cost efficiency you could generate, I think the cell culture at scale could be a very interesting asset and guarantee or further guarantee supply of flu vaccine.

Mr. Stupak. Mr. Burgess, for questions.

Before you start, I should mention that you are one of the members that had written to myself and Chairman Pallone and asked for this hearing, along with other members. We appreciate it.

We will start with the questions.

Dr. Burgess. You are kind to point out that I didn't whine.

You just finished up on an excellent point, Doctor. Mike Leavitt came and testified here in, I guess it was 2005, that it was going to be very, very difficult to develop the number of eggs that would be needed to produce the vaccines if we culled all our chickens the month before.

Let me just ask a couple of questions of all four of our manufacturers, and I would appreciate brief answers. But when in the sort of timeline that has been going on since last April, when did you find out about the delay? When did you really appreciate we were a month behind?

Mr. Perreault. I will respond first. I think that we did not, because we did not participate in the pandemic RFP that was

put out by the U.S. Government a couple of years ago, our contract was a bit different. So we started the negotiation in May and finished in May, which is the fastest I have ever done a government contract, by the way, which was quite nice to see. And we had to submit at that time our schedule that we assumed, based on average yields, when we signed the contract.

Within 3 weeks, we could see that the virus was not growing well. So we started at the beginning of June, and we could see the seed strains we had were not developing. In fact, they were a half to a third of what we expected. Again, our expectations were set on 10 years of seasonal assays. But as all of the manufacturers here will tell you, each new flu season is a new flu season. You just can't tell. And I think you have a medical background as well, or are a physician, so you understand that.

But I think we knew right away. We had weekly conference calls with HHS and BARDA, and we informed them and put a new delivery schedule in July.

Dr. Burgess. So you did conference calls, and that would be in June?

Mr. Perreault. We communicated in June, and then put a new delivery schedule together in July based on our assumptions.

Dr. Burgess. What was Novartis' experience?

Dr. Narasimham. With Novartis, we saw the reduced yields in July. And I just would point out for clarity's sake, we actually can't confirm yields until we receive FDA reagents, and those

reagents were really made available in August. But with initial testing, we saw the reduced yields in July. We communicated our situation weekly with HHS, as did all the manufacturers.

Dr. Burgess. Well, MedImmune is different, but what about Sanofi Pasteur?

Mr. Hosbach. Actually, it is the same for us in terms of realizing we first started out on a very conservative estimate in terms of yield of the virus, and it actually was about 60 percent of what we thought it was going to be, even on a conservative number. And we had weekly phone calls with BARTA-HHS and schedules were revised all throughout the way periodically as we gained new information.

Dr. Burgess. Well, I am a little concerned, because I had some conversations in August with CDC and NIH and was given assurances that when school started, we would be well on our way to having, depending upon the approval process, well on our way to having satisfactory doses by mid-October. And that was kind of the timeline that I was laboring under.

Let me ask you a question. In the end of October, Secretary Sebelius at a Senate hearing said she was going to put out a call to the manufacturers to accelerate production, but I am going to assume you had already done so at that point, is that correct? Is there anything you did differently as a result of that call?

Mr. Perreault. At CSL, what we did is when we did receive the call, we took another look at our ability to fill and finish

vaccine. Producing the antigen is one piece of it. Then you have to actually get it into a formulation and put it either into vials or syringes.

Our manufacturing plants for fill-and-finish of flu vaccine are inside plants that produce other therapies. So our CSL business includes protein plasma therapies for rare diseases. So we had to adjust our lines and our manpower in order to see if we could free up some manufacturing slots, and we did that.

Dr. Burgess. You did that as a result of the call on October 29th?

Mr. Perreault. We were evaluating all along the way, but that was also a call to reinforce what we had been discussing with BARTA.

Dr. Burgess. Let me just ask any of the manufacturers, was it problematic for you that you were at the point where you were gearing up for the seasonal flu and suddenly had this H1N1 task added to the equation?

Dr. Narasimham. I think it was just a compression of the timelines. We had to complete our seasonal flu, at least for the case of Novartis, complete our planned season flu doses, which was what we were requested to do, and then we started in our case H1N1 in July, which obviously brings us to have a very short timeframe, a short runway to sort of get the plane off the ground.

Dr. Burgess. But still there has been difficulty getting seasonal flu vaccine out. I know our community has been lacking

for several weeks. Are we back on schedule with the seasonal flu?

Dr. Narasimham. In our case, we completed our seasonal deliveries in early October.

Dr. Burgess. Completed them. But the House physician here is out, for example. My Wal-Mart back home is out. I know I could get the MedImmune, and I should do that. But for the other vaccine, in our area it has been harder to come out. I know Dr. Lakey may know more about what difficulty we are encountering there.

Let me just ask MedImmune, on the issue of adjuvants, are there adjuvants that you use with your attenuated live virus?

Dr. Machielse. We don't use any adjuvants.

Dr. Burgess. Because your yield and the method of immunogenicity is such that the yield is so high?

Dr. Machielse. It is live virus, and basically it replicates in the nasal cavity. You don't need an adjuvant.

I just want to highlight that we completed our seasonal manufacturing also in time and were even able to accelerate it to free up more manufacturing capacity for H1N1.

Dr. Burgess. Thank you.

Dr. Lakey, let me just ask you, because Texas has had some problems, and some of them made their way into the front page of the newspapers. But when did you learn that Texas was going to be having some difficulty delivering on the vaccine shipments?

Dr. Lakey. I think we learned as vaccine was coming out that

it wasn't what we had anticipated. So in early October, as I recollect, was when we figured out that what we were being told we were going to get was not what we had been told in the past.

Dr. Burgess. Do you feel that CDC and HHS shared information with you in a timely fashion?

Dr. Lakey. We have had multiple calls with the CDC and the Office of the Secretary of Preparedness and Response, and they showed predictions, but a lot of them changed pretty quickly.

Dr. Burgess. Now, have they been helpful in helping you adapt to the change in the vaccine availability?

Dr. Lakey. The CDC has been very helpful to us in the State of Texas when there have been issues that have arisen. We have called them individually. We have conference calls two times a week with their leadership, with all the State health officers, to discuss issues and to have a question and answer time period. So they have been available and have answered questions.

Dr. Burgess. And how about the manufacturers themselves? Have they similarly responded with information when you needed it, or do your communications go directly through CDC?

Dr. Lakey. My communication would go through the CDC. The manufacturers would discuss that information with the CDC. So there hasn't been a direct conversation between State health departments and the manufacturers.

Dr. Burgess. And you and Mr. Pallone talked a little bit about funding. Do you get the feeling that the level of funding,

the \$1.5 billion, was not satisfactory? Do you have an idea in mind of what would bring us to a level of funding that would be satisfactory?

Dr. Lakey. So this is for the funding right now? The Association of State and Territorial Health Officials talked to State health officers to figure out what they think they would need. That survey thought that about \$800 million would need to be available in order to continue this response through March.

Some State health departments are in better shape than others. Some, I believe about half of them, are predicted to run out of their FIR funding by the end of this year. So, again, State health departments are in different situations, but when we have tried to look at this systematically throughout the United States, the number was about \$800 million to get all State health departments through the end of this pandemic.

Dr. Burgess. Now, you have indicated to me that you see the number of cases has actually diminished over what it was even just a few weeks ago, and yet we are coming up to the holiday season between Thanksgiving and Christmas. People will be traveling a great deal in this country. I just remember my days in the clinics, you would typically see a great increase in viral syndrome around Christmastime and the weeks shortly after.

Now, could we anticipate a resurgence of the number of cases toward the end of the year because of the amount of travel people are going to be doing?

Dr. Lakey. That is correct. So, as a State, we monitor the percentage of visits to physicians that are for influenza-like illness. We peaked in Texas around 13 percent. We have gone down to about 7 percent. But the nature of pandemics is they occur in waves and we predicts there will be a third wave. The challenge will be how that third wave corresponds to the seasonal flu. Do we hit one and then the other, or do we have seasonal flu on top of H1N1, which would be a challenge for State health departments.

Mr. Stupak. Mike, I have to wrap it up.

Dr. Burgess. Just as a final thought. We are right next door to Mexico, which is where this began a year ago. Is there any thought what might be happening to the evolution of the pandemic in Mexico? Will they be on their second, third or fourth wave around February or March, around the same timeframe this was introduced last year?

Dr. Lakey. I don't know if I can intelligently answer that. I think we predict they are going to have an additional wave. I think what we have -- one of the challenges for us is there correspondence between the severity and socioeconomic factors? So in poorer areas of our State or in poorer countries, do we have more significant disease. So we are wrestling with that currently.

Dr. Burgess. It definitely impacted us last year. When they became ill, we developed symptoms very quickly in our State.

Dr. Lakey. Infectious diseases do not respect borders. It

came across our border very rapidly, and throughout the southern part -- the hardest part of Texas, the part of Texas that was hit the hardest, was our southern border. If you look at our fatality rates, et cetera, there is a significance difference of our border versus the rest of our State.

Dr. Burgess. Thank you, doctor.

I yield back, Mr. Chairman.

Mr. Stupak. Just to summarize, we are going to have votes in a few minutes, and we will finish up with the panel and finish up this hearing.

Dr. Lakey, it is fair to say we are going to get another wave of this H1N1? Right now, it seems like we are at a calm before the storm. Is that because there is more vaccines out there, or what is it? We are going to get hit again, are we not?

Dr. Lakey. I am not sure if it is -- there is probably several factors interacting. One, the natural history of pandemics coming in waves, and I think that is what we are seeing. And you will see differences across the United States. Activity is decreasing in Texas, it is rapidly increasing in other parts of the State, in the New England part of the Nation.

But the natural history of pandemics is they occur in waves. So our goal as we vaccinate individuals is that we can blunt that third wave, and that is why it is not too late to immunize individuals. Even though this wave is decreasing, we need to block the third wave.

Mr. Stupak. So as Mr. Burgess said, as we move about during this holiday season of Thanksgiving and Christmas, that could spread it in areas that have not seen the intensity we have seen in other parts of the country.

Dr. Lakey. As we get into the colder season, as people are more inside, as the humidity changes, as the environment is more conducive to the spread of infectious diseases, it is likely there will be additional spread.

Mr. Stupak. And then we could very well have the seasonal flu on top of it?

Dr. Lakey. Exactly, sir.

Mr. Stupak. Okay. Let me ask you this question, just to summarize. It is my understanding from listening throughout this hearing there really was a pretty good cooperation with the government in working this one out between communications, coordinations, and even moving some contracts fairly quickly. Is that fair to say?

I mean, usually we are on the government, but it sounds like this time actually all the preparedness they have done for a pandemic has actually worked out fairly well. Is that fair to say?

You are all nodding your head "yes."

Mike, any other questions before we close it down? Wrong question to ask.

Dr. Burgess. I am disturbed because Secretary Sebelius did

indicate to us we would have the doses that we needed. And, again, my calls to the CDC and HHS, although they were off the record in August, yes, I got the information that they had studied what was happening in the southern hemisphere, it wasn't as bad as what they thought, but there were certain populations that would definitely be at risk, but not to worry, we would have the vaccine done and approved and in the hands of providers certainly by mid-October.

At that point, the fear was what if it is worse when the school year initiates on the first of September and we have to push this stuff out the door before the clinical trials are finished at the end of September. So I am still uneasy about all of that timeline.

My very first statement on this was when I had that very first conference call, I was worried that we were going to underestimate the severity of this virus, and, I mean, it is just incumbent upon us to constantly stay vigilant and not get complacent about our ability to fight it off.

Mr. Stupak. There is no doubt we had rosy forecasts from the Secretary that has not held true. But I think between the low egg production of the virus and the condensed timeline and the great demand, it probably has led to the frustrations that we all feel, and that is the purpose of this hearing, to get to it. And I think we learned from this panel and the previous panel.

But overall, I think the government cooperation in working

together and trying to resolve this has been pretty good, probably above par.

So with that, let me conclude this hearing.

That concludes all questioning. I want to thank all of our witnesses for coming today and for your testimony. The committee rules provide that the members have 10 days to submit additional questions for the record.

That concludes our hearing. This joint hearing of the Health and Oversight and Investigations Subcommittee is adjourned.

[Whereupon, at 3:06 p.m., the subcommittees were adjourned.]