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EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO SEASONAL INFLUENZA

TUESDAY, FEBRUARY 3, 2015

House of Representatives,

Subcommittee on Oversight and Investigations

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:02 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Tim Murphy [Chairman of the Subcommittee] presiding.

Members present: Representatives Murphy, McKinley, Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, Cramer, Upton (ex officio), DeGette,

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Schakowsky, Castor, Tonko, Clarke, Kennedy, Green, Welch, and Pallone (ex officio).

Also present: Representative Ellmers.

Staff present: Charlotte Baker, Deputy Communications Director; Sean Bonyun, Communications Director; Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Brittany Havens, Legislative Clerk; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Emily Newman, Counsel, Oversight; Alan Slobodin, Deputy Chief Counsel, Oversight; Peter Bodner, Democratic Counsel; Elizabeth Letter, Democratic Professional Staff Member; and Nick Richter, Democratic Staff Assistant.

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Mr. {Murphy.} Good morning. Today we convene the first meeting of this session of the Subcommittee on Oversight and Investigation of the 114th Congress. I welcome back Members who served here last session, particularly, my friend and colleague, Diana DeGette, the Ranking Member from Colorado, and the new members from the 114th Congress, which we hope, as we come up, you may introduce them today, and I will introduce ours on our side.

The Subcommittee is here to examine a very serious U.S. public health response to seasonal influenza. America is experiencing a severe flu season with an unstable predominant strain that could result in one of the deadliest and costliest flu seasons in recent memory. An estimated 50,000 people will die. Over 200,000 will be hospitalized, and most of these will be senior citizens.

Last February, when public health officials needed to decide what strains would go into this year's seasonal flu vaccine, the FDA bet on the wrong predominant strain. Just a few weeks after the FDA's decision, doubts already were already beginning to creep in the scientific community about

the FDA's decision. By September, the U.S. vaccine was such a poor match for the dominant strain of flu that the World Health Organization, with consultation from the CDC, revised the vaccine formula, but not for the United States. It was changed for the southern hemisphere nations. In other words, the American people were stuck with a vaccine that wasn't going to work for nearly 4 out of 5 people, and for nearly 9 out of 10 seniors. Despite a growing body of knowledge that the vaccine for the United States would not be effective, production went forward anyway for a number of reasons that we hope to discuss today.

With a mismatched strain, this year's vaccine is estimated to be only 23 percent effective. It is even lower for the elderly at 12 percent. While this season's vaccine has lower-than-usual effectiveness, CDC is still recommending vaccination for everyone 6 months or older. In addition to vaccination, CDC has also recommended that all high-risk patients should be treated with antiviral drugs as soon as possible when influenza is suspected.

So what are agencies doing to communicate with the public? Many are choosing not to vaccinate against the flu

because they hear the vaccine doesn't work, so why bother. We are seeing a similar result with measles vaccinations but for every--but for very different reasons, and now we are paying the piper for more than 100 cases have been stricken with a disease of measles that had once been eradicated from our shores.

False rumors still exist that vaccines and a preservative for multi-dose vaccines, which once used a microscopic amount of mercury as a preservative to prevent bacteria growth, led to autism. There is no credible evidence to support that claim. In fact, mercury is not used as a preservative in the MMR vaccine, and in developing nations where vaccination rates have increased, autism rates have not changed. So in addition to understanding why this year's flu vaccine missed so badly, and what should be done to protect the public in future years, I hope we can use this platform to educate the public and advance vaccine development in the interest of public health.

Now on to the flu vaccine. We must know: Did the federal government do everything it could at the right time to respond to the challenge of this year's flu season? As I

noted, the CDC knew in late September that there was a significant mismatch, as great as 50 percent, with the U.S. vaccine, however, the CDC did not issue a health advisory in response to this mismatch until more than 2 months later. Did the CDC make the right public health decision to delay the health advisory, especially on delaying a recommendation to treat high-risk patients with antivirals? Could vaccine manufacturers have developed a new vaccine for high-risk groups? The CDC and the FDA tell us that the significant change in the strain could not have been addressed any earlier than September 2014, way too late to make changes in the U.S. vaccine. However, one flu expert at the University of Utah School of Medicine has stated on the record that there was a pretty good indication that the drifted strain by April or May 2014, that probably would have led to a decision to change at that time if strain selection decisions for manufacturing were made in May instead of February.

In hindsight, it was a bad decision, and thousands will die. Surely there are lessons to be learned here to do something different in the future, and we want to know how we can partner with these agencies to come up with some

solutions.

In 2009, when there was a similar outbreak of the swine flu, federal agencies declared a public health emergency and responded by producing a monovalent, or single strain, vaccine to protect the public in a short time. In only 12 weeks, they had developed this new vaccine. Here, we must know, was a monovalent rescue vaccine targeting the drifted strain a possible response? Who made the decision to not go forward with a different vaccine? If not, was this partly because the FDA and other agencies lacked emergency authority to respond? Did they recognize the problem and ask for authority to respond quicker? If an astounding 50,000 deaths and 200,000-plus hospitalizations does not equal an emergency then what is? Shouldn't we be treating this problem with more urgency, and is there even a backup plan in the event a vaccine mismatch to a deadly strain exists?

HHS has set a goal for vaccines to vaccinate 70 percent of their population as part of the Healthy People 2020 initiatives, but overall vaccination rates in the U.S. have been around 45 to 46 percent in the last few years. CDC has not even met its target of 50 percent. Does the CDC have an

effective strategy to increase vaccination rates, or is there a better strategy for reducing flu deaths than seeking further increases of vaccination rates in all sub-groups?

So we are here today to challenge some of the policies and decisions, but in the spirit of us all working together to make improvements in the public health response to seasonal flu. I am encouraged by the potential of ongoing research and innovation. We appreciate the cooperation and attendance of these excellent witnesses from the CDC, the FDA, NIH and BARDA. We need your input to help us decide how we change this system for the better. I welcome our witnesses today, and thank them for help in this inquiry.

[The prepared statement of Mr. Murphy follows:]

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Mr. {Murphy.} And I recognize the ranking member for 5 minutes.

Ms. {DeGette.} Thank you so much, Mr. Chairman. I am really happy that our first hearing of this new Congress is on an area of bipartisan concern and interest. And I want to join you in welcoming our new members on both sides of the aisle to this committee. This is a venerable committee that has a long history of bipartisan investigations, and I think it is going to be a really important year to continue this trend.

Flu preparedness and response is incredibly important, and this committee has a long hearing--history of hearings and investigations on this issue. What we need to do is come together in support of a strong public health infrastructure that prevents outbreaks, and responds quickly and appropriately when they occur.

These past several months have been a harsh reminder that infectious disease is all around us. Last October and November, this subcommittee convened hearings on the Ebola outbreak and the dire situation in West Africa. We saw and,

frankly, continue to see, the deadly consequences of a breakdown in the public health infrastructure there. Fortunately, we are now seeing the lowest number of new Ebola cases since last June, largely because of international efforts both to build and operate effective Ebola treatment centers, and also education of local populations on Ebola prevention and control. But, you know, it is interesting because as much attention as we have given to Ebola in this country, far more people die every month from influenza than they do of Ebola, and this is a continuing problem.

This month, we are hearing about the measles outbreak which was linked to Disneyland in California, and has now spread to at least 14 states. Infectious disease experts at the CDC and the State Health Departments have mounted a fast an aggressive response to prevent this highly contagious disease from spreading.

And, Mr. Chairman, I know you have received a letter from me and Ranking Member Pallone and Ranking Member Green on--asking this committee to hold a targeted hearing on the measles outbreak, and the urgent public health threat. I would like to make a copy of that letter part of the record,

Mr. Chairman.

And, you know, while that letter is pending, and I want to commend you, Dr. Fauci. I saw you on the news last night telling all of the families in America to get their measles vaccine, and I really appreciate that. I want to add from this podium, as the mother of two daughters; one of whom is immunocompromised, vaccinate your children against measles. There is no reason not to, and there is every reason that they could be a threat to themselves and other children if they don't get that vaccine. So I just want to pile onto that. It is very, very important.

But on to the flu, which is the topic of this hearing, the predominant strain of flu is H3N2, which is resulting in increased hospitalizations, particularly for vulnerable populations like seniors and young children. And the CDC announced several weeks ago that the flu vaccine has only 23 percent effectiveness. That is significantly lower in private--in--than in recent years, and as the chairman mentioned, it is largely due to changes in the virus that have resulted in a mismatch between the strain of the virus used in vaccine production and the one actually circulating.

But even with a 23 percent effectiveness, we still need to protect ourselves as much as we can. Dr. Frieden recommend-- reminded us several weeks ago that even a vaccine with 23 percent effectiveness will still prevent millions of people from getting sick. And so, therefore, as the chairman said, people also need to get this vaccine. And it is not too late; flu season is still going on. We have to do everything we can to protect our vulnerable populations; young children, seniors, pregnant women, and others with compromised immune systems.

So I am looking forward to hearing from our wonderful witnesses today about what we can do to mitigate the effects of this flu season, and how doctors and hospitals are prepared to respond. I also want to look to the future. What can we do to inform our prevention and response efforts in future flu seasons? I want to hear about the research and technological developments in diagnostics, antiviral treatments and vaccines.

In our last hearing on this topic in February 2013, we heard about FDA approval of quadrivalent vaccines and cell base technology. Today, I am hoping our witnesses can give

us encouraging news about the development of a universal flu vaccine.

So regardless of the particular effectiveness rate in a given season, the flu vaccine remains the best tool that we have to protect as many people as possible, and we need to have ongoing work on that. This flu season reminds us that it is almost impossible to predict what the strain will be, but it underscores the importance of a strong public health infrastructure.

And so, Mr. Chairman, I just want to say I appreciate the witnesses coming today. I hope we can all work together to move the country toward better flu preparedness.

[The prepared statement of Ms. DeGette follows:]

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Mr. {Murphy.} I thank the gentlelady. And now recognize the chairman of the full committee, Mr. Upton, for 5 minutes.

The {Chairman.} Well, thank you, Mr. Chairman.

This is an important issue, that is for sure, and it has been an especially harsh flu season, and preliminary estimates show that this year's vaccine is only 23 percent effective in preventing folks from going to the doctor for treatment, even lower for high-risk groups, which is often the case I know.

Usually, the flu vaccine is about 50 to 60 percent effective, and I, like many folks back in Michigan and across the country, would like to see this--see us do better in addressing this major public health threat.

Every year, between 5 and 20 percent of Americans get the flu. In a severe flu season like this one, there could be more than 50,000 deaths, over 200,000 hospitalizations, and more than $10 billion spent on direct medical costs. The flu is and should be a top priority for all of U.S. public health.

This year's vaccine, we know, is less effective because it is not a good match for the flu strain that has become dominant. The flu virus strain changed significantly during the 6 months after the strain selection decision for the U.S. was made. The World Health Organization, in September, recommended changing the flu vaccine for the southern hemisphere to use in their upcoming flu season that starts in April but by the time the change in virus was evident, it was too late to change the U.S. vaccine.

Now, it is worth pointing out that the CDC continues to recommend vaccinations in the U.S., even with a lower effectiveness, and that high-risk patients should be treated as soon as possible with all antiviral drugs.

When we learned that there was a shift in the virus, what options were available to respond to the mismatch in viruses? Was there a way to deploy a rescue vaccine targeting just the changed virus? Was there a way to improve the effectiveness of this year's vaccine by adding substances to boost the immune response? Those are some of the questions that we need to have answered as we proceed with this hearing.

And I appreciate the folks that are testifying today and yield to Dr. Burgess and then to Marsha Blackburn.

[The prepared statement of Mr. Upton follows:]

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Mr. {Burgess.} I thank the chairman for yielding. And, Mr. Chairman, thank you for holding the hearing today.

In fiscal year 2014, the estimated federal investment in seasonal flu preparedness exceeded $850 million. The public-private partnership striving research and development has had successes but we must do better.

First, communication between agencies and with the public must improve. If there is a mismatch in the vaccine, which became apparent in May or even as late as September, it is unacceptable that advisories were not issued until December. Second, there must be transparency and consistency in the regulatory pathways for innovation in vaccines. Experts have recognized the promise of--in vaccines for over a decade, yet not one is licensed in the United States, and no guidance has been issued. Third, greater emphasis must be placed on modernizing the development of manufacture of flu vaccines. I would add my acknowledgement to the ranking member of the subcommittee, I too at one time was promised a universal flu vaccine, I think in this committee at a hearing just like this. That was probably in 2004, 2005. We are

still waiting. We want to see it.

So I appreciate the opportunity to be able to speak on this. I look forward to hearing from our witnesses.

And I will yield the balance of the time to Mrs. Blackburn, Vice Chair of the full committee.

[The prepared statement of Mr. Burgess follows:]

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Mrs. {Blackburn.} Thank you, Mr. Chairman. And I want to continue our conversation about vaccinations. And, yes, we are talking about flu today, but there is another issue out there and Ms. DeGette mentioned this. Vaccine politics injected into 2016, measles outbreak infects politics and debate.

Now, this is far too serious an issue to be treated as a political football. People still die from measles. And the CDC Web site tells us it was eliminated from the U.S. in 2000, but yet we are seeing this outbreak. And I have to tell you, it is of tremendous concern to me as a mother and a grandmother. I am hearing so much about this from my constituents, and they want to know some answers, they want to know how you all are addressing this. And I will tell you, when I hear about counties in California that have lower immunization rates than the Sudan and Chad, this is something that is of concern to me.

I am a Rotarian. We have invested decades into eliminating and wiping out polio, and then to hear this about the U.S., I am concerned.

We know the measles outbreak started in California. It has affected over 100 people in 14 states, and that most of those people were not vaccinated. So we do want to veer off and ask you some questions in this realm today.

And I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. {Murphy.} The gentlelady yields back.

And now--who is the--

{Voice.} Pallone.

Mr. {Murphy.} Recognize Mr. Pallone. You are down there. Mr. Pallone for 5 minutes.

Mr. {Pallone.} Thank you, Mr. Chairman, and thanks for holding this hearing today.

I have to tell Ms. DeGette that this is actually the first time that I have been a member of the O&I subcommittee, so I am very happy.

Ms. {DeGette.} And we are happy to have you, Mr. Pallone.

Mr. {Pallone.} Thank you.

Mr. {Murphy.} Welcome aboard. It is the best subcommittee in Congress.

Mr. {Pallone.} Thank you. So this year, we are seeing a severe flu season. Across the country, hospitalization rates are higher, especially for seniors over age 65, and for young children, and public health experts predict these flu activity levels will continue and even increase in the next

few weeks.

The Centers for Disease Control and Prevention continues to recommend that we all get the flu vaccine. Initial estimates show that this year's flu vaccine is 23 percent effective, meaning that 23 percent of those vaccinated for the flu will still have to visit a doctor because of the flu. But despite being less effective this year than the recent past, flu shots will still protect against and decrease the severity of flu-related illnesses. Moreover, flu shots don't only protect the vaccinated, they also protect those who have not been vaccinated from getting sick, and as members of Congress, I think we all have to play a role to ensure that message gets out and it is not too late to get your flu vaccine.

This hearing is also a good opportunity to talk about how we can improve vaccination rates. We took important steps in the ACA to provide coverage for preventative services like immunizations. Since the law went into effect, nearly 76 million Americans have received no-cost coverage for preventative services, and as millions more receive coverage through the ACA, we hope to see the vaccination rate

improve so that we can realize the benefits of a better-protected population. However, we still must improve public awareness, and continue to improve access to these preventative services. This is especially of concern as we hear reports of the measles outbreak that began at Disneyland, and is now spreading throughout the country. Just yesterday, the President urged all parents to get their children vaccinated against measles, and I would certainly echo his comments.

Dr. Tom Frieden, who heads the CDC, is warning that the U.S. could see a large outbreak of measles. There are now over 100 cases in 14 states, and measles is extremely contagious, 90 percent of those exposed to the disease will be infected unless they have been vaccinated. According to Dr. Frieden, there has been growing evidence that more parents are not vaccinating their children against measles, and that these lower vaccination rates have led to the latest increase in measles cases. The CDC is further assuring families, and parents especially, that the measles vaccine is safe and effective, and we were able to eliminate measles in the U.S. in 2000, largely because of a highly-effective

vaccination program. So it is important to reiterate that measles is a preventable disease for which there are safe, effective and available vaccines.

So I look forward to hearing from our public health officials today about how we can improve vaccination rates for the flu, but we also need to learn how we can improve vaccination rates for the future for other infectious diseases, including measles.

I know that Ms. DeGette mentioned that both herself and Mr. Green and myself sent a letter yesterday asking for a hearing with regard to the measles public health emergency, and I hope that we can actually see that occur. I think it would be very important. And I just want to thank everyone.

And I would now yield the balance of my time to Representative Castor.

[The prepared statement of Mr. Pallone follows:]

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Ms. {Castor.} Well, thank you for yielding the time, and good morning. Thank you, Mr. Chairman and Ranking Member DeGette, for holding this important hearing to better understand the flu and the flu vaccine.

Vaccines are incredibly valuable tools to protect and improve the health of all of our neighbors. And as we have seen with the recent and surprising measles outbreak, vaccines protect lives. According to reports, there have been 102 cases of measles reported across 14 states, and those who do not vaccinate their children are putting them at risk, and they are putting others at risk. Vaccines are safe and effective.

I want to give particular thanks to Dr. Schuchat from the Centers from--for Disease Control for traveling to the Tampa Bay area a few months back to raise awareness with another important vaccine, the anti-cancer vaccine of HPV. Thank you for meeting with our public health students, and cancer--anti-cancer advocates to explain. See, Florida had one of the lowest rates of HPV vaccines, and we can save lives and prevent cancer if people will understand the

443 importance of the HPV vaccine. Your visit was a great boost
444 to our efforts to prevent cancer through the HPV vaccine, so
445 thank you again for the work you do to educate the public on
446 vaccinations.
447 You know, we are so fortunate to live in America where
448 we have studied and investigated and tested all of these
449 vaccines to ensure that they are safe and effective. So
450 thank you to all the panelists for all the work you do, and I
451 look forward to your testimony.
452 I yield back.
453 [The prepared statement of Ms. Castor follows:]

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Mr. {Murphy.} Thank you.

I would now like to introduce the witnesses on the panel for today's hearing. We are--first is Dr. Anne Schuchat. Did I pronounce that correctly? The director of the National Center for Immunization and Respiratory Diseases at the Center for Disease Control and Prevention. Dr. Karen Midthun is next, is the director for the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. Dr. Robin Robinson, the director of Biomedical Advanced Research and Development Authority, otherwise known as BARDA, within the Office of the Assistant Secretary for Preparedness and Response. And Dr. Anthony Fauci is the director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. I welcome you all here and we look forward to your testimony.

I will now swear in the witnesses.

You are aware that this committee is holding an investigative hearing, and when doing so, has the practice of taking testimony under oath. Do any of you have any objections to testifying under oath? Seeing no objections,

the Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today? Everybody has said no. In that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. {Murphy.} Thank you. You are now under oath, and subject to penalties set forth in Title XVIII, section 1001 of the United States Code. You may each now give a 5-minute summary of your written statement. Make sure you pull the microphone close to you, and watch that red light.

Dr. Schuchat, you can begin.

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^TESTIMONY OF DR. ANNE SCHUCHAT, DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION; DR. KAREN MIDTHUN, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; DR. ROBIN ROBINSON, DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DR. ANTHONY FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH

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^TESTIMONY OF DR. ANNE SCHUCHAT

} Dr. {Schuchat.} Good morning, Mr. Chairman, and members of committee. I am Dr. Anne Schuchat, Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention.

Influenza virus is a formidable adversary. Influenza's propensity to change presents unique challenges. New flu vaccines must be developed each year based on the predictions

of which viruses are likely to be most common during the next season. Vaccine development is complex and time-consuming, typically requiring vaccine candidates that grow well in eggs and provide immunity in humans. And while we tackle seasonal flu, we must conduct constant global surveillance and prepare for the emergence of dramatically changed or shifted influenza virus that could trigger the next pandemic.

Over the past decade, we have made significant improvements in our ability to detect, prevent and respond to influenza, yet, despite our improvements, the current severe influenza season has been difficult. My colleagues and I represent agencies that work together to respond to seasonal and pandemic flu. The NIH supports research on vaccines, diagnostic tools, and antiviral drugs for seasonal and pandemic influenza. The Food and Drug Administration regulates influenza vaccines, convening public health and influenza disease experts to recommend which influenza virus strains should be included in FDA-licensed vaccines.

The Biomedical Advanced Research and Development Authority, BARDA, supports advanced research, development and procurement of innovative medical countermeasures to address

manmade and emerging infectious diseases, including influenza pandemics. And at CDC, we support surveillance and diagnostic capacity to rapidly detect, prevent and respond to annual influenza epidemics, and novel and pandemic influenza threats.

Our CDC systems provide the scientific basis for global vaccine virus selection for seasonal flu, vaccine as well as for pandemic vaccine stockpiling. We monitor for genetic changes in the flu virus, and identify how these changes affect disease transmission and severity. We build public awareness and provide our knowledge about prevention and early treatment, and support public sector delivery of routine and emergency immunizations.

The 2014/'15 influenza season has proven a particularly bad season. The virus that is predominant, H3N2, is associated with more severe disease. The vaccine we are using is not well matched to circulating H3N2 strains. Antivirals can be important aids in some patients, but clinicians are underutilizing them.

How do we find ourselves with vaccine that isn't well matched to the circulating H3N2 viruses? When the 2014/'15

flu vaccine strains were selected last February, the drifted virus we are seeing now was not yet detected. A small number of these drifted viruses were first detected in March 2014, and CDC continued to monitor them throughout the summer, looking for genetic patterns and geographic spread.

In September 2014, when we began promoting seasonal vaccination, about 1/2 of the H3N2 viruses circulating were like the vaccine component. When the influenza season took off at the end of November, only 1/3 of the H3N2 viruses CDC detected were like the vaccine component. Our early vaccine effectiveness estimate found people vaccinated had about 23 percent lower risk of influenza infection requiring a medical visit. While this is lower than we usually see, the vaccine is providing some protection.

Influenza viruses follow their own schedules, not ours. New strains can emerge at any time. Some appear and die out, and others persist and spread. Our actions are proportional to risks. We work year-round to detect and characterize viruses of concern that circulate globally, monitor their emergence and geographic spread, and develop viable vaccine candidates for drift viruses as they occur. When we detected

relatively small numbers of the drifted H3N2 strain late last spring, CDC began preparing candidate vaccine virus strains.

As the Nation's public health agency, we are committed to provide the information people need to protect their patients' and families' health, and to be transparent in our assessments and the evidence base that supports our recommendations.

As a physician and a public health professional, I too wish we could guarantee better protection each year, yet, we have made significant advances on several fronts. Our surveillance network is characterizing more viruses with improved methods. Significantly more Americans get flu vaccine each year, and information on viruses, disease and vaccination is released more rapidly.

In closing, this flu season has caused more suffering and serious disease than many previous years, and there will be more challenging seasons ahead, but collaboration across the agencies, and with our public and private partners, holds promise for the future, including progress toward development of universal influenza vaccines, since better, broader, and long-lasting protection could transform our approach to this

challenging virus.

[The prepared statement of Dr. Schuchat follows:]

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Mr. {Murphy.} Thank you.

Dr. Midthun, you are recognized for 5 minutes. Thank you. Make sure the microphone is turned on and it is close to you. Thank you. You still have to turn it on. Press the--there you go.

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^TESTIMONY OF DR. KAREN MIDTHUN

} Dr. {Midthun.} Thank you. Mr. Chairman and members of the subcommittee, I am Dr. Karen Midthun, Director of the Center for Biologics Evaluation and Research, the center within FDA that is responsible for regulating vaccines. Thank you for the opportunity to be here today to discuss our role in a highly collaborative, multi-partnered effort in preventing influenza through vaccination in the U.S.

Influenza viruses continually undergo changes in their genetic makeup, and the resulting proteins that interact with the immune system. Due to these continuous changes, the composition of influenza vaccines must be periodically updated so that they are effective against what are anticipated to be the predominant circulating viruses in the upcoming influenza season.

The strains of virus in the vaccine include 2 distinct subtypes of influenza A, H1N1, and H3N2, and 1 or 2 influenza B strains, depending upon whether the vaccine is trivalent or quadrivalent. To identify virus strains likely to cause

illness during the upcoming season, the World Health Organization convenes influenza and public health experts to study recently circulating influenza viruses from around the world, and recent global disease patterns. After careful evaluation of the assessment, WHO makes recommendations on the composition of the influenza vaccines, usually in late February for the upcoming season in the northern hemisphere, and in September for the upcoming season in the southern hemisphere. The recommendations must be made months in advance because of the time required for manufacturing, testing, release and distribution of a very large number of vaccine doses.

Each year, following the WHO recommendations, FDA convenes its vaccines and related biological products advisory committee, typically in late February or early March. The committee considers the WHO recommendations and reviews information regarding viruses that caused illness in the previous year, how these viruses are changing, and disease trends. Based on the data available at the time of the meeting, the committee makes recommendation for the composition of the influenza vaccines licensed by FDA for the

upcoming season in the U.S. Once the strains are selected, candidate influenza viruses that are adapted for high growth are generated and accepted by WHO collaborating centers, and are provided to manufacturers who generate the seed viruses for manufacturing vaccines. The manufacturing demands are tremendous and the timelines are tight. No other vaccine is produced, FDA approved and distributed every year across the U.S. within a six-month time frame.

This season, more than 150 million doses were manufactured. Given the yearly need for a new vaccine, there is limited flexibility in the timelines of vaccine manufacturing and availability. And parallel with vaccine manufacturing, FDA develops and calibrates reagents which are used by both FDA and the manufacturers to test vaccines for potency and identity before FDA approves the new formulation for distribution. Manufacturers submit their vaccine testing results, along with samples from each lot, to FDA for lot release. As FDA releases lots, the manufacturers can make these lots commercially available throughout the U.S.

In February 2014, when the strain selection recommendation for the correct influenza season was made, it

reflected the circulating viruses. The drifted H3N2 viruses were first detected in March 2014 and were uncommon. Over the ensuing months, the drifted strains gradually increased. By late September, when WHO made its recommendations for the 2015 southern hemisphere influenza vaccine, the drifted H3N2 strains were common, prompting a recommended change in the upcoming southern hemisphere vaccine composition. Because of the manufacturing time required, there was not enough time to make a similar change to the current northern hemisphere influenza season. The drifted strains have caused the majority of influenza cases this season, however, vaccination is still important to prevent disease and minimize the public health burden of influenza. Influenza vaccines contain three or four influenza viruses, so even when there is a less than ideal match or a low effectiveness against one virus, the vaccine may protect against the other viruses.

FDA has made progress in our preparedness efforts and collaboration with BARDA, CDC, NIH, manufacturers, and other stakeholders, and we thank Congress for your support of these efforts. New influenza vaccines have been licensed, including cell-based, recombinant protein vaccines and

quadrivalent vaccines. To enhance pandemic preparedness, FDA licensed an adjuvanted H5N1 avian influenza vaccine, and has worked with U.S. Government partners and manufacturers to facilitate the development of candidate vaccines directed at H7N9 avian influenza. Surveillance efforts are more extensive than ever before, and offer the potential for early detection of emerging viruses. The number of candidate vaccine virus strains available to manufacturers has greatly increased over the last few years, providing them with more options to increase vaccine yields. We continue efforts with our government partners to develop high-yield candidate vaccine strains, as well as more modern, faster testing methods for vaccine potency and sterility. To further address the challenges presented by the constantly changing nature of influenza viruses, scientists and government laboratories, academic institutions, vaccine manufacturers, are all working to develop new generation vaccines that might provider longer-lasting and broader protection against influenza viruses, including drifted strains. Although these development efforts are still in early stages, some may have the potential to increase and broaden protection against

influenza.

FDA will continue to work with its government partners, manufacturers and other stakeholders to facility development of new vaccines, and identify methods that have the potential to speed the manufacturing process for existing vaccines. Our goal is to better protect the American public against influenza.

Thank you.

[The prepared statement of Dr. Midthun follows:]

********** INSERT 2 **********

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Mr. {Murphy.} Thank you.

Now, Dr. Robinson, you are recognized for 5 minutes.

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^TESTIMONY OF DR. ROBIN ROBINSON

} Dr. {Robinson.} Good morning, Chairman Murphy, Ranking Member DeGette, and distinguished members of the subcommittee. Thank you for the opportunity to speak with you today. I am Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority, of the Deputy Assistant Secretary for Preparedness and Response, as well as a former developer of influenza vaccines in industry.

BARDA is a federal government agency mandated to support advanced research and development, and procurement of novel and innovative medical countermeasures such as vaccines, therapeutics, diagnostics and medical devices for the entire Nation to address the medical consequences of manmade and naturally-occurring threats like the H1N1 pandemic in 2013, H7N9 influenza outbreak, and the current Ebola epidemic.

Pandemic influenza is one of our primary concerns. We understand that preparedness for pandemic influenza is directly tied to seasonal influenza. Medical countermeasures

for seasonal influenza underpin the vaccines, antivirals and diagnostics used for pandemic influenza. BARDA has invested in the advanced development of medical countermeasures that have utility for both seasonal and pandemic influenza preparedness.

BARDA transitions medical countermeasures from early research and development at NIH, to advanced development toward FDA approval and potential procurement. BARDA has funded and successfully managed the advanced development of more than 60 medical countermeasures for pandemic influenza. More than 20 of these medical countermeasures for influenza have been FDA approved, with 6 receiving approval in the last 3 years, as Dr. Midthun indicated. Additionally, BARDA developed and procured vaccines and antivirals used in the 2009 H1N1 pandemic, and stockpiled vaccines for preparedness against H5N1 and H7N9 viruses. BARDA, through partnerships with NIH, CDC and FDA, industry and academia, has met and overcome many, but not all of the challenges inherent to making medical countermeasures associated with seasonal and pandemic influenza. Specifically, BARDA, with our partners, has made major progress in the following pandemic areas.

First, modernization of influenza vaccine manufacturing through the development and licensure of new cell- and recombinant-based influenza vaccines, and antigen-sparing pandemic vaccines with adjuvants towards meeting our strategic goal of more and better influenza vaccines sooner. These new vaccines were part of our successful H7N9 response in 2013.

Second, shortening influenza vaccine manufacturing time by weeks, effective through the Influenza Vaccine Manufacturing Improvement initiative, as recommended by PCAST, to optimize the generation of high-yielding vaccine seed strains, and alternative potency and sterility assays. Many of these improvements, such as biosynthetic technology, were employed during the H7N9 vaccine response in 2013, which was the fastest on record.

Third, establishment and maintenance of pre-pandemic influenza vaccine stockpiles for H5 and H7N9 viruses that may be used to immunize tens of millions of persons at the onset of an influenza pandemic with these viruses.

Fourth, and last, multi-fold expansion of domestic pandemic influenza vaccine production capacity, afforded by

retrofitting of older manufacturing plants, building new state-of-the-art manufacturing facilities for making 21st century influenza vaccine, and establishing three centers for innovation and advanced development and manufacturing, with rapid, nimble and flexible manufacturing capabilities through public-private partnerships with industry.

The new national infrastructure responded in 2013 to the H7N9 outbreaks, and today, in the Ebola epidemic. Despite these significant accomplishments, our pandemic preparedness work is not over. Making a more effective influenza vaccine remains a significant scientific challenge. Indeed, progress towards more effective influenza vaccines has been noted in recent years, but much more is needed.

Going forward, there is reason for hope that more effective influenza vaccines may be within our grasp. The discovery of new influenza viral targets within the last 4 years has renewed interests and efforts to develop new universal influenza vaccine candidates.

Developing more effective pandemic influenza vaccines is one of our top priorities, and BARDA will support new methods based on evolutionary biology that may help forecast in

selection of new seasonal and pandemic influenza vaccine strains.

In parallel, we are launching this month an initiative to support advanced development of new, more effective influenza vaccine candidates that may elicit greater, broader, longer immunity in all populations against divergent influenza virus variants, and that may serve as primers for pandemic influenza vaccines.

In conclusion, influenza viruses with pandemic potential continue to evolve and change, infect animals and man, and pose significant threats to global and domestic public health. This year's limited seasonal influenza vaccine effectiveness, and the arrival of the first human case of H7N9 virus in North America underscore our urgent need to complete this mission. To be better prepared, our Nation must continue to invest in domestic pandemic preparedness, and work with key global partners.

I thank you for this opportunity to discuss how we can be better prepared for seasonal and pandemic influenza, and I look forward to your questions.

[The prepared statement of Dr. Robinson follows:]

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Mr. {Murphy.} Thank you, Dr. Robinson.

Dr. Fauci, you are recognized for 5 minutes.

|

^TESTIMONY OF DR. ANTHONY FAUCI

} Dr. {Fauci.} Mr. Chairman, Ranking Member DeGette, members of the committee, I appreciate the opportunity to discuss with you today very briefly the role of the National Institute of Allergy and Infectious Diseases in research addressing both seasonal and pandemic influenza.

As shown on this slide, the NIH research agenda is really based on the traditional approach that the NIH has taken with all diseases, namely fundamental basic research, clinical research and field research, the provision of research resources both to the academic community, as well as to the biotech and pharmaceutical companies. The endgame is to ultimately produce interventions in the form of diagnostics, therapeutics and vaccines. You have heard about the diagnostics and therapeutics. We can talk about them a little bit later. I want to focus the remainder of my remarks on a subject of obvious importance; namely, the development of influenza vaccines.

Traditionally, the classic, what we call, platforms or

the way you develop the vaccine, have been based on growing the virus itself either in eggs, which is somewhat cumbersome, or more recently using it in cell lines, which are a bit more predictable. You either have an inactivated live vaccine, or a--excuse me, a live attenuated vaccine or an inactivated vaccine, and that has been the traditional approach towards vaccines. It is cumbersome, it takes a long period of time because you have to grow the virus.

Our researchers, both at the NIH and our grantees and contractors, over the last several years have been attempting, with some success, to make a conversion to what we call a recombinant DNA technology, molecular-based approach that would obviate the need to actually continue to grow the virus to make a vaccine. Several of these are illustrated on this slide. We don't have time to go into each and every one of them, but they are particularly suited to develop a vaccine that we are all hoping for, and that Dr. Burgess mentioned in his 5-minute remarks, and that is a universal influenza vaccine.

This is the cover of a Nature Medicine article that I wrote with my colleague, Dr. Gary Nabel, the former director

of the Vaccine Research Center, namely, how we can induce what I called unnatural immunity; namely, immunity that a normal vaccine induction or the virus itself doesn't induce, and that is broad protection against subsequent exposures to different types of influenzas that have a tendency to drift over a period of years, and sometimes to even shift, which gives us a pandemic.

Now, the reason we can do this, and I just want to point out on this slide, on the lower right is a blown-up schematic of the influenza virus. The proteins that coat the outside are referred to as hemagglutinin, and that is where we get the H for H3, H2 or H1. It is a designation of a major protein. The other one is N for neuraminidase. But notice how those proteins are clustered on the surface of the virus, so that what the immune system sees generally is just the top, what we refer to as the head or the bulb of that protein. If you look at this slide, that head is where most of the antibodies that protect you and I against influenza are made. That is the good news. The sobering news is that is a variable region, which tends to change as influenzas drift from season to season, and change an awful lot when it

goes to a pandemic.

If you look at the little stem, the thin part of that protein, that the immune system doesn't see very well, interestingly, we found out several years ago that that is the part--that is what we called highly conserved. It doesn't change from necessarily a Texas H3N2 to a different type, a Singapore or a variety of others, they stay the same, which means that if you can induce an immune response against that unchangeable one, you might be able to get what we call a broader reactivity. And over the last several years, we have made considerable progress and--let me go back here--as shown on this slide here, where a number of candidates have used molecular techniques to essentially show the body predominantly the part of that protein that doesn't change. And there are a number of ways of doing that. Instead of giving the body the entire virus, either killed or attenuated, by molecular techniques, you show the body only the part that you want it to respond to, unencumbered by the physical structures that don't allow the body to see it. And we now have done this in several candidates in mice, in ferrets, and what we call phase one studies in humans, which

means we know it is safe, we know it can induce the kind of response that is more broad, and in collaboration with BARDA, we are now starting to produce that to go into larger trials. And as Dr. Burgess said, we are not there yet, but we are clearly many steps further than what we were the last time I testified before this committee.

So I will stop there, and be happy to answer any questions.

[The prepared statement of Dr. Fauci follows:]

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Mr. {Murphy.} Thank you.

I will now recognize myself opening questions for 5 minutes.

But let me just start off, and I know that a lot of concerns about vaccines and autism. As a psychologist, I have seen many a child with autism. It is a deeply concerning problem with the families. Past publications have been discredited, and data was deemed fraudulent. Multiple studies said there is no link between developmental disorders such as autism and vaccines.

I want to ask each of you, do you agree, Dr. Schuchat? Dr. Midthun, do you agree? Dr. Robinson, do you agree? Dr. Fauci, do you agree? And--yeah, you can say this verbally. Should parents have their children vaccinated? Dr. Schuchat?

Dr. {Schuchat.} Vaccines save lives and are the best way for parents to protect their children--

Mr. {Murphy.} Yeah, right.

Dr. {Schuchat.} --from vaccine-preventable diseases.

Mr. {Murphy.} Dr. Midthun, yes or no? Yes?

Dr. {Midthun.} Yes. I have three children and they

were all vaccinated on time with all the recommended vaccines.

Mr. {Murphy.} Dr. Robinson?

Dr. {Robinson.} Absolutely.

Mr. {Murphy.} Dr. Fauci?

Dr. {Fauci.} Definitely.

Mr. {Murphy.} Okay. Now, let us talk about--moving into this one. Dr. Schuchat, flu expert, Dr. Andrew Pavia at the University of Utah School of Medicine, said, ``By April or May, there was good evidence of the drifted A/Switzerland strain. It wasn't clear it was going to be a dominant strain, but there was a pretty good hint, we probably would have chosen the vaccine differently.'' Dr. Schuchat, do you agree that there was good evidence of the drifted strain by, say, April or May of this last year?

Dr. {Schuchat.} We were certainly keeping a close eye on this drifted strain last May, and that is when the CDC began to develop a candidate vaccine virus, but as you know, it can be very challenging to develop candidate vaccine viruses, and to take it from a candidate to all the way to production of vaccine, all the way to production of hundreds

of millions of doses of vaccine.

Mr. {Murphy.} But by May, there was evidence of a 17 percent mismatch. Do you think that 17 percent mismatch was a concern at that point, and were there any discussions about that at CDC?

Dr. {Schuchat.} Yes, there were. In fact, in March, we started to reach out to the global community, the international WHO collaborating centers, when we saw the first handful of this drifted strain to ask others were they seeing it.

I think it is important to realize that strains emerge and can disappear, and in the spring, it is very difficult to know which ones will still be around in the summer or fall. We actually respond to these new drifted strains by working on candidate vaccine viruses, but it is very difficult with influenza to predict what strains will dominate, whether it is going to be an H3N2 year or a 1--H1N1 year. And so we continue to go through the routine seasonal flu work while we are also developing the candidate vaccine virus--

Mr. {Murphy.} Well, let me ask about this pattern. We have here, I am looking at the mismatch notes, by March there

is about a 10 percent mismatch drift, by May, 17 percent. We understand by September it was already up to 50 percent. Do we know in these gaps of April or June or July or August what those drift rates were? Was there a problem by those times that was being seen?

Dr. {Schuchat.} Yes, we have information for the summer. It is important to remember that there is very limited influenza circulating here in the U.S. in the summer, and it takes off in the fall. That is one of the reasons we do global worldwide surveillance--

Mr. {Murphy.} Sure, but right here--

Dr. {Schuchat.} --and we have greatly increased the numbers there.

Mr. {Murphy.} But here in September, a decision was made for the World Health Organization to change this for the southern hemisphere. And so I am wondering because--big gaps here, were there discussions between all your agencies that we ought to be doing something differently or--other than telling people to have some kind of an antiviral medicine.

Dr. {Schuchat.} Thanks. I think it is important--Dr. Fauci talked about the idea of drift and the idea of shift,

and I think the members remember in 2009 where, in the spring of 2009, we did decide it was important to go forward with a monovalent vaccine--

Mr. {Murphy.} Right.

Dr. {Schuchat.} --against a pandemic. We think of pandemics as having catastrophic risk because they generally are defined by a new strain that the population has no protection against at all. It is so differing from--

Mr. {Murphy.} But you could do that fairly quickly during that--the issue of the Swine--from 2009. Once it reached this level where we are now only 23 percent effectiveness, and about 12 percent for senior citizens, a high-risk group for death, for mortality and morbidity, why not move forward at this point with at least a monovalent strain for high-risk groups and high-risk geographical areas?

Dr. {Schuchat.} The time between developing a candidate vaccine virus, which we started working on in May, and the ability to have a lot of doses is about 6 months. So it really wouldn't be available--

Mr. {Murphy.} So--but you did it in 12 weeks in 2009.

Dr. {Schuchat.} The large amounts of vaccine were only

available in November in 2009, after having really started in May.

Mr. {Murphy.} But you did it in a much shorter time, but not the 6 months. My point is, when you identify somebody that is going to have that level of mortality and morbidity, and it can be done in a short period of time, were your agencies talking with each other and says--clearly, a decision was made in September, hey, for the southern hemisphere, we need to change that, but for the northern hemisphere it says let us keep going with what we have, recognizing that it is only effective for 1 out of 5 people and 1 out of 10 seniors. It seems to me that you need a different decision-making process.

Dr. {Schuchat.} Thanks. I think another point that is important to make is the difference between the laboratory mismatch and the clinical protection. In 2003/'04, we had a laboratory mismatch. It turned out that when we measured clinical protection, protection was about 50 to 60 percent in different populations. So seeing that in the lab in that hemagglutinin inhibition testing that there is drift or that there is a difference between the strain and the vaccine, and

the strains that are circulating, doesn't perfectly predict how the vaccines will work in practice. So I think it is very important to differentiate that decision to make a monovalent vaccine against a pandemic where we know there is not going to be the widespread protection because people haven't seen the strain before, and where it is a race against time in terms of the--although it is challenging with current technology, the value of trying to make a vaccine is worth it.

Mr. {Murphy.} I am way over time. I need to--

Dr. {Schuchat.} By which--okay.

Mr. {Murphy.} --pursue other members.

Recognize Diana DeGette for 5 minutes.

Ms. {DeGette.} Thank you very much, Mr. Chairman.

Well, following up on the chairman's question, Dr. Schuchat, would it be fair to say, and this--really yes or no would work here, would it be fair to say that the way we are going to be able to substantially reduce the time between when we identify a strain and developing the vaccine will be what Dr. Fauci is talking about, which is development of new platforms and ways to get the vaccine?

Dr. {Schuchat.} Absolutely.

Ms. {DeGette.} Now, Dr. Fauci, I want to turn to you because, over the years, you have come and talked about the development of these vaccines. I remember when we had a hearing in this committee when we were trying to move from the egg to the cell vaccine. And now you say you have the cell techniques, but you also say that you are getting ready to go into larger clinical trials on these new platforms, is that correct?.}

Dr. {Fauci.} That is correct, Ms. DeGette. The important point is that we really think that anything that needs to grow the virus--

Ms. {DeGette.} Right.

Dr. {Fauci.} --and produce it just is a time sync. So that is the point that I made on the--

Ms. {DeGette.} Right.

Dr. {Fauci.} --slide.

Ms. {DeGette.} No, and we actually, even those of us who only took high school biology, understood that point.

Dr. {Fauci.} Yeah.

Ms. {DeGette.} So--

Dr. {Fauci.} Yeah.

Ms. {DeGette.} --good work again. But what I want to know is now that you have done your phase 1 trials, and you are trying to move beyond that, what is your time frame for that?

Dr. {Fauci.} Well, you know, it is going to really depend on, first of all, testing it in a season to show that even though you don't specifically have it against this particular strain, that it is covering that strain. So when you are trying to prove universality, you want to test it in a season in which it is a broader response. One of--

Ms. {DeGette.} Right.

Dr. {Fauci.} Yeah. One of--

Ms. {DeGette.} So would that be like next season--

Dr. {Fauci.} Well, we--

Ms. {DeGette.} --do you think?

Dr. {Fauci.} --we actually are going to try now with the--in collaboration with BARDA, to make enough of that new concept to be able to test it--

Ms. {DeGette.} Test it in this season.

Dr. {Fauci.} --in the following season.

Ms. {DeGette.} Dr. Robinson, you are--

Dr. {Fauci.} Following season.

Ms. {DeGette.} --you are nodding your head, yes. Is--

Dr. {Robinson.} Yeah, the following season.

Ms. {DeGette.} Okay. So what can Congress do to help you with that? Do you need additional resources, do you--what do you need to be able to start to expedite that research?

Dr. {Fauci.} Well, I mean, obviously, you ask a scientist if they need resources, the answer is an automatic kneejerk--

Ms. {DeGette.} Well--

Dr. {Fauci.} --of course we can do better with more resources, but we actually need your continued support to keep the focus on the need for this, because when we do these tests, remember, it isn't--we don't have control over the companies that make the contracts with the various--

Ms. {DeGette.} Right.

Dr. {Fauci.} --health organizations that distribute this, but I think the focus that this committee has continually put on this has been very helpful to us.

Ms. {DeGette.} Now, in your written testimony, you talk about the difference between seasonal flu and pandemic flu. Can you briefly explain that to us?

Dr. {Fauci.} So I mentioned in my oral testimony a few moments ago that viruses tend to--influenza viruses tend to change slightly. We call that a drift.

Ms. {DeGette.} Right.

Dr. {Fauci.} Right.

Ms. {DeGette.} Every season.

Dr. {Fauci.} That is a little bit. Now, if it changes slightly, even if you don't get the vaccine match right, there is enough background immunity in the community against similar viruses that the vast majority of the population are not going to have a catastrophic outbreak where people would be completely unprotected.

Ms. {DeGette.} Right.

Dr. {Fauci.} When you have an influenza that has what we call a shift, not a drift, that means major changes, so when you look at the general population, the overwhelming--

Ms. {DeGette.} Right. They don't have that.

Dr. {Fauci.} --majority don't have any background

protection. So it is almost as if you are totally naïve to this new--

Ms. {DeGette.} And that is what happened in--

Dr. {Fauci.} --virus.

Ms. {DeGette.} --2009 and 2010.

Dr. {Fauci.} Indeed. The bad news, it happened in 2009. The somewhat comforting news that it wasn't a particularly varied--

Ms. {DeGette.} Right. Exactly. And that is what we--

Dr. {Fauci.} --virus. So we--

Ms. {DeGette.} --were worried about.

Dr. {Fauci.} --were lucky.

Ms. {DeGette.} So, Dr. Robinson, now, you said in your testimony that there remains significant technical challenges before a substantially better influenza vaccine is available, and I would assume that the biggest concern for both of you gentlemen, well, for all four of our witnesses, would be that if we don't develop that significantly better vaccine system, and we get a virulent pandemic flu, is that right, Dr. Robinson?

Dr. {Robinson.} That is right. I mean as Dr. Fauci

pointed out, we actually have new ways to actually look in making these vaccines by looking at a different potion of one protein. We normally make the vaccines against the hemagglutinin and our immunities to that, the head of that, and now we can actually look at the stalk which we are making these candidates. We may be able that way to protect against many different drifted strains, and serve as a primer for a pandemic so that you have one dose of this, so you only need one dose of pandemic vaccines instead of maybe two.

Ms. {DeGette.} Yes, and so what we are concerned about, or what I am concerned about, what keeps me awake at night, is if we don't do enough, both Congress and also our research institutions, to be able to have that vaccine available if we get a virulent pandemic flu. Dr. Fauci, and--

Dr. {Fauci.} So another important point besides the fact that all of the issues, the advantages of this universal flu vaccine, namely, molecular biology rather than growing--

Ms. {DeGette.} Right.

Dr. {Fauci.} --the critical issue is if you--if we get it right, you could actually stockpile it.

Ms. {DeGette.} Right.

Dr. {Fauci.} So we wouldn't have to worry about the chart that the chairman put up about it changing and trying to keep up with it--

Ms. {DeGette.} Right.

Dr. {Fauci.} --because if you stockpile it, you could stockpile it the same way you stockpile polio vaccine, measles vaccine, et cetera. That is really the endgame.

Ms. {DeGette.} Thank you. Thank you very much, Mr. Chairman.

Mr. {Murphy.} Thank you.

Now recognize Mrs. Blackburn, Vice Chair of the full committee, for 5 minutes.

Mrs. {Blackburn.} Thank you, Mr. Chairman. And as I said earlier, I want to focus on measles because we are hearing so much about this. And bear in mind, I have a daughter who has two children. They are in kindergarten and pre-K, and I can tell you, and I am sure you all and your teams, are fully aware that a lot of the mommy blogs are focused on this issue right now. And it is a big issue with our constituents.

And, Dr. Schuchat, let me come to you first. I just

want to be sure what we are--what the known knowns are about the measles virus. If you would elaborate for just a second. We are hearing 102 cases, that out of these only five had a vaccination against measles. Do you know what the rate is how they are affecting elderly as well as children? If you will give us just 1 minute on this.

Dr. {Schuchat.} Yeah, the--so far, there have been 102 people from 14 states that have developed measles in 2015. There are another 11 cases of measles from the end of 2014 that were linked to the Disneyland outbreak. Not all of the 102 cases this year are linked with Disneyland, but the majority are.

The majority of people in these outbreaks so far have not been vaccinated. Only a small number have--are known to have been vaccinated. Important to remember that there are about 20 million measles cases around the world each year, and so measles is literally a plane ride away. When it gets into communities like the United States now, in certain pockets where a lot of people are unimmunized, it has a chance to spread. And so that is why California is really, you know, working day and night to follow every lead and put

an end to it there. And that is why the health departments in every state are really on alert right now.

Mrs. {Blackburn.} Okay. Let me ask you this. As a physician, and a representative of our Nation's public health agency, if you are talking to a parent, should they be more fearful of the disease, measles, or the measles vaccine?

Dr. {Schuchat.} Every parent wants their child to be healthy and safe, and I absolutely respect that. As a physician and as a public health expert, I can tell you the measles, mumps, rubella, or MMR, vaccine is very effective and very safe.

Measles can be serious, and I would hate for a parent to think that everything will be fine, and have a bad outcome with their child. So I strongly recommend people talk with their physicians and get the right information, but personally, I would definitely have my child vaccinated.

Mrs. {Blackburn.} Thank you.

Dr. Fauci, same question to you.

Dr. {Fauci.} Same answer from Dr. Schuchat. I--there is no doubt, if you do a risk/benefit of the vaccine versus the disease, I think it is very, very clear that you have one

of the most highly-effective vaccines against any virus, and you have a highly-contagious disease, measles, that can have serious complications, so to me it is really a slam dunk what the decision would be.

Mrs. {Blackburn.} So if it were you child or grandchild, you would say vaccinate?

Dr. {Fauci.} Without a doubt, and I have done that with my three children.

Mrs. {Blackburn.} Excellent. Thank you, sir.

I--Dr. Robinson, I am going to let you off the hook today. I usually have quite a group of questions for you. So--but I--and I do, I have some questions on Tamiflu and on the stockpile and the shortage, and--but as one of my researchers from Vanderbilt told me this weekend, we don't always get the flu right, and had a way of terming how we go about looking at this. I am going to, in the interest of time, submit these and would love a response from you.

And I yield back.

Mr. {Murphy.} Thank you. Gentlelady yields back.

And now--

{Voice.} Mr.--

{Voice.} Mr. Pallone.

Mr. {Murphy.} Mr. Pallone is recognized. Thank you.

Mr. {Pallone.} Thank you, Mr. Chairman. I wanted to start out with Dr. Midthun. I am concerned about the low flu vaccine rate for children. By November 2014, only 42 percent of children between the ages of 6 months and 17 years have been vaccinated for the flu, and I think we need to change this. And, of course, the measles outbreak raises more concerns about childhood vaccination. Yesterday, I--we mentioned that Ms. DeGette, Mr. Green and myself called for a separate hearing on the outbreak, and the importance of vaccination to prevent the spread of measles.

I am sorry, actually, my question is of Dr. Schuchat. What can we do to increase childhood vaccination rates, both for the flu and for other infectious diseases?

Dr. {Schuchat.} You know, I think that parents' decisions to vaccinate their kids are often related to their sense of the threat and their sense of the value of the intervention. And we are so fortunate in this country that our disease rates have been quite low, that many parents don't realize these diseases are still out there, and that if

their children aren't vaccinated, they will come back. So with the measles outbreak, I think most parents who weren't vaccinating didn't realize measles was still around and could be dangerous.

In terms of the value of the intervention, it is important for parents to have all the information they need about the safety, the effectiveness, the risks and benefits. It is important to me that parents know that the immunization system is deeply committed to transparency, to monitoring vaccine safety, to sharing information that--about risks when we determine them, and to updating our recommendations whenever there is new data. Right now, we know that the vaccines we are giving are saving lives and saving money. For each dollar we put in, we get about $10 back for the childhood immunization series.

So what we do to try to support and promote immunization is a strong public-private partnership between healthcare professionals, doctors and nurses, and pharmacists, and community groups and consumer groups, to get information where it is needed, when it is needed, in many different formats. We know that most people trust their doctors and

nurses more than they trust me or other public figures, and so we really try to support the doctors, nurses, pharmacists, that are that frontline.

Mr. {Pallone.} Well, thank you. Let me continue with you. I know that the flu activity began in early December, and continued to increase through the end of 2014. Has the flu activity peaked for this year or--and what data do you evaluate to make that determination?

Dr. {Schuchat.} We are well along in the season, but it is difficult to say whether there will be a long tail or not. In many areas it is flattening off but not deeply declining yet. And sometimes later in the season, we see another strain increase. We have had many seasons where one of the H1N1 or H3N2 starts off the season, and one of the B strains will be quite common later on. So we are not out of the woods. It is important for people to be thinking about this. And we particularly want people to know that if they develop flu-like symptoms, and they are pregnant or they are very elderly, or have other immuno-compromising conditions, early treatment with antivirals could be very helpful to them. So let--they should speak with their clinician.

Mr. {Pallone.} All right, let me go back now. I did have a question of Dr. Midthun. The flu vaccine comes in different forms. There is the high-dose shot recommended for seniors, a quadrivalent nasal spray recommended for young children, and a recombinant trivalent, I don't know if I am pronouncing it right, recombinant trivalent shot recommended for those with egg allergies. How do you communicate to different groups about the variety of vaccines, and can the greater number of options for vaccines increase the rates?

Dr. {Midthun.} As you point out, there are a number of different options now, and what we try to do is really communicate clearly the information that we provide on our Web site in our package inserts as to what groups were studied and for which age groups the product is indicated. So, for example, the high-dose vaccine you were referring to was actually evaluated in individuals 65 years of age and older, and was shown to decrease the rate of influenza by 23 percent, relative to those who got the normal dose vaccine. And so--and likewise, quadrivalent vaccines are now available for four different manufacturers; three are inactivated and one is the live attenuated. They are indicated for somewhat

different groups across that spectrum, and again, that information is put forward.

The recombinant vaccine that you mentioned is--has only so far been evaluated and shown to be safe and effective in 18 years of age and above, and so again, our prescribing information will reflect that. But I think I should really turn to Dr. Schuchat because that is really the advisory committee on immunization practices, which is an advisory committee for the CDC that then recommends how these vaccines should be used.

Dr. {Schuchat.} And just briefly, we recommend people get vaccinated with the vaccine that is available. And so while providers and pharmacists get all that information about the different types, it is much more important to get a vaccine than to worry about which one is there.

Mr. {Pallone.} All right, thank you. Thank you, Mr. Chairman.

Mr. {Murphy.} Thank you.

Now recognize the vice chairman of the subcommittee, and welcome aboard as vice chairman, Mr. McKinley of West Virginia.

Mr. {McKinley.} Thank you, Mr. Chairman. Just a quick observation as this--what I have heard and read in your testimony and done a little research is, this whole process designating which vaccine we are going to come up with in September just seems archaic. In fact, it seems more of a game of chance and probability. And by virtue of us continuing this process, erroneously now with this mismatch, we have 50,000 Americans who are going to die this year. 50,000 Americans. That is more than died in combat in Vietnam, over a decade in--of that warfare. And they are going to die because of a game of chance and probability.

I am just astounded by that. I wonder what better techniques can we use to predict ahead. And that leads me then to the second question perhaps, or maybe associated with that, is that the high-dose vaccine has been found to be 24 percent more beneficial to senior citizens, and you have a meeting coming up late in February and it is not on the agenda as a possibility for September. Could one of you explain just briefly why that is not on the agenda if it has been proven to be helpful for senior citizens?

Dr. {Schuchat.} Yes. Let me answer sort of both parts.

The high-dose vaccine is one of the licensed vaccines that is recommended, and the company that makes it doesn't make enough of it for all people 65 and over--

Mr. {McKinley.} Um-hum.

Dr. {Schuchat.} --but they have been increasing the production. So it is included in the September and February recommendations. The recommendations are really just which vaccines to--which virus strains to target, and then there are all these different formulations like high-dose.

The other thing I just wanted to comment on about is sort of the mismatch. I want to just point out that in the past 20 years, this is the fourth time that we have had an important mismatch between one of the circulating viruses and the vaccine and what dominates. So it is very disturbing when we have this and we have excess disease burden, but the vast majority of recommended strains have actually been on track. Even though, when we have a good match, a well-matched vaccine type, we have a lot of morbidity and mortality from influenza, and I think it is one of these diseases that we as scientists take very seriously, but the American public takes a bit for granted. So we wish that we

had more people vaccinated each year, and that we wish that people who need to get the antivirals would get them early, but we have work to do in terms of the medical community and the public--

Mr. {McKinley.} Thank you.

Dr. {Schuchat.} --and in having them take--

Mr. {McKinley.} Thank you, doctor. Is--

Dr. {Schuchat.} --it seriously.

Mr. {McKinley.} I want to build a little bit of background for the chairman and his chart. When it was discovered first in May, I guess it was, that--or March, there was some anomaly showing up. May, 17 percent, September, 50 percent. It was obvious there was a problem with it. So if I go back to Robinson's testimony, he said that they fulfilled the PCAST report recommended improving vaccine manufacturing to meet a national goal of making the first dose within 12 weeks. Now, yes, the--it would have taken to go to a national supply to go 6 months, which again, is a real concern about the production, and some of the techniques that we can use to reduce that--but if we could have produced a vaccine, knowing in September it was 50

percent, so September, October, November, the 1st of December, we could have had a modified drug, even if it is limited supply, that we could have tried--whether it is an antigen or a new virus, or--excuse me, a new vaccine entirely, wouldn't we--wouldn't you have recommended let us try this and see what--do trials, what the result is. Did we solve it. Can we do this in 12 weeks ago and--the next time. But--so my question, did you do it? Did you try to do anything to modify the vaccine that was wrong?

Dr. {Schuchat.} Um-hum. I want to stress that we were not--

Mr. {McKinley.} It is a yes or no, isn't it?

Dr. {Schuchat.} There were many activities taken to address the emergence of drifted strain, including preparing a candidate vaccine virus--

Mr. {McKinley.} Did you try and modify it?

Dr. {Schuchat.} The issue of protection is both what strains are dominant, what efficacy the vaccine has, and how many people can get the vaccine. So a highly-effective vaccine with very few doses available may not be as good as a moderate- or a low-efficacy vaccine and a lot of doses

available.

Mr. {McKinley.} I will take your answer--

Dr. {Schuchat.} I don't think that--

Mr. {McKinley.} --as a no, that you didn't try and--

Dr. {Schuchat.} No, what I am saying is that we did begin to prepare the candidate vaccine virus so that companies would be able to produce a vaccine against the drifted strain. This particular strain has been quite challenging to produce vaccines against.

Mr. {McKinley.} Thank you. 50,000 Americans die.

Mr. {Murphy.} Now recognize Ms. Castor for 5 minutes.

Ms. {Castor.} Thank you very much.

Dr. Schuchat, on average, maybe take the last 10 or 20 years, how many Americans suffer each year from influenza, how many are hospitalized, and how many die?

Dr. {Schuchat.} Thank you. Yeah, for the past 5 years or so, we have ranged between 19 and 35 million cases of influenza illness each year, between 110,000 and almost 600,000 hospitalizations each year, and 5,300 to 39,000 deaths attributable to influenza. Those are in the past 5 years. In that same period, the vaccination efforts we have

had have been reducing the full burden by about 16 to 17 percent. You know, we would have more disease, deaths and hospitalizations without vaccination, but it is not as high a prevented--

Ms. {Castor.} Um-hum.

Dr. {Schuchat.} --fraction as we see for measles, where we are preventing 99 percent, you know, of the disease. And that is partly because we don't have high coverage.

Ms. {Castor.} How many are vaccinated?

Dr. {Schuchat.} Well, we have gone from 19 percent of Americans getting vaccinated against flu, to 46 percent. So that is a big improvement, but it is not the majority yet. The other factor though besides the coverage is the effectiveness, and even in a good year, we are seeing vaccines that work about 60 percent efficacy, and so that is why we are very committed to the interagency work on developing vaccines that could have higher effectiveness, particularly in the most vulnerable populations.

Ms. {Castor.} And when it comes to the deaths, what age range? We know the elderly are more vulnerable, but what are the--

Dr. {Schuchat.} Yeah, you know, the vast majority of deaths are in seniors, but unfortunately, we do have children die every year. There is--more than 60 children have died so far this flu season, and I fear that is not going to be the end of it. So we know that statistics say if you are elderly, if you have medical immunocompromising conditions, if you are under 2, you have more chance of being hospitalized or dying from flu, but many parents can tell you that their child was perfectly healthy and they actually lost a child. So I really want parents and the general public to know to take flu seriously.

Ms. {Castor.} And this year, it is a particularly severe flu season with higher rates of hospitalization and mortality. This is especially worrisome for those vulnerable populations; children, the elderly, pregnant women, and others with weakened immune systems. Dr. Midthun, the severity of this year's flu can be partially attributed to the fact that it is an H3N2 predominant year. Tell us what that means in simple terms. The fact that this is an H3N2 predominant year. Dr. Midthun.

Dr. {Midthun.} I think oftentimes in H3N2 prevalent

years, there may be more morbidity and mortality, although I think it is very important to remember that all influenza can cause morbidity and mortality. H1N1 was responsible for 2 pandemics, 1918 and the one in 2009. And also B strains can be very serious, especially for children, and cause very serious outcomes. But Dr. Schuchat may want to add to that.

Dr. {Schuchat.} Yeah. Overall, the H3N2 serious years have higher total morbidity and mortality, but as Dr. Midthun says, the H1N1 has a predilection for younger people.

Ms. {Castor.} Uh-huh. So you were talking about the effectiveness of the current vaccine before this year's flu vaccine shows 23 percent effectiveness. I want to hear more about how we assess the flu vaccine effectiveness, and better understand this. How do we gather information on infections and mortality and then test for vaccine effectiveness?

Dr. {Schuchat.} One of the things that the investments in influenza have permitted, the resources that CDC has gotten over the past several years, is expansion of the systems by which we track influenza, and track influenza vaccine coverage, and track influenza vaccine effectiveness. So we have much better data today than we had several years

ago. We are able to provide estimates in the middle of the year of how many people have gotten vaccinated, as well as how well the vaccine is working so far.

We work with state and local health departments in the surveillance systems, and we work with academic university partners in measurement of influenza vaccine effectiveness, essentially, comparing people who have influenza laboratory-confirmed disease with others to look back at their vaccination history and basically quantify the vaccine effectiveness that way. We release our data every week on something called FluView. It is on our Web site. And so you can essentially look in October 3 and see the first information about the drifted strain. So every week as that comes out, you can follow what is going on. But in mid-January, in fact, we sped up the vaccine effectiveness estimates so that the public would know them as quickly as possible.

Ms. {Castor.} Well, I know I marched my whole office down to get the flu vaccine, but I think this is very important that people understand what the experts are saying today, that this mismatch, parents with children need to be

especially careful because of the predilection for younger folks. But in America, if we only have 46 percent, and that is kind of high watermark for flu vaccinations, we can do a whole lot better. So thank you very much.

Mr. {Murphy.} Thank you.

And now recognize Dr. Burgess for 5 minutes.

Mr. {Burgess.} Thank you, Mr. Chairman.

And, Dr. Schuchat, let me just pick up for a moment on what you were discussing with the vice chair of the subcommittee, Mr. McKinley. Now, you had a drifted strain that kind of appeared on the scene. The southern hemisphere designation is out of phase with what the viral--the vaccine release in the northern hemisphere, correct? So you had identified the drifted strain when the recommendation was made for the inclusion in the vaccine that was released in the southern hemisphere, is that correct?

Dr. {Schuchat.} The--yes, that is right.

Mr. {Burgess.} So why not then come forward with a recommendation for a booster shot or some additional protection for people in the northern hemisphere if we already were developing a different vaccine based on a

drifted strain for the southern hemisphere? Your neighbors to the north might have been interested in that, don't you think?

Dr. {Schuchat.} You know, the manufacturing capacity to respond in September to vaccine strain recommendations in large number of doses would get us a large number of doses probably February or so. So I mean Dr. Robinson might be able to comment a little bit more, but the ability for us to make a northern hemisphere recommendation for a vaccine in September, and have doses in time for the flu season, would be very low. And we take that type of step when we are worried about a pandemic, and I think the committee is raising the question of should we take that type of step when it is not a pandemic situation but a drift.

Mr. {Burgess.} We would like you to react with a little bit more clarity and be flexible when so many lives are on the line, as Mr. McKinley outlined. And I mean, look, we are dealing with a, what, a 40 percent uptake of the vaccine as it is. If people read the headlines and say only 1 in 5 are protected anyway, I would just as soon not get stuck.

Dr. {Schuchat.} Yeah.

Mr. {Burgess.} So I would think you, as an agency, you would want to have that flexibility and want to show utility for people that we are on top of this, we are working on this 24 hours a day, 7 days a week, 12 months out of the year. We are monitoring your health and your safety when it comes to the flu virus, and we can't be perfect every time, but when we are not, we are going to be there to help you stave off the effects. I mean, again, that is what I am hearing as a result of this hearing. And as Dr. Fauci acknowledged, we have had these hearings before. We had a hearing when we only had a trivalent vaccine, and we talked about a quadrivalent vaccine. I mean these things, they are important, people do pay attention to them. Our vaccine rates for influenza are lower than they should be for the country.

Dr. {Schuchat.} Um-hum.

Mr. {Burgess.} I have gotten my flu shot every year except 2004 when it was politically inadvisable for a Member of Congress to receive a flu shot because there was a shortage--

Dr. {Schuchat.} Right.

Mr. {Burgess.} --because of the serratia contamination that occurred in one of the manufacturing labs. Separate story, but every other year I step up and get the vaccine because I meet a lot of people every day, I ride on an airplane twice a week, this is just a commonsense reaction to an--what is an inevitability on the ground.

I want to shift gears for just a moment, and I do feel obligated to talk about the measles issue because it has achieved so much in the way of headlines, and I am going to breach--I am going to violate HIPAA, and I just want to tell HHS that I am going to violate HIPAA. I am going to release sensitive clinical information about myself. So I never had the measles vaccine. I didn't have it because I was too old. I mean I was--well, when I was a child in the '50's, it hadn't--it wasn't there, it wasn't available. I don't remember every scraped knee, every sniffle from my childhood, but I remember the measles.

Dr. {Schuchat.} Um-hum.

Mr. {Burgess.} It was bad. I mean you can see--and I see in Harrison's here online, hard, shaking chills. I mean that--it--yeah, hard, shaking chills doesn't even begin to

describe it. The chills are so hard they are painful. You want to cover up, you want to pull a blanket around yourself, but you don't want anything touching your skin. That is measles. I mean it is a different disease. And we had forgotten about it, quite frankly, because, you know, you just never see it, and now we are faced with the prospect that we are seeing it. It is important for parents to have their children vaccinated.

Dr. {Schuchat.} Um-hum.

Mr. {Burgess.} There are things that can happen to you as a consequence of having had the measles. I remember in medical school learning about subacute sclerosing panencephalitis, and I remember asking at the time why do I have to learn about this, no one is going to get it anymore. But, in fact, people may get it because it is a consequence of having had a measles--an infection with measles. So these issues are important.

Now, if I recall correctly, and suddenly somehow this is interjected into presidential politics, which is inappropriate because, if I recall correctly, since President Gerald Ford, there has not been a federal mandate for any

vaccination. And I will ask that question generally to the panel, Dr. Fauci, is--am I correct on that?

{Voice.} Microphone.

Dr. {Fauci.} When President Ford essentially mandated through the department that there be massive vaccination for the 1976 influenza, the--that famous catastrophic event with the Guillain-Barre, but I don't think there has been official mandating about--

Mr. {Burgess.} Correct. So these are state-mandated vaccines that people have to take before attending public schools, and there is a reason for that. It should be a state mandate. There is no one asking for a federal mandate. It doesn't mean that the vaccination is not important. And for people who are listening and paying attention today, please have your children vaccinated.

Thanks, Mr. Chairman. I will yield back.

Mr. {Murphy.} Thank you.

Now recognize Mr. Green for 5 minutes.

Mr. {Green.} Thank you, Mr. Chairman. Thank our panel for being here.

Data from the National Immunization Survey found that

fewer than half of children and adults are vaccinated by November of this current flu season. My numbers said 40.3 percent, but, doctor, you said 46 percent. Forty-six percent of the people and 6 months or older received the flu vaccine. These numbers seem similar to what we have seen in the last few years.

I wanted to hear why these vaccination rates continue to be so low and what we can do to improve it, although I have to admit, the recent news that it is only 20 percent--23 percent effective, and those of us who are much older it may only be 12 percent, that would probably tell people not to get it. But somehow along the way, we need to do it, and encourage much more than 46 percent to be able to get that. The data showed that nearly 60 percent of the people had not taken advantage of it. Is that accurate?

Dr. {Schuchat.} We--the 46 percent that are vaccinated is based on last year's end-of-season, so the 40-some percent was the early, you know, by November, how many had gotten vaccinated.

You are right that the majority still haven't gotten the flu vaccine, and this is something that we think is going to

take years of work. Part of the issue is whether there is a concern about the disease, and part of the issue is whether there is confidence in the intervention. And as you know, the intervention has different efficacy, different years. So it is not a simple message and it is one that we work hard to communicate honestly and clearly.

Mr. {Green.} Well, I guess part of the problem is if we think it is bad now with the news coverage about the less effectiveness, what can we do to make next year that we have, one, an effective flu vaccine, I know it is almost like throwing darts against the wall, but--and that way we will convince more people to get it, because again, the more people vaccinated, the more we will defeat it.

Dr. {Schuchat.} The vaccine prediction is most of the time good. So out of the last 20 years, this is the fourth time where there has been an important mismatch. And in some of the previous times where there has been mismatch, there has still been much higher efficacy than what we are seeing this year. This year will be a difficult year to follow in terms of our messaging. We do want people to know that influenza can be serious, and that the vaccine is still the

most effective way to reduce your risk, but we also want people to know about antivirals, because those are also underutilized and could actually reduce the duration of the illness, and even reduce the chance of being hospitalized in some patients. And so we think it is important to get both messages out.

Mr. {Green.} Is there anything that Congress could do because when you found out that the effectiveness was so low, I know there were some questions earlier from Dr. Burgess on--saying, okay, this is--we need a booster for those of us who got the vaccine, is there resources available where you could do that and make it an issue, saying, you know, it is only 23 percent but this booster will get you to 50 percent?

Dr. {Schuchat.} You know, I think the resources that have been provided have been incredibly valuable, and there is both a short-term and a long-term strategy. You know, the short-term strategy, to use available tools better, and to make incremental improvements in the production and distribution of vaccine, and the long-term strategy that Dr. Fauci and Dr. Robinson were talking about with the research and investments in universal vaccines. So I think we can't

just do one or the other, we really have to do both, but it will be years before there is that really much, much, much better flu vaccine. And we are fortunate that we have a lot of options now and a much better supply horizon than we have had, you know, 5 or 10 years ago. So I think we really need to just stick with it and make those incremental improvements, and make sure that the public gets the correct information, the accurate information, that we are honest when he have a year like this where it is quite difficult. And unfortunately, the vaccine is only preventing about 23 percent of what it might be, but that is still significant protection.

Mr. {Green.} Well--and again, since the percentage is lower for the most vulnerable population of the elderly, that is also--we need to encourage the elderly to--even if it is only, I don't know what percentage it was, 12 percent, because it still gives them that 12 percent. But we would sure like to see it up above the efficiency much better.

Dr. {Schuchat.} Yeah. Ironically, the elderly are the best at getting vaccinated. It is about 70 percent or so of them, but the vaccine works the worst in that population.

And they really do rely on the rest of the population being protected to have more confidence that they will be safe too. So it is one of those vaccine-preventable diseases where the more people that are immunized, the better. And, of course, in the future we hope that we will have even more effective tools.

Mr. {Green.} I know this has come up before, but--

Mr. {Murphy.} Thank you.

Mr. {Green.} --Ranking Member Pallone and DeGette yesterday talked about the measles outbreak in Disneyland, and I know that is a concern too that--to do it. And let me just follow up, Mr. Chairman, I remember when I was in the fifth grade, the whole county, we got a polio vaccine. Was that mandated by the Federal Government?

Dr. {Schuchat.} You know, in that era, you didn't need to mandate polio vaccines. People were lining up. I think the whole country was so thrilled that there was a polio vaccine licensed--

Mr. {Green.} Um-hum.

Dr. {Schuchat.} --in 1955 because that was such an incredible scourge. The mandates, the school requirements,

really were shown in the 1980's to massively reduce the risk of measles outbreaks in schools, and it was really only when states required kindergarten entry to have measles vaccine documentation that we started to get a better handle on--

Mr. {Green.} Thank you.

Dr. {Schuchat.} --measles, and then--

Mr. {Green.} Yeah.

Dr. {Schuchat.} --of course, in 2000, we were able to eliminate native measles here in the U.S.

Mr. {Murphy.} The gentleman's time has expired. Thank you.

Now recognize Mr. Griffith of Virginia for 5 minutes.

Mr. {Griffith.} Thank you, Mr. Chairman.

Let me try to fill in some--or get some blanks filled in here. I don't have the answers. The meeting took place with who in CDC and FDA and others in February. In March, we know that there was a drift that was picked up of about 10 percent, is that correct?

Dr. {Schuchat.} Actually, it was lower than that.

Mr. {Griffith.} About 7 percent I think I saw in your testimony.

Dr. {Schuchat.} It was like 4 percent.

Mr. {Griffith.} Okay. Do we know what April was, because we have a few numbers on the chart but we have a lot of question marks? And if you don't--

Dr. {Schuchat.} In April--

Mr. {Griffith.} --you can provide it--

Dr. {Schuchat.} --14 viruses were shown that had reduced susceptibility to the strain, and that came out--that was out of 127, so that would be 11 percent.

Mr. {Griffith.} Okay. And then we have a number from May. Then June and July, we don't have another number on this chart until September. What were you all seeing in June, July and August?

Dr. {Schuchat.} There were 80--in June, July and August, there were 88 viruses identified from the whole world that had reduced reaction, and so that comes to 36 percent.

Mr. {Griffith.} Okay.

Dr. {Schuchat.} With reduced, you know, that were mismatch.

Mr. {Griffith.} And then there is another meeting, and there is a different southern hemisphere recommendation made,

and we don't make the--I think that is five. If you can get us the other numbers just so we can kind of track it, that would be great. But then--

Dr. {Schuchat.} Absolutely.

Mr. {Griffith.} --my question comes up, and I am happy for anybody to answer it, why didn't we have the manufacturing capacity for the virus to do turn somewhere in this process, I think you said by June we were in the 36--June, July, we were in the 36 percent range, recognizing that flu season doesn't generally hit in a big way for another fair number of months, why does the United States lack that manufacturing capacity, and as a subpart of that, if there was the capability of producing, and I am trying to pronounce this correctly, monovalent vaccine, why didn't we do so? And if you all could focus on that. Any member of the panel please.

Dr. {Schuchat.} Yeah, maybe I can start and let Dr. Robinson continue.

I think one thing to recognize in the summer is that we were looking at increasing proportions of H3N2 that were not well matched the vaccine, but we still had the other 2 or 3

different strains that were in the vaccine. So the concept of producing a monovalent vaccine, you--we might have been asking the American public to take a monovalent vaccine plus the tri or quadrivalent seasonal vaccine. As we have been hearing, the American public isn't all that keen to get one flu vaccine a year. Would they really be lining up to get 2? But there are, of course, major limitations in the manufacturing capacity to make 2 different products for the same season. So I will let Dr. Robinson answer that.

Mr. {Griffith.} Dr. Robinson?

Dr. {Robinson.} Thank you. During the manufacturing season, they are producing three or four vaccine strains all the way to June, maybe even July if it is a tough year for them. At that time--and most of those are egg-based. At that time, they within the summer are putting those together, we call them blending and putting together, to go forward with the vaccine that was released in September to go out on the shelves.

The ability to have what was called a competent vaccine that could be very quickly--that is certainly true, it can be maybe faster than some of the egg-based vaccines, but the

capacity that we have right now with the licensed vaccine, the only one recombinant-based vaccine, is very, very small. It would have made a--only been able to produce maybe hundreds of thousands of--

Mr. {Griffith.} Okay. Let me--

Dr. {Robinson.} --doses.

Mr. {Griffith.} Let me ask the why on that. Is it because there is not a profit--

Dr. {Robinson.} No, no.

Mr. {Griffith.} --to be made?

Dr. {Robinson.} One instance, it is a new vaccine--

Mr. {Griffith.} Okay.

Dr. {Robinson.} --and, two, they--since it is a new vaccine, they are just scaling up to the market. They--this is an incumbent market, very competitive, and they were licensed in 2013. We are actually supporting their efforts in building a much larger facility to produce maybe tens of millions of doses, and so that they actually can going forward be able to produce, say, 50 million doses in 4 months of a monovalent vaccine for a pandemic or, maybe in this case, another influenza vaccine.

Mr. {Griffith.} So you anticipate that our capacity will be greater in the next couple of years than it is today to react?

Dr. {Robinson.} Indeed, it will be, because we will actually have the cell-based influenza vaccine facility down in North Carolina that has a large capacity, and we will be able to have that product on the market. But again, they are limited in that they are making seasonal flu vaccine at the same time that we may have wanted to do that.

The other thing is that these manufacturers also produce vaccines for the southern hemisphere. So when they came off of making the vaccine for the northern hemisphere, then they started back to actually making the vaccine for the southern hemisphere. So we would have had to make a decision and tell them in September, stop doing that and go forward with the new vaccine. And we know that that is a difficult midcourse shift.

Mr. {Griffith.} But if we--

Dr. {Robinson.} The future will be--

Mr. {Griffith.} But we could have done that even in, say, July when we knew we were at 36 percent that had

drifted?

Dr. {Robinson.} It would have been very, very difficult, sir.

Mr. {Griffith.} Okay. All right. I appreciate it. I see my time is up and yield back.

Mr. {Murphy.} All right, I want to clarify something. So you said 36 percent, June, July, and we have a 50 percent cutoff. So some time in September the 50 percent number was significant enough to say, okay, we need to do something different in the southern hemisphere. What is the magic number where you say we need to make a change here?

Dr. {Schuchat.} Actually, it wasn't that there was something different, it is that every September the strains are reviewed worldwide. All--

Mr. {Murphy.} Why not--

Dr. {Schuchat.} --of them.

Mr. {Murphy.} Why not August? Why--I don't--what I am concerned here is, we want to break through, if there is some bureaucratic hurdles, this committee wants to help--

Dr. {Schuchat.} Thank--yes.

Mr. {Murphy.} --but if you say, well, we don't look at

this until--we don't really meet and discuss this until September, that is not a lot of solace for what Mr. McKinley was raising for the hundreds of thousands of seniors and--who are going to be sick. What--what is--what do we do?

Dr. {Schuchat.} Right. In September every year, the groups convene to review all the data for the southern hemisphere production, and that is because it takes that long to get vaccine that will be ready by that time. It is not--

Mr. {Murphy.} I am not--

Dr. {Schuchat.} --because we are not looking all the way between.

Mr. {Murphy.} Yeah, but you have said--you have already said you can get a vaccine ready in 12 weeks when you need a monovalent strain when there was a pandemic.

Dr. {Schuchat.} Not--

Mr. {Murphy.} Wasn't that done in 2009, you did something quickly--

Dr. {Schuchat.} No.

Mr. {Murphy.} --Dr. Robinson?

Dr. {Robinson.} Okay, go ahead.

Dr. {Midthun.} No--

Mr. {Murphy.} I want to be clear.

Dr. {Midthun.} --I think in 2009 the virus emerged in April. In May it was recognized that it was causing significant disease, and at that time a decision was made across the HHS that a monovalent vaccine would be pursued. And so all stops were pulled out to do that, but in point of fact, the first vaccine was not available from--for that H1N1 monovalent until the end of October, and the bulk of vaccine was not available until late December, into January. So just point taken that the manufacturing process itself takes many months, and although we--

Mr. {Murphy.} To get to the critical number. I know it is Mr. Tonko's turn, but we are talking about just to start to give it to some seniors and high-risk group.

Mr. Tonko, you are recognized for 5 minutes.

Mr. {Tonko.} Thank you, Mr. Chair. And welcome to the panel.

There has been much discussion here today about parents and the advice they get about having their children vaccinated or not vaccinated. I would like to ask it from yet another perspective. Yesterday, a United States senator

asserted that routine vaccinations could cause, and I will quote, ``walking-talking normal children to wind up with profound mental disorders.''

And so my request of the panel is a simple yes-or-no response. Is there any shred of credible evidence that shows that this, in fact, is the case? Dr. Schuchat?

Dr. {Schuchat.} Not the vaccines we are using today.

Mr. {Tonko.} Dr. Midthun?

Dr. {Midthun.} No, not for the vaccines we are causing--using today, although I think it is important to note that any vaccine can have some safety issues associated with it, but typically, they are very rare, and that is why we also have the Vaccine Injury Compensation Program.

Mr. {Tonko.} Dr. Robinson?

Dr. {Robinson.} I am in agreement with Dr. Schuchat and Dr. Midthun.

Mr. {Tonko.} Dr. Fauci?

Dr. {Fauci.} Agree.

Mr. {Tonko.} Pardon me?

Dr. {Fauci.} Agree with my colleagues.

Mr. {Tonko.} Thank you for clarifying.

In addition to promoting vaccination, Dr. Schuchat, how else does the CDC work to prevent spread of the flu? For example, does the CDC recommend symptomatic individuals to stay home from work?

Dr. {Schuchat.} Yeah, we have a multipronged approach to prevention. The best protection is to get vaccinated. We also recommend sensible measures like washing your hands, covering your cough, staying home when you are sick, staying away from other people when you are sick. And then, of course, if you are ill, and particularly those with underlying conditions or the elderly, we think prompt antivirals can be important, and so talk to your clinician about that.

Mr. {Tonko.} Are there any data showing how many flu transmissions occur in the workplace when symptomatic individuals do come to work?

Dr. {Schuchat.} I don't have that date, but it--there have been analyses showing the value of vaccination to reduce workplace absenteeism and to improve productivity.

Mr. {Tonko.} Um-hum.

Dr. {Schuchat.} So we think it is a good thing for

health, and it is also a good thing for the workplace to be protected against flu. To stay home for when you are sick for a variety of conditions is good counsel.

Mr. {Tonko.} I do know that in speaking with my constituents, there are a number of working moms and dads who can't afford to take time off of work because it would mean they are not paid, and so they attempt to come to work even though they really shouldn't. In your opinion, would paid leave policies help to prevent the transmission of the flu and other illnesses by encouraging more workers to stay home when they are indeed sick?

Dr. {Schuchat.} We think the easier it is for people to do the right thing, the better.

Mr. {Tonko.} Okay, thank you.

Dr. Midthun, the FDA has licensed a number of new vaccines since the year 2009. How have these new vaccines contributed to preparedness efforts in the last several years?

Dr. {Midthun.} Thank you for that question. I think what they have done, especially with regard to the cell-culture-based vaccine and the recombinant protein vaccine, is

they offer an alternative manufacturing platform relative to the egg-based manufacturing that was the basis for the vaccines that had been approved up until that time. And it is always important to have a diversified way in which you can manufacture vaccines. It also widens the platform available in the event of a pandemic because, typically, the pandemic vaccines are made on the same manufacturing platforms that the seasonal vaccines are made on, and so it really provides greater diversity and more resilience.

Mr. {Tonko.} And, doctor, in your testimony you talked about work to speed up the manufacturing process for existing vaccines. Can you tell us more about that work?

Dr. {Midthun.} Yes. It is actually a very strong collaboration between BARDA, CDC, NIH and ourselves, and it looks at a number of different aspects. One aspect is to look at the potency testing that is done for vaccines. Right now, that relies on reagents that are made by immunizing sheep, you develop antiserum, this usually is a process that can take up to 2 months. And so, obviously, having potency assays that are much more rapid would really decrease the time that it takes to do this, to make these reagents. And

so there are some approaches using more modern platforms, and in conjunction with some of our colleagues, there actually are some tests that are being planned that will be embarked upon later this year to compare some of these newer assays to the standard assay that is used right now, the radial immunodiffusion test, to see how these compare to each other in actual testing of vaccine samples that the manufacturers are providing to us. And some of the manufacturers have actually expressed interest in also participating in the testing to see what the feasibility is. So that is one aspect that we are working on.

Another one that has been very important, and that the CDC and others have really done a lot of work on, but we have also contributed to, is to try to identify high-growth viruses that will lead to good yield when you grow the virus in the eggs or in the cell culture. As you recall, Dr. Fauci was referring to the fact that that can often be a wait-limiting step. And so trying to develop viruses that you know will yield high growth when these new strains emerge could really facilitate and take time off that process.

And then also there was the sterility testing, and the

FDA actually changed its regulations in 2012 to allow for more flexibility in sterility testing. Up until that time, it was very prescriptive and this 14-day test by USP had to be used, but now manufacturers can come in with novel testing, and we actually know that some, you know, testing that has been described in the literature could actually be accomplished in 5, 6 days potentially.

Mr. {Tonko.} Thank you.

Mr. {Murphy.} Thank you.

Mr. {Tonko.} I yield back, Mr. Chairman.

Mr. {Murphy.} Thank you.

Now recognize a new member of the subcommittee, Dr. Bucshon, who is a cardiothoracic surgeon by training, and is here from Indiana. Welcome to the subcommittee, and you are recognized for 5 minutes.

Mr. {Bucshon.} Thank you, Mr. Chairman. First of all, I would like to associate myself with the comments of our--unanimous comments of our expert panel in recommending that parents get their child--children immunized to prevent childhood diseases. All my children are immunized.

Based on the testimony we have heard today, it seems

like we could have had a monovalent vaccine available by maybe December, and if that is true, do you lack--Dr. Schuchat, do you lack the authority to make that happen in a--in that way, or whomever is--what--because through the testimony, we have asked--I think a lot of members have asked what can we do to help, but for us, for Congress to help, we have to have a specific thing to help with. So is there new authority or any other authority that would be helpful to make this happen?

Dr. {Schuchat.} I don't believe so. The key issues is a risk assessment and trying to predict the most likely course of events, but I believe there are authorities if the decision is made to go ahead with the monovalent, whether for pandemic or for drift.

Mr. {Bucshon.} Okay. As a healthcare provider, I know that, you know, liability is a significant issue in our American healthcare system, and not only physician malpractice, but product liability is a substantial issue, I know, that has an effect on the healthcare industry. Anyone can comment on this. Do product liability issues affect our ability to act in a more nimble way when it comes to

vaccines, because you do have private companies that product these. And so let us start with that and then I will spearhead off from there.

Dr. {Schuchat.} The Vaccine Injury Compensation Program exists so that product liability won't be a factor, so that we can make sure that we have vaccines made but the people who are injured by vaccines are compensated. And so that is--the funding from that comes from an excised tax on the--on every vaccine dose that is sold, so that we know that vaccines are very safe, but there are sometimes rare, important complications, and the Injury Compensation Program exists for those families who have been injured.

Mr. {Bucshon.} Okay. Thanks for clarifying that, but--and I think that is important to understand.

Dr. Midthun, from the FDA's standpoint, is there--are--is there--how do I want to say this, a risk averse, you know, regulatory process? It seems like at the FDA, you know, over a number of years--but for a variety of reasons have--I think been, in my view, sometimes overly cautious with new products or changing quickly. Do you see that as an issue, you know, and that comes into the liability issue again, is there

resistance or reluctance to quickly move based on the concern about these type of things?

Dr. {Midthun.} No, I don't see that. I think in the influenza domain, we, every year, are primed to approve the new vaccine strains that are recommended for inclusion of the vaccine those years. I think also our record of having approved since 2003--I think in 2003 we had three licensed influenza vaccines. Today we have 16 licensed influenza vaccines, including our cell-based, recombinant-based, quadrivalent, high-does, and also I should point out that many of those we actually approved using accelerated approval which actually allows us to approve something based on the new response that is likely to predict clinical benefit. And so we have used accelerated approval regulations to approve any of those and get them to market more quickly. So I think we--and also I should point out we approved the novel adjuvanted H5N1 vaccine in 2013. So I think that we really looked very carefully, and balanced the benefits and the risks, and are really very flexible.

Mr. {Bucshon.} Great. That is good to hear.

There is a recent CDC study that looked at clinician

practices on patients that come to the emergency room with--and the date is striking, only 16 percent or patients with laboratory-confirmed influenza were prescribed antiviral drugs.

So the first question I have, do they work? Do the antiviral drugs work?

Dr. {Schuchat.} Yeah, last week there was a new meta-analysis of all the published and unpublished randomized control trial data on Oseltamivir, and it shed new light on the benefits as well as potential risks that--there is--

Mr. {Bucshon.} So they--

Dr. {Schuchat.} --benefit for the work.

Mr. {Bucshon.} Short answer, they do work, because I am running out of time.

Dr. {Schuchat.} Yes.

Mr. {Bucshon.} Because surprisingly, 30 percent of the patients with laboratory-confirmed influenza were--30 percent were prescribed one of three common antibiotics, which are for bacteria, not viruses. Is there anything that we can do to better, you know, as a physician, better make the, you know, change that practice? Maybe Dr. Fauci can answer that.

Dr. {Fauci.} Yeah, that is another whole issue of antimicrobial resistance which we have even discussed before this committee. So certainly, over the last year, there has been the extraordinary effort on the part of the Congress and the Administration in--from everything from executive orders to 5-year plans to counter the kinds of practices that lead to antimicrobial resistance, and one of the most common, as I am sure you are aware, sir, is that someone comes in with a viral infection and they get an antibiotic. That is very, very common, unfortunately.

Mr. {Bucshon.} I yield back, Mr. Chairman.

Mr. {Murphy.} Thank you.

Now recognize a new member to the committee, Ms. Yvette Clarke, who represents--Ms. Schakowsky is next? I am sorry, I thought it was--Clarke was next.

{Voice.} Okay.

Mr. {Murphy.} No, by sitting down we--all right. I had it down by the person sitting here at the time of the gavel, so I am sorry. We can go with Schakowsky or whatever you say.

Ms. {Schakowsky.} I was here earlier.

Mr. {Murphy.} All right, thank you.

Ms. {Schakowsky.} Thank you, Mr. Chairman.

So if the--the vaccine that we are using now has been viewed as 23 percent effective, and usually in the past it has been 50 to 60 percent effectiveness, are we seeing--is that--maybe it is Dr. Schuchat, are seeing a commensurate increase in the incidents of flu?

Dr. {Schuchat.} Yes. When we compare this season with 2 years ago, the 2012/'13 season, the last big H3N2 season, we have--much of the pattern is similar, but our hospitalizations in the elderly are much higher at the same time this year. So we will get, you know, the end-of-season statistics, but it has been a very bad year for the elderly.

Ms. {Schakowsky.} I see. So the lab tests predicted 23 percent--

Dr. {Schuchat.} Um-hum.

Ms. {Schakowsky.} --but you are seeing it actually out in the country, that it is also much higher?

Dr. {Schuchat.} Right. Yeah, we are seeing, you know, both the lab mismatch and then our vaccine effectiveness low estimate, and then the incidents of the hospitalizations is

high.

Ms. {Schakowsky.} Okay. With the passage of the Affordable Care Act in 2010, we took important steps on preventive medical coverage for free, and since the law went into effect, approximately 76 million Americans have received no-cost coverage for preventive services. So I am wondering if we are seeing that there actually was an impediment to getting these preventive services, vaccines, because of the cost, and now without the cost, that more people are making that available to themselves.

Dr. {Schuchat.} For influenza vaccine, I think it is too soon for us to see, but we do know that there are important disparities in influenza vaccination coverage, and that insured people have been more likely to be vaccinated than uninsured. So I think that over the years ahead, we may start to see some progress there.

Ms. {Schakowsky.} So we do think, although we don't have the new data--

Dr. {Schuchat.} Um-hum.

Ms. {Schakowsky.} --that cost has been a barrier to--in the past--

Dr. {Schuchat.} That is right. We--

Ms. {Schakowsky.} --is that what you think?

Dr. {Schuchat.} And we know even for the workplace, for instance, when workplaces will offer flu vaccine for free for workers or, you know, particularly for healthcare workers, the uptake is better than when it is out-of-pocket, off-site, need-to-seek vaccine.

Ms. {Schakowsky.} I think it is great that we are having this hearing today because this whole question of vaccines, as many of my colleagues have mentioned, has really been in the news, and it is disturbing that a number of high-profile political figures have weighed in on this in a negative way, I would say, that this is, you know, parents should make the decision, and I have seen some children that have been deeply affected by this--by vaccines in a negative way. What I am wondering is what is the public health outreach effort to make sure that--you heard my colleague, Marsha Blackburn, talking about the mom blogs. I mean there is a lot that is going on, not only on television, and I am glad you were on, Dr. Fauci, and that is very important that we get the message out in every medium, but I am just

wondering if we are also just looking at how people are communicating with each other in the social media and getting the facts out.

Dr. {Schuchat.} Yeah, we spend quite a bit of time and attention monitoring the social media as well as the general media, and we work closely with--at the national level, but also at the state and local level on communication, both direct to consumer as well as through clinicians and other trusted partners, because we think getting information that speaks to you close to where you are is really important in your health behaviors.

There--I would just like to say that the vast majority of parents vaccinate their kids against most of the recommended diseases on time, and yet there are some minor voices that get a lot of attention.

Ms. {Schakowsky.} Exactly. I think maybe we need to make sure we communicate with all political voices as well that are out there to make sure that we are communicating the science, the facts, that suggest that all parents should vaccinate their children.

So I yield back.

Mr. {Murphy.} Who is next?

{Voice.} Mr. Flores.

Mr. {Murphy.} All right, now we recognize Mr. Flores from Texas, who is also new to this committee. Third term in Congress, and we welcome him to this subcommittee.

Mr. {Flores.} Thank you, Mr. Chairman. I also want to thank the panel, particularly for your positive comments regarding the benefits of having children vaccinated for measles. I have an extended family member who has not done that for her children yet, and it just baffles me why she can't do that. And so I hope she is hearing this today, that she heard your comments, and that she will do so.

I want to talk about the weakness in the strain selection process, and talk about the opportunities to mitigate that weakness. And I want to focus my questions to you, Dr. Robinson, because you--BARDA is a tool, I think, that we have to do this.

And so my first question is this. Are--is BARDA funding any projects or initiatives to develop two things; one, better technologies--testing technologies, or two, better approaches for making the vaccine candidates?

Dr. {Robinson.} So the answer is yes on both--let me just--in my testimony, I identified that we were supporting the development of evolutionary biology methods that would actually help the existing methods inform what strains are out there. There are only so many ways a virus can mutate.

Mr. {Flores.} Right.

Dr. {Robinson.} And we know that actually--you can do the experiments to show which ones would predominate, and that may actually inform of which ones we may see the next season. And certainly, the underpinning of that the NIH has funded over the years, and so we are moving forward primarily for our pandemic purposes, but certainly could be used in seasonal. So that is one way towards the selection, and then informing new vaccine designs.

Mr. {Flores.} Okay.

Dr. {Robinson.} Secondly, with the technologies, we have supported with our colleagues here from NIH, CDC and FDA, ways--new technologies to make these vaccines, whether it be cell-based or recombinant. And working with the NIH, we are looking at universal flu vaccine candidates with a number which Dr. Fauci enumerated of going forward. It is

not because those haven't--technologies haven't been tried before, but as he explained, there is a limitation in how the body actually sees these viral proteins. And so there are some new ways now that we can do that, we couldn't do before.

Mr. {Flores.} And in terms of looking at BARDA's priorities, where would you say that this--getting these better technologies for the strain selection process is in your sort of list of all the things you have to do on your wish list.

Dr. {Robinson.} Yeah. Well--

Mr. {Flores.} Is it in the top third, or the middle or the bottom or--

Dr. {Robinson.} No, it is at the top.

Mr. {Flores.} Okay.

Dr. {Robinson.} Yeah.

Mr. {Flores.} Great. Sounds like we should keep it there and--from what I am hearing today.

The third question is how can we expedite the development and deployment of better technologies, say, use of genetic sequencing, to detect virus change, which you have talked about, to ensure that the U.S. has a vaccine that can

be matched to a drifted H3N2 strain?

Dr. {Robinson.} Certainly, one of the ways that we actually have employed with biosynthetic technology work with the Craig Venter Institute and then one of the manufacturers. We did that in 2013 with H7N9 to actually come up--what we didn't need the traditional way of having the virus actually sent from one laboratory to another. We actually had the nucleotide sequences available, then made--using that, and actually made the virus seed strains and went forward with H7N9. Regardless it is an egg-based or cell-based or recombinant, we can do that.

Mr. {Flores.} Okay.

Dr. {Robinson.} And we are moving forward with those efforts also.

I just want to say one other thing that Dr. Midthun had talked about, and that is high production yield seed strains. Why is that important? It means that the virus doesn't have to be passaged to eggs or cells or medium many times because, very early on, we can actually have high production seed strains, and that is why the manufacturers keep passaging the virus to get high production. If we had that immediately,

then the virus that actually is in the vaccine is going to be very similar to the circulating virus.

Mr. {Flores.} Um-hum.

Dr. {Robinson.} Much more so.

Mr. {Flores.} Okay. And then the last question I have has to do, you know, I have always been fascinated with the initiatives to try to develop the universal flu vaccine, and I appreciate what Dr. Fauci talked about today, and educating the committee and subcommittee on how to do that.

What role does BARDA play in the development, deployment and stockpiling of a universal flu vaccine?

Dr. {Robinson.} So certainly hand in hand with the NIH, we are moving forward with the development, not only for seasonal, as I had pointed out, for pandemic purposes. It may serve as a primer for future pandemic vaccines. Again, you may only need one dose of the pandemic vaccine as opposed to two which you normally would need. And so we can stockpile that vaccine or actually have it as part of our commercial products that are out there every year.

Mr. {Flores.} Okay. Thank you for your responses. As you know, it is a--this is important to me because you have a

facility in my district that I think is doing some great work.

Mr. Chairman, I yield back.

Mr. {Murphy.} Thank you.

And now recognize Ms. Clarke of New York, the Brooklyn area, as a new member of the subcommittee. Welcome. You are recognized for 5 minutes.

Ms. {Clarke.} Thank you very much, Mr. Chairman.

Being the low one on the totem pole, oftentimes, it comes with the territory.

Let me welcome our panelists as well, and pick up on some of the line of questioning that my colleague, Mr. Tonko, raised with respect to research.

So, Dr. Fauci, your testimony discussed the potential for a universal flu vaccine that could provide protection against numerous strains of the flu over several seasons. What can you tell us about the research on this vaccine?

Dr. {Fauci.} Okay. So the research on this vaccine, as I had mentioned, really starts off with the fundamental basic observation that a part of the protein that is the target of the vaccines that we have developed over decades is one that,

unfortunately, has a component of it that tends to change from season to season. We refer to that as a drift. Big change is the shift. The part that doesn't change is the part that we have just recently recognized on the thin stem part of the protein that we now know that if you show it to the immune system in a certain way, and you can only do that by molecular biological techniques because, generally, when you show the immune system the whole virus, the part that you really wanted to make an immune response is crowded out and covered by the larger part. So now you are essentially teasing it out and showing the immune system just the part that you want to make a response again. And we have done that. We have done it with a number of different platforms, and we have shown now in a small animal, in a ferret, and now even in a human, that, A, it is feasible, B, it is safe, and C, it does induce the kind of response that you would predict would have a much broader effect.

So that is the real first solid step. We have to perfect that, and then we have to show in a broad study that it actually does protect against multiple strains.

Ms. {Clarke.} That sounds very promising, Dr. Fauci.

Dr. Robinson, you mentioned in your testimony a new initiative to support development of new flu vaccine candidates that offer broader, longer-lasting immunity. Can you tell us more about this initiative?

Dr. {Robinson.} Certainly. We are working with Dr. Fauci with many of the candidates that he has talked about, and in addition, there are other ways in which we can broaden the immunity. Some might be with adjuvants, and other designs of the vaccines going forward, and not only for seasonal but for pandemic purposes.

Ms. {Clarke.} So it sounds like we are moving into the 21st century.

Dr. {Robinson.} Yes.

Ms. {Clarke.} Very well. Very well. I would like to shift a bit to the idea of strains, the strain selection process, Dr. Midthun. Can you outline the role of the FDA's Vaccines and Related Biological Products Advisory Committee in the strain selection process, and when does this process actually begin?

Dr. {Midthun.} The process is actually year-round. I-- as, you know, CDC and other WHO collaborating centers for

influenza are monitoring influenza strains year-round to be looking for trends, changes, emerging situations, so that is going on all the time. Then you have--

Ms. {Clarke.} How does the advisory committee arrive at its recommendations on the selection of a strain?

Dr. {Midthun.} Okay. So what happens in usually February or early March, when the Vaccines Advisory Committee meets, is that we have experts come and present the data on the influenza strains that have been circulating over the last--really the last year, and those strains are evaluated to see which appear to be prevalent, and really based on those data a decision is made about which vaccine strains should be included in the vaccine manufacturing. And then once that recommendation is made, of course, the manufacturers then use that information to start manufacturing their vaccines. But I think a very important point to note is that, typically, manufacturers actually start manufacturing the vaccine before the advisory committee is even held. They usually start in January. Why? Because they are aware of the data also. As I mentioned, this is an ongoing process year-round, and so they will usually

anticipate what they think will be the strain that is not going to change. They do this at risk, but the point is that--

Ms. {Clarke.} That is what I was going to ask--

Dr. {Midthun.} --it is a process--

Ms. {Clarke.} --has there ever been an incident where perhaps the advisory committee did not necessarily agree and the manufacturer is already proceeding?

Dr. {Midthun.} Yes, that can happen. I mean you would have to ask individual manufacturers--

Ms. {Clarke.} Yes.

Dr. {Midthun.} --but I suspect that that has definitely happened, although, you know, typically, I think they will go with something that they think, based on the data, is unlikely to change. But it really is a process where we make the recommendation in February, but clearly, there is a lot of work that precedes that and there is a lot of work that continues after that to actually have vaccine available. And usually vaccine becomes available in July, August, that time frame, and then it is continued to be released really throughout end of October. So you can see it is a process

that, even though you do a recommendation in February, and much work starts before that even, it really does take many, many months to actually have vaccine available for the influenza season--

Mr. {Murphy.} Thank you.

Dr. {Midthun.} --which, you know, typically can begin, you know, October, November, although sometimes not until later.

Mr. {Murphy.} Thank you.

Ms. {Clarke.} Thank you.

Mr. {Murphy.} Thank you.

Now recognize another new member for the committee, Susan Brooks of Indiana, who has a second term of Congress, previously she was in the Homeland Security Committee and was a U.S. Attorney. We look forward to you being a part of this committee. You are recognized for 5 minutes.

Mrs. {Brooks.} Thank you, Mr. Chairman. I do want to thank all of the witnesses for your work with respect to the public health and safety of our citizens. On Homeland Security, I chaired the subcommittee on emergency preparedness response and communications, and this is

something that we know everyone is passionate about. I think, obviously, when we have an epidemic the way we have right now, the public pays a lot more attention to it, but I think the public also expects us to get it right. And the public is expecting us to, you know, leave no stone unturned, and to continue to ask the questions and figure out how can we do it better, how can we do it faster, what mistakes, you know, have we learned from in the past and, you know, how do we--what do we do to keep our country safe.

This year is a much higher death toll, as you have said. In Indiana, there were 72 deaths statewide. The year before, 70. We have already had 108 deaths in Indiana, and it is just the end of January, and the flu season, as I understand it, goes often in through May, so we have a lot that we are very, very concerned about. I spoke with the head of our Marion County, which is Indianapolis' Public Health Department, and she has indicated that the flu has gotten so severe in Indianapolis that she is barring anyone under the age of 18 from visiting hospitals. So if you are 15 years old and your mom is in the hospital, you can't visit your mom. If you--and so we have reached, just to let you know,

as I am sure you know, and you are very focused on this, but these types of precautions are obviously being taken for the safety of the patients, but we also know, as we have heard, vulnerable, you know, whether they are children or seniors, are so vulnerable. But yet one of the things she also shared with me, and she was explaining the ag. culture technology that we use, and it takes a long time, but yet she shared the new cell mediator technology that you have mentioned in production is faster, but yet it is not widely used. And so I would like to explore why.

You mentioned a cell-based facility in North Carolina. Can we please talk a bit more about if these technologies are out there, why are they not being, you know, more widely used? And I don't know if, Dr. Schuchat, you want to start, and, Dr. Robinson.

Dr. {Schuchat.} Yeah, I will just make an overview comment that production of flu vaccine has been increasing over the past decade, with more, you know, factories in the U.S., more companies, more products, but we also have to work on demand, and the more vaccine we use every year, the more the companies will make. They don't make lots of vaccine at

a risk. And so it is a, you know, a cycle that is interdependent. But Dr. Robinson can talk about the cell-based plant and some of the other manufacturing efforts.

Mrs. {Brooks.} And is that correct, that a cell-based technology would allow vaccines to be produced faster? Is that correct or is that not correct?

Dr. {Fauci.} Not significantly faster. The cell-based is more consistent, whereas eggs, you know, it depends on supply of eggs, whereas you can keep growing up cells. I think that is a common misconception that there is a game-changing difference in the amount of time it takes. And the answer to that, and I am sure Robin will verify that, isn't the case. You both have to grow the virus, that is the problem, as opposed to in a recombinant DNA or molecular technology, be able to make it more quickly. So even though we welcomed the transition, and hope we even do more from egg to cell, the answer for the time frame itself is not going to be solved by cell-based technology.

Mrs. {Brooks.} What is the answer to increase the time--to shorten the time, rather, of production?

Dr. {Fauci.} And that is what I just said when I was

talking about changing from a need to grow the virus, to the ability to do it from a molecular way where you actually develop a vaccine by recombinant DNA technology, which doesn't require your having to grow the virus. That is really the major transformation from one platform to another.

Mrs. {Brooks.} Dr. Robinson, how do we--

Dr. {Robinson.} No, I agree with them. I mean that is where we see the biggest savings in time is with recombinant vaccines, but they are new and they are just with very limited capacity, they will grow in time. With the cell-based vaccines, we may even be able to have--shave a couple of weeks off than what we have with the standard egg-based vaccines at this time.

The other issue is that it is a new product, and this is the--a very competitive industry, and they are trying to get their market share at this time. And as they improve and--to be equal to be equal to or better, then they will actually become more commonplace in the overall vaccine supply.

Mrs. {Brooks.} Can--so are you saying that there is just one manufacturer that is manufacturing in that manner?

Dr. {Robinson.} That is cell-based in the U.S., there

is only one licensed manufacturer.

Mrs. {Brooks.} Is there any issuing--is there any issue in the licensing process?

Dr. {Midthun.} No, there is no issue of the licensing process. We have approved on cell-based manufacturer and one recombinant-based manufacturer. We basically work with anyone who wants to come in and make a product, and we are there to facilitate that process, but it really is up to, you know, the sponsor to come in and say we would like to do this. Certainly, you know, BARDA has done much to support some of these new technologies, and certainly, again, we are grateful for the support you have given in that regard.

Mrs. {Brooks.} Okay.

Mr. {Murphy.} Thank you.

Mrs. {Brooks.} Thank you.

Mr. {Murphy.} We now recognize another new member of the committee, Markwayne Mullin of Oklahoma. We welcome you, and you are recognized for 5 minutes.

Mr. {Mullin.} Thank you, Mr. Chairman.

Dr. Robinson, my state of Oklahoma has been hit particularly hard this year. According to Walgreens,

Oklahoma City is the number one place for prescriptions to be issued out for Tamiflu. Tulsa is number five. I think we have had somewhere like 50 deaths, and in the neighborhood of 1,300 individuals being hospitalized. My family was hit real hard this year. Out of my five kids, four got it. My fourth daughter, who is 6, received actually two different strains of the flu. My wife and all my family missed the swearing in because of the flu. And now it is kind of ironic that I am sitting up here talking about this.

I--just some follow-up questions. My understanding is part of the challenge of being able to respond to the mix-match vaccine is the burden of regulations, but underneath declaration of maybe an emergency, those regulatory burdens change. Is that correct?

Dr. {Robinson.} Certainly, if a public health emergency is declared then we can move forward, but there are regulatory issues, I think Dr. Midthun may want to testify--

Mr. {Mullin.} No, I just wanted a yes or no on it. If--there is--if it is declared an emergency, those regulatory burdens change quite a bit, right? Okay.

In 2009, the President declared a public emergency

during the swine blue--flu, or the HN--or H1N1 crisis. That is correct, right?

Dr. {Robinson.} Correct.

Mr. {Mullin.} How many cases of swine flu had been confirmed, not deaths but had been confirmed in the U.S., when the President declared that public emergency?

Dr. {Robinson.} I think Dr. Schuchat can answer that.

Dr. {Schuchat.} I don't have the numbers, but there was a--

Mr. {Mullin.} It was 20.

Dr. {Schuchat.} --an enormous change in the epidemiology--

Mr. {Mullin.} There--we do have the number, there was 20 of them that was in that--

Dr. {Schuchat.} Well, but instead of flu coming down, it was going up after the season--

Mr. {Mullin.} Right.

Dr. {Schuchat.} --with a completely different strain.

Mr. {Mullin.} But there was--

Dr. {Schuchat.} So--

Mr. {Mullin.} But there was an emergency declared with

only 20 confirmed cases in the U.S. There has already been 50 deaths in just my state of Oklahoma.

Dr. {Schuchat.} Um-hum.

Mr. {Mullin.} So I am trying to make a comparison here. I believe the flu season goes through May in the northern hemisphere, is that correct? Right?

Dr. {Schuchat.} It can extend to May. It can end earlier.

Mr. {Mullin.} Okay, what exactly is the definition of public health emergency? Dr. Robinson, do you want to take that? What is the criteria of us meeting a public emergency?

Dr. {Schuchat.} Yes, the--a public health emergency is not a black-and-white definition.

Mr. {Mullin.} So there is no set of specific criteria that we can look at, like the number of deaths or hospitalization to determine what is in the public's best interest as far as a health emergency?

Dr. {Schuchat.} Yeah, the issue with a pandemic is that the potential impact is exceptionally greater than the normal range. It--

Mr. {Mullin.} So it doesn't matter how many deaths we

have, it is just 100 percent of--

Dr. {Schuchat.} One would be--

Mr. {Mullin.} --CDC to make that--

Dr. {Schuchat.} One would be declaring that much in advance of seeing the deaths, because of the time needed to take steps to intervene.

Mr. {Mullin.} Would it help if Congress or you guys could come up with maybe some criteria that we could look at that could maybe trigger it, rather than just waiting for the next crisis to happen, or, honestly, a public outcry?

Dr. {Schuchat.} I think we could probably provide the language about a public health emergency. What I was trying to say was that it is not the same for each condition, for each disease or--

Mr. {Mullin.} I understand there is some type of flexibility and, you know, there has got to be a little bit of more understanding of what we are dealing with, but it seems odd that there is no criteria at all for us to understand it--

Dr. {Schuchat.} Yeah, I--

Mr. {Mullin.} --when something like the swine flu, that

just had 20 cases in the country, was declared an emergency by the President, and yet we have a pandemic going on right now with the flu, and we could have maybe changed some of this with the regulatory burdens going through if we would have declared it an emergency faster, where maybe we could have got help to individuals.

Dr. {Schuchat.} In 2009, a new strain emerged from animals that had genetic re-assortment that has--was completely unique to humans. And so what we are dealing with with the drift is slight changes, a very different scenario. But what you indicate is correct that the ultimate burden of disease from a drifted H3N2 strain may end up being greater than a completely new to humans re-assortment like the H1N1--

Mr. {Mullin.} So--

Dr. {Schuchat.} --swine-origin pathogen in 2009.

Mr. {Mullin.} Could you maybe help us maybe draw some type of criteria that needs to be laid out so the next time this happens, we could have something to compare it to?

Dr. {Schuchat.} We would be happy to provide follow-up on the public health emergency and how that is defined. Sure.

Mr. {Mullin.} Thank you. I yield back.

Mr. {Murphy.} Thank you. Gentleman yields back.

Now recognize another new member of our committee and subcommittee, Chris Collins of New York, a second term in Congress. Welcome aboard, and you are recognized for 5 minutes.

Mr. {Collins.} Thank you, Mr. Chairman.

I will be as quick as I can to get the information really directed more at Dr. Fauci and Dr. Schuchat.

And I appreciate your issue of the jump on swine flu, the same thing we were worried about with the bird flu, that didn't happen. That is the good news of RNA viruses, they don't jump off to--but if they do, it can be devastating. So my question is really on the universal vaccine discussion. And I don't think it has been made clear here. We have DNA viruses and we have RNA viruses. And when we talked about the vaccine for HPV, the vaccine for herpes, smallpox, chickenpox, those are all DNA vaccines. And it is relatively straightforward to get a vaccine for a DNA-based virus. Then you have your RNA viruses; HIV, Ebola, West Nile, SARS, influenza. They mutate a lot, that is what they do, but they

don't jump species much.

So my question is this, since we are talking about an RNA virus, so you can't compare influenza with HPV, you can't compare influenza with herpes, they are--and I don't think that was made clear, but now that we are talking about an RNA-based virus, I guess my question is this, because they mutate, drift so often, that is the insidious nature of RNA viruses, which is why the answer to a lot of the questions coming here is more because they do mutate, that is the basis of that virus. So how is it that since measles is an RNA virus, polio is an RNA virus, rubella is an RNA virus, and so is mumps, so you have mumps, measles, rubella and polio on the one hand, RNA, and we have vaccines for them, what is the difference in the reason we don't have vaccines for things like influenza?

Dr. {Fauci.} You have asked a very complicated question, and I can tell you that there is not a one-to-one relationship of whether you can or cannot get a vaccine, whether it is an RNA or a DNA vaccine. And also, RNA vaccines--RNA viruses do jump species. I mean the--

Mr. {Collins.} Rarely.

Dr. {Fauci.} Yeah--well, HIV, influenza, I mean there is the fowl virus that jumps, HIV, the chimp virus that jumps, so--

Mr. {Collins.} Yeah, but much less--

Dr. {Fauci.} Yeah.

Mr. {Collins.} --likely than a DNA virus.

Dr. {Fauci.} But the things that go into whether or not--your point is very well taken, that if you have in general, and--

Mr. {Collins.} Um-hum.

Dr. {Fauci.} --you have to be really careful when you pick this one or the other one, in general, a virus that has a proofreading mechanism, which RNA viruses have--

Mr. {Collins.} Right.

Dr. {Fauci.} --they don't correct their mistakes when they mutate, allows it to do what influenza does--

Mr. {Collins.} Right. Right.

Dr. {Fauci.} --drift. It allows it to do what HIV does. If you give it one drug, it will mutate to be resistant unless you give it--

Mr. {Collins.} Sure.

Dr. {Fauci.} --three drugs.

Mr. {Collins.} Sure.

Dr. {Fauci.} You are perfectly correct on that. However, it really isn't specifically that. These are easy to make one against, and these are difficult. It just doesn't work that way because there are a lot of other things that go into whether or not you are going to have a successful vaccine. But the fundamental principles that you mentioned are correct.

Mr. {Collins.} So how did we end up with one for measles, polio, and why has it been so God awful, if not impossible, to get one for HIV or influenza? Is there any--

Dr. {Fauci.} Well, the body makes a very good immune response against measles, even if--when it is a serious disease. Ultimately, the body will completely clear measles in the--

Mr. {Collins.} Right.

Dr. {Fauci.} --overwhelming majority of people. So we already know the body has the capability of inducing an effective immune response, therefore, you follow what the body does and you induce the same response that natural

infection does. With HIV, the body does not make an adequate immune response against HIV, so there is no proof of--

Mr. {Collins.} Yeah, but now, HIV, that is where the immune system doesn't even see the viral particles.

Dr. {Fauci.} Well--

Mr. {Collins.} Now, that is different than influenza.

Dr. {Fauci.} Well, I am sorry, sir, it does see it, it just doesn't make a good response.

Mr. {Collins.} It doesn't react to it.

Dr. {Fauci.} It doesn't make a good response--

Mr. {Collins.} Right.

Dr. {Fauci.} --against it.

Mr. {Collins.} Right, but that is what is unique about HIV.

Dr. {Fauci.} Exactly. You need the body's ability to do it naturally to mimic it. That is what vaccines are all about; mimicking natural infection without--

Mr. {Collins.} Sure.

Dr. {Fauci.} --hurting the host.

Mr. {Collins.} So one real quick question for Dr. Schuchat. They use adjuvanted--adjuvant-based vaccines in

Europe. We don't do it here. The question on the monocrobial, if we did that with an adjuvant, we could use-- extend that production, we could produce much less, extend it, because you were saying production is the big issue. If it was adjuvant-based, you wouldn't need as much. Should we be looking at that as a natural part of the monocrobial?

Dr. {Schuchat.} You know, I think that adjuvanted influenza vaccines hold a lot of promise, and I know that the FDA has licensed one so far in the U.S. In terms of extending the supply and also--

Mr. {Collins.} Right.

Dr. {Schuchat.} --and also potentially expanding the immune response. As you heard from some of the measles discussions, here in the U.S. our population has a lot of questions about vaccines and about their safety, and they have, even in 2009 when we were doing community engagement around H1N1 vaccination, we had lots of questions about whether there would be adjuvants in those vaccines or not. In Europe, they use adjuvanted--

Mr. {Collins.} Right.

Dr. {Schuchat.} --H1N1 vaccines and we didn't. Our

public really needs to come along with us in the scientific endeavor, and so I think that is an area where the FDA is really critical in reviewing the safety data.

Mr. {Collins.} Yeah. Thank you very much.

Yield back, Mr. Chairman.

Mr. {Murphy.} Thank you, Mr. Collins.

And now as a tradition of this committee, if another member of the committee wishes to be part of this, we will welcome back a former member of the subcommittee for this special visit, Mrs. Ellmers of North Carolina. You are recognized for 5 minutes.

Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you to our ranking member also, for allowing me to be part of this important subcommittee hearing on this very timely issue. And to our panel, thank you for being here today.

And I just want to point out a couple of things. One, in October, looking at this issue and knowing the importance of it moving forward, especially when it comes to vaccine production, I had the honor of hosting a roundtable discussion in the District of the--in the research triangle. Dr. Midthun and Dr. Robinson, thank you again for

participating in that very important discussion. We learned a lot from that. As we all know, Dr.--or, excuse me, Chairman Upton is leading the 21st Century Cures Initiative, and the vaccine space fits right in there. And I am working on very important legislation right now to actually bolster vaccine production and bring vaccines to market. As we know, it is very, very important. And I have also the honor of having the facility in Holly Springs, North Carolina, which has been referred to already, which will be addressing the issue of seasonal and pandemic vaccine production, using the cell culture technology. Very important to my district. And I also want to point out, and I think this is something that we need to look at into the future when we are trying to solve these problems. This was a public-private partnership between Novartis, HHS and BARDA. So, again, thank you all for your input today. This is a very, very difficult situation, but I believe that we can get out of it and we can move forward, and we can identify ways that we can identify improve upon this process.

Dr. Schuchat, I have a question for you. In the legislation that I am working on right now, my Bill, we

create mechanisms to help increase the communication and sharing between the CDC and industry, and, you know, ways that we can get that information out to impact public health. In your opinion, how can the CDC work more closely in partnership with industry to reduce the risk and uncertainty of investing in the novel vaccines?

Dr. {Schuchat.} We appreciate the chance to work closely with industry as they are doing their early development and research.

Mrs. {Ellmers.} Um-hum.

Dr. {Schuchat.} We welcome companies to come meet with us to share their ideas, and we--

Mrs. {Ellmers.} Um-hum.

Dr. {Schuchat.} --share all of the information--

Mrs. {Ellmers.} Um-hum.

Dr. {Schuchat.} --we have in terms of the public health burden--

Mrs. {Ellmers.} Um-hum.

Dr. {Schuchat.} --need and likely interest in terms of public or providers.

Mrs. {Ellmers.} Um-hum.

Dr. {Schuchat.} So we do that regularly, and we welcome the opportunity to do it systematically.

Mrs. {Ellmers.} Dr. Midthun, again, thank you for being here, and again, thank you for being a participant in the roundtable discussion that I had back in the District in October. As we are looking at vaccine manufacturers to more readily export vaccines from the U.S. and make them available to people around the world, again, the legislation that we are working on right now helps to expedite the licensure process. In addition to expediting export licenses, what else can the FDA do to help speed up production and approval on delivery of flu vaccine availability?

Dr. {Midthun.} No, I think we currently use all the expedited pathways that are available. So we can use accelerated approval, which we--

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} --have done for numerous influenza vaccines.

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} We also did recently for the 2 meningococcal B vaccines that we approved; one in October and

one just last month. We also used the breakthrough designation which basically means that there is a very concerted interactive approach early on and throughout the process with industry to really accelerate the development of products. So we use all of these tools, and they are very important. They, of course, do rely on having certain science.

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} So, for example, to use--

Mrs. {Ellmers.} Sure.

Dr. {Midthun.} --accelerated approval, you typically rely on what we call a surrogate endpoint. Usually in the case of a vaccine it would be some immune response. But you need to have information that actually indicates that this immune response is--

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} --is, you know, you know, really likely to predict clinical benefits. So there is also a scientific piece that is very, very important that others, for example--

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} --in industry, NIH and other partners,

need to work on--

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} --to make that kind of--

Mrs. {Ellmers.} Um-hum.

Dr. {Midthun.} --process available, but we work very closely, obviously, with our sponsors to facilitate whatever their development plans are.

Mrs. {Ellmers.} Thank you. And one last comment that I would like to make, Mr. Chairman, if you would indulge me. One of the concerns that was raised by Mr. Tonko from New York, having to do with the issues that our families are dealing with, with sick children and, you know, having to take time off of work, I would advocate for my good friend, Martha Roby from Alabama, she has a wonderful Bill, Working Families Flexibility Act, that actually addresses this issue and allows our workforce to be able to take part in the availability and ability to use overtime and bank it so that in the event that pediatric appointments need to be made, or any of these things, families can make those choices. So I would advocate to the co-sponsorship of that Bill. It is a very good Bill, and it addresses the very issues that we are

talking about today.

Mr. {Murphy.} Thank you.

Mrs. {Ellmers.} So thank you, Mr. Chairman, and I--

Mr. {Murphy.} Thank you.

Mrs. {Ellmers.} --yield back.

Mr. {Murphy.} And I want to thank the panelists. Look, I think we are all frustrated, we need to be speeding up this process and the science, and if there are other legislative things we need to do, please let us know. I don't--this is the day after Groundhog Day, and I don't want to be here with another Groundhog Day a couple of years from now running into the same problems, with the same issues, and having the same crisis with so many Americans getting sick and dying for whatever this is. So I ask--

Ms. {DeGette.} Would the gentleman yield for one second?

Mr. {Murphy.} Yes.

Ms. {DeGette.} I completely agree with the Chairman, but I will say I want to commend this panel and others at the CDC and NIH because, having been on this committee now for 18 years, we really have made advances from when we first

started with those early hearings on egg-based technologies. We just need to accelerate that. So anything we can do to help, we are here to help. Thank you.

Mr. {Murphy.} Appreciate that. I ask unanimous consent that Members' written opening statements be introduced into the record, and without objection, the documents will be entered in the record.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Murphy.} In conclusion, thank you again to the witnesses, and Members that participated in today's hearing. I remind Members they have 10 business days to submit questions for the record, and I ask that all witnesses agree to respond promptly to those questions.

And with that, this committee is adjourned. Thank you.

[Whereupon, at 12:34 p.m., the Subcommittee was adjourned.]