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FLU SEASON: U.S. PUBLIC HEALTH PREPAREDNESS AND RESPONSE

WEDNESDAY, DECEMBER 4, 2019

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m., in Room 2123, Rayburn House Office Building, Hon. Diana DeGette [chairman of the subcommittee] presiding.

Present: Representatives DeGette, Kennedy, Ruiz, Kuster, Castor, Tonko, Clarke, Peters, Pallone (ex officio), Guthrie, Burgess, McKinley, Griffith, Brooks, Mullin, Duncan, and Walden (ex officio).

Staff Present: Kevin Barstow, Chief Oversight Counsel; Jesseca Boyer, Professional Staff Member; Jeff Carroll, Staff Director; Austin Flack, Staff Assistant;

Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Zach Kahan, Outreach and Member Service Coordinator; Chris Knauer, Oversight Staff Director; Meghan Mullon, Staff Assistant; Tim Robinson, Chief Counsel; Nikki Roy, Policy Coordinator; Emily Ryan, GAO Detailee; Andrew Souvall, Director of Communications, Outreach and Member Services; Benjamin Tabor, Policy Analyst; C.J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Brannon Rains, Minority Legislative Clerk; Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations; and Natalie Sohn, Minority Counsel, Oversight and Investigations.

Ms. DeGette. The Subcommittee on Oversight and Investigations hearing will now come to order.

Today, the committee is holding a hearing entitled "Flu Season: U.S. Public Health Preparedness and Response." The purpose of today's hearing is to examine the Federal Government's efforts and forecast for the 2019-2020 influenza season and ongoing influenza-related research and innovation.

The chair now recognizes herself for purposes of an opening statement.

As I said, we're here this morning to discuss the topic of our Nation's preparedness for this year's flu season. Ensuring our public health agencies have the tools they need to prepare and respond to seasonal and pandemic flu has and will remain a bipartisan effort. That's why this is the 11th hearing the committee has held related to influenza over the last 15 years. And I'm very pleased that we are having this hearing so early at the beginning of the flu season this year so we can talk about what we predict during this flu season and also encourage Americans to please, please, please go get their vaccinations.

According to the CDC, a majority of States are already seeing increased flu activity, and history has shown that we're still likely weeks away from the first peak of the season that often occurs December through February.

Today, we have the Nation's leading health experts about how people can better protect themselves and their children from this illness before peak flu season. And I want to thank all of our witnesses for being willing to come here year after year to address this important topic. I really feel like we're getting the band back together again in a way that I hope will be effective to let Americans know what's happening.

You know, we know from past flu seasons that our Nation's preparation and response efforts are critical. During the particularly severe 2017 and 2018 flu season, for example, as many as 80,000 people died as a result of the flu. So many people became sick that hospitals were forced to put tents in parking lots to treat people who had become ill.

The more recent 2018-2019 flu season was the longest one in a decade. And again, while it's still too early to tell how severe this year's flu season will be, given the unpredictability and serious nature we face, the fact that our Nation's flu vaccination rates continue to be well below our national target of 70 to 90 percent is alarming.

Last year, for example, only 63 percent of children and only 45 percent of adults received a flu vaccine. While those rates are disappointing, the fact that they are 5 to 8 points higher, respectively, compared to the year before means at least we're going in the right direction. But we have a lot more to do to protect the public health. I hope that the witnesses today can provide us an update on the efforts underway to further strengthen vaccine confidence and improve the annual vaccination rates.

I also look forward to hearing from the witnesses about the effectiveness of the flu vaccine and what research is underway to improve its efficacy. While last year's vaccine was up to 44 percent effective against the H1N1 flu strain, which was the initial flu strain that was circulating, it was only 9 percent effective for the H3N2 strain, which became the dominant strain at the end of the season.

And I know our witnesses will remind us, even a vaccine with low effectiveness is still able to protect millions of people from getting sick and help reduce the severity of symptoms for those who do. And that's why the flu vaccine remains the best tool we have to protect the public's health during these threatening times. But as I've said

numerous times before, we can and will do better to improve the effectiveness.

The NIH recently began conducting the first in-human trials for a universal flu vaccine -- and I'm really looking forward to hearing about that -- and the National Influenza Vaccine Task Force was recently established. These developments are promising, but the importance of a strong public health infrastructure necessary to prepare for and respond to seasonal flu cannot be overstated.

I have confidence that our Federal, State, and local public health officials have put us in a strong position to respond to this year's flu season, but there's always more work to be done. And I'm looking forward to hearing from our witnesses about just what kind of work we can do.

Another issue I know that many people will be raising is the issue of producing flu vaccine here domestically in the United States, because, God forbid, we have another flu pandemic. We want to make sure that we can protect our own people.

And so, again, I'm thankful that we have such a distinguished panel today. I understand that you've brought slides, so we will not be disappointed. It's our job to -- that you have the tools and the resources to remain on the cutting edge of science, and I hope today that you can tell us what you need going forward.

With that, I am pleased, filling in in the ranking position is the ranker on the full committee today, Mr. Walden, for 5 minutes.

[The prepared statement of Ms. DeGette follows:]

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

Mr. Walden. Well, thank you, Chair DeGette, we appreciate the hearing today. As you've said, this is a longstanding bipartisan tradition of this committee to check in ahead of flu season and find out where we stand and continue to support innovation in this space and other medical device space and prescription drug space and the whole thing. When we're trying to find cures for diseases, we're all on board.

So every year millions of Americans put themselves at an increased risk of getting the flu because they don't get the flu vaccine. Just for the record, I have. I'm not a big guy on shots, but I -- you know, I do it every year, and I'm glad I do. They also -- people who don't, though, are increasing the risk for the individuals who cannot be vaccinated, including young children who are not old enough to get the flu vaccine, will get the flu. So if you've not gotten the flu vaccine yet this year -- I spent a night or two in a Holiday Inn, so I'm going to play doctor here -- go get the flu vaccine. If they shouldn't, I'll let our panel of real live doctors counter me on that, but I think that would be your counsel to all of us as well.

If you think you may have the flu, please go see your doctor. There are antivirals available to reduce the symptoms you experience with the flu and short-lived duration of the flu. Great advances there.

Our senior citizens are the group at greatest risk of serious flu-related complications. According to the Centers for Disease Control and Prevention, people 65 years of age and older account for about 70 to 85 percent of seasonal flu-related deaths in recent years, and between 50 to 70 percent of seasonal flu-related hospitalizations. Seniors can get the regular flu shot or one of the two flu shots that are specifically designed for people 65 years of age or older -- the high dose flu vaccine and the

adjuvanted -- I'll get that -- flu vaccine.

I, along with some of my fellow Republican members of the committee, sent a letter to the director of the CDC last February about improving flu vaccination coverage for seniors. We asked whether a preferential recommendation from CDC's Advisory Committee on Immunization Practices, ACIP, for vaccinating adults 65 years of age and older with a high dose or an adjuvanted influenza vaccine could reduce deaths and hospitalizations or even improve vaccination coverage. CDC told us they did not believe that there was adequate information on these vaccines to rise to a level of ACIP making a preferential recommendation.

Given what appears to be substantial evidence substantiating superior effectiveness for seniors with each of these alternatives compared to the standard-dose flu vaccine, and the preferential recommendations from other respected foreign health authorities for one of these alternatives, I do want to explore the reasons for CDC's hesitancy about supporting preferential recommendation when it appears there's real reason to believe it could help save lives.

I'm also looking forward to hearing more about research efforts to improve the flu vaccine and hopefully develop a universal flu vaccine. A universal flu vaccine would provide long-lasting protection against multiple seasonal and pandemic flu viruses, and I expect Dr. Fauci will update us on HHS' progress in implementing the strategic plan for a universal influenza vaccine that was first published in February of 2018.

Now, the President's recent executive order promotes the development of better flu vaccines, and I support its emphasis on the need to modernize the manufacturing process for the flu vaccine. The current egg-based manufacturing process that's used for most flu vaccine doses administered in the United States takes about 22 to 24 weeks

to produce the flu vaccine.

Earlier this year, advisers at the World Health Organization delayed their recommendations for the H3N2 vaccine strain to include in the flu vaccine this year by a month. And there were considerable concerns that that delay might adversely affect the vaccine supply at the beginning of this season. Thankfully, the delay did not impact the supply.

So I look forward to today's discussion. I hope to hear more about faster and more scaleable manufacturing platforms, the role of antiviral drugs to mitigate the severity of the flu, and the concern over possible drug-resistant flu strains.

With that, I would yield the balance of my time to the gentlelady from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Mr. Walden.

It's been over a hundred years since the 1918 pandemic flu killed millions of people around the world, and actually, 675,000 Americans lost their lives then. Last flu season, and I think most people don't realize, 61,000 Americans lost their lives, including a hundred Hoosiers.

Although the development of vaccines and drugs is a challenging process, it is so important that we continue to take action to modernize our influenza vaccines in this country.

This committee, led by this committee, we passed PAHPA into law earlier this summer, the reauthorization of PAHPA. It established a pandemic influenza program as well as an emerging infectious disease program at BARDA to deal with known and unknown threats. The research funded by BARDA has already significantly expanded our domestic vaccine production capacity from the ability to produce just 60 million doses

of antigen influenza to the ability to produce more than 600 million doses. And with PAHPA, it supports the increase of our manufacturing capacity and our stockpile medical countermeasures, but we have much work left to do.

I want to thank all the incredible witnesses here today for your expertise. You and your teams are the ones that are going to ensure that our Nation is better prepared for pandemic flu. I look forward to hearing from our witnesses.

I yield back.

Mr. Walden. And I yield back.

[The prepared statement of Mr. Walden follows:]

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Ms. DeGette. The chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes for purposes of an opening statement.

The Chairman. Thank you, Chairwoman DeGette.

Every year, influenza causes millions of illnesses, hundreds of thousands of hospitalizations, and tens of thousands of deaths across the United States. Last year, more than a hundred children died as a result of this preventable and treatable disease, and while we're still in the early months of this year's flu season, it has already resulted in the deaths of five children.

Today, we're continuing this committee's long history of examining flu preparedness and response, and I want to thank Chairwoman DeGette in particular because I know that she annually -- pretty much annually has these hearings because she thinks it's very important. And I do want to also thank our ranking member of the full committee, Mr. Walden, for pointing out, as an example, that he had his flu shot, and I had mine too, because I think we do have to serve as an example.

The flu is one of the many preventable infectious diseases that threaten public health. We know that seasonal flu is particularly challenging to address. Flu viruses are mutating and changing constantly, and we do not yet have the ability to predict how severe flu season will be, when it will peak, or what flu strains will dominate. We also have a lot of questions about why the flu vaccine is more effective for some people and how someone's health status may affect the body's immune response.

I've been encouraged by recent efforts at the National Institutes of Health to study these issues with the goal of producing a universal flu vaccine that is effective against a broader range of flu strains. I'm also encouraged by the ongoing research supported by

the Biomedical Advanced Research and Development Authority, or BARDA, and the ongoing leadership in coordination among all of the agencies testifying before us today. These efforts are vitally important.

While we wait for the results of this research, it's still critical that we continue to stress the importance of getting vaccinated every year. Thankfully, cost should no longer be a barrier for anyone to receive their annual flu vaccine. Thanks to the Affordable Care Act, flu and other immunizations are required to be covered by health insurance at no cost to the patient. The Vaccines for Children Program has also provided free vaccinations for eligible children for nearly 25 years.

Annual flu vaccination is the best method for preventing flu and its potentially severe complications. This is true even when the flu vaccine is less effective for various strains. For example, during the 2017-2018 season, the effectiveness of that year's flu vaccine was estimated at 40 percent overall. Yet the Centers for Disease Control and Prevention estimated that it still prevented over 6 million illnesses, 91,000 hospitalizations, and 5,700 deaths.

Vaccinating yourself not only increases the odds that you won't get sick this season, but also protects everyone you come in contact with. And this is particularly important for those more vulnerable to the flu and its symptoms, such as people with chronic health conditions, older parents, or a baby niece or nephew.

And all of this demonstrates the importance of getting a flu shot, but unfortunately, 55 percent of adults were not vaccinated against the flu last season. So I look forward to hearing from the CDC about its communications and outreach strategies to increase the rates in the future.

And I know that one of the issues continues to be public confidence in vaccines,

but it's critical that we continue to get the word out that vaccines are safe. While harmful misinformation campaigns continue to proliferate online and in communities across the country, the agencies must continue to spread the message of vaccine safety. And we also have to continue to improve our vaccine manufacturing process to make flu vaccines even more effective and our ability to treat patients if they do come down with the flu.

So again, I thank our witnesses for joining us, for the critical leadership role your agencies play in our Nation's flu preparedness and response efforts. And again, thank you, Chairwoman DeGette.

I yield back.

[The prepared statement of Chairman Pallone follows:]

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Ms. DeGette. The gentleman yields back.

The chair now recognizes and welcomes the chair -- the ranking member of the subcommittee, Mr. Guthrie, for 5 minutes.

Mr. Guthrie. Thank you very much. Thank you, Chair DeGette, for holding this hearing on such an important issue.

This committee has a long history of conducting oversight of the Federal Government's response to the seasonal flu. The flu is a leading cause of death in the United States. Thousands of Americans die from flu every year, and hundreds of thousands of Americans are hospitalized.

Last flu season alone, the CDC estimates that up to 42.9 million people got sick with the flu, up to 647,000 individuals were hospitalized, and up to 61,200 individuals died from the flu. Individuals 65 years and older accounted for 90 percent of the deaths and 70 percent of the hospitalizations for the 2017-2018 flu season.

In light of this tremendous burden on our seniors, in February of this year, I, along with Republican leaders Walden and Dr. Burgess, wrote to the CDC director about whether the CDC is doing enough to improve flu vaccine coverage and to promote high-dose and adjuvanted flu vaccines. I practiced that word twice, and I still couldn't get it out.

While we examine how to improve the response to seasonal flu, we know the best way to prevent getting the seasonal flu is to get vaccinated each season. If you have not already gotten your flu vaccine this season, please go get your flu vaccine today.

Although the flu vaccine does not have the level of effectiveness of other well-known vaccines, it is absolutely better than doing nothing. The flu vaccine saves

thousands of lives each year. The flu vaccine also helps reduce severe outcomes when someone does become sick with the flu.

According to CDC data, about 80 percent of the flu associated with deaths in children have occurred in children who were not vaccinated. Moreover, a 2017 study showed that the flu vaccine also reduces severe outcomes in hospitalized patients.

I have questions today on how we can continue to improve the flu vaccine. Preliminary CDC data shows that the seasonal flu vaccine was only 29 percent effective for the 2018-2019, the lowest it has been in a decade. For more than 70 years, most flu vaccines administered in the United States have been made through the egg-based manufacturing process. We have seen some innovation over the last decade, however, with the introduction of the new manufacturing technologies, using a cell or recombinant DNA technology. Most of the flu vaccine doses distributed in the United States are still manufactured using egg-based process.

Indeed, the CDC estimates that about 82 percent of the projected vaccine supply produced for the 2019-2020 flu season will be produced using egg-based manufacturing technology, while the remaining vaccine will be produced using the cell-based and recombinant technology.

During the hearing on March 2018, Dr. Rick Bright, the HHS Deputy Secretary for Preparedness and Response, testified that we can improve the effectiveness of a vaccine in four ways: Expand domestic capacity for the cell-based and recombinant-based technologies enhances the effectiveness use of flu vaccines; and the addition of adjuvants or higher doses of antigen; conduct clinical trials to expand vaccine in all age groups; and continue to modernize the vaccine production processes for speed and flexibility.

At that hearing, Dr. Bright noted that cell-based and recombinant-based

technologies offer greater speed and flexibility than the traditional egg-based manufacturing process. And some studies have shown that they may also be more effective than egg-based vaccines.

For these reasons, I was pleased to see the President make modernizing and improving influenza vaccines a top priority through his executive order on September 19, 2019. Modernizing flu vaccines will help protect lives through prevention and promote public health and national security.

Pandemic and seasonal flu are interdependent, and our approaches to seasonal and pandemic influenza are inextricably interwoven. What we do in one area directly impacts the other area. For example, when we expanded our domestic manufacturing capacity for pandemic response, manufacturers then also had the capacity to include an additional flu strain in the seasonal vaccine, moving from three-strain to four-strain seasonal vaccines for better coverage.

I appreciate the administration's commitment to improving our flu preparedness. I welcome all of today's witnesses, and look forward to today's discussion about how we can keep Americans healthy during flu season and improve our Federal response to both pandemic and seasonal flu.

And I yield back.

[The prepared statement of Mr. Guthrie follows:]

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Ms. DeGette. I thank the gentleman.

I ask unanimous consent that members' written opening statements be made part of the record.

Without objection, so ordered.

I now want to introduce the witnesses for today's hearing. Dr. Nancy Messonnier, who's the director of the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention. Welcome. Dr. Anthony Fauci, director, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Dr. Robert Kadlec, Assistant Secretary for Preparedness at U.S. Department of Health and Human Services; and Dr. Peter Marks, director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration.

I want to thank again, I thank all of you for coming before the committee. You're aware, I know, that the committee's holding an investigative hearing, and when we do so, we have the practice of taking testimony under oath.

Does anyone have an objection to testifying under oath today?

The witnesses have all responded no.

The chair then advises you, under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel.

Does any of you wish to be accompanied by counsel?

Let the record reflect the witnesses have responded no.

If you would please rise and raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms. DeGette. Let the record reflect that the witnesses have responded

affirmatively. And you're now under oath and subject to the penalties set forth in title 18, section 1001 of the U.S. Code.

The chair will now recognize our witnesses for a 5-minute summary of their written statement. In front of you is the microphone and a series of lights. The timer counts down your time, and the red light turns on when your 5 minutes has come to an end.

Dr. Messonnier, you're now recognized for 5 minutes.

TESTIMONY OF NANCY MESSONNIER, M.D. (CAPT, USPHS, RET), DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE FOR ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; ROBERT P. KADLEC, M.D., M.T.M.&H., M.S., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND PETER MARKS, M.D., PH.D., DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF NANCY MESSONNIER, M.D.

Dr. Messonnier. Good morning, Chairman DeGette, Ranking Member Guthrie, and members of the committee. I'm Dr. Nancy Messonnier, director of the National Center for Immunization and Respiratory Diseases at CDC. And I want to thank the committee for the opportunity to discuss CDC's work to protect Americans from influenza.

Influenza is a serious and ongoing public health threat. Each year, millions of Americans get sick, hundreds of thousands require hospitalization, and tens of thousands die. The one certainty with influenza is that it is unpredictable. The virus is constantly changing and generating new flu strains that can lead to more severe flu seasons and devastating pandemics.

These changes have also allowed the virus to evade existing human immunity and require us to develop a new vaccine every single year. CDC recommends an annual flu

vaccine for everyone 6 months of age and older. Influenza vaccination remains the single best way for Americans to protect themselves from the flu.

The 2019-2020 flu season has officially begun. National levels of influenza-like illness have been increasing for nearly a month, with the highest activity in the South and the West. Despite the significant benefits, the effectiveness of the flu vaccine and the number of Americans being vaccinated are not optimal. That's why we at CDC are working with our Federal colleagues to use cutting-edge science to make influenza vaccines better and ensuring providers and the public are choosing to vaccinate with confidence. This is a complicated multiyear process that must be both stepwise and iterative.

Under the recently announced executive order to modernize influenza vaccines, CDC will work with our partners to promote new technologies to improve vaccine manufacturing and effectiveness.

While the long-lasting broadly protective universal vaccines that Dr. Fauci will talk about are the ultimate goal for flu prevention, these vaccines are still years away. In the nearer term, we can save millions of Americans from the flu by making incremental improvements to vaccines. If we increase vaccine effectiveness by just 5 percent, we can prevent over 17,000 additional hospitalizations in a single year.

Despite overwhelming and consistent scientific evidence that flu vaccines are safe and effective, nearly 40 percent of children and over half of adults did not receive their flu vaccine last season.

Flu vaccines are very safe. During the 2018 to 2019 flu season, nearly 170 million doses of flu vaccines were distributed nationwide. Of these, less than 0.01 percent of those receiving a vaccine reported a potential adverse event. Injection site reactions

were the most commonly reported event.

CDC has a central role in every part of influenza vaccine development and administration. Over the last decade, CDC has significantly improved worldwide surveillance and characterization of influenza viruses. Global epidemiological and biological data is the foundation of the influenza vaccine virus selection and development process. We develop diagnostic assays for public health laboratories in the United States and globally, and we ship them around the world.

CDC uses next-generation sequencing to gather and analyze genomic data and share this data with other stakeholders. Genomic data help us make better decisions about what goes in each year's flu vaccine and also help us to evaluate viruses for their pandemic potential.

CDC has invested in each State public health department to have automated real time electronic laboratory reporting of influenza test results to CDC using cloud-based messaging. CDC has supported manufacturing innovations by developing candidate vaccine viruses for the cell-based vaccine and providing genomic sequences used to make the recombinant protein vaccine.

Genomic sequencing equipment, which once filled the room, now fits in the palm of your hand. We now have a mobile mini laboratory that can be taken on a plane as a carry-on and set up almost anywhere around the world. Both cell and recombinant vaccines have the potential to be manufactured more quickly and may be more effective than traditional vaccines that are grown in eggs.

CDC was the first to establish a national system for the routine monitoring of influenza vaccine effectiveness, and we're currently expanding this network to add new immunity tests. This system provides critical information for manufacturers and

researchers in developing enhanced vaccines by collecting specific data about how well the vaccine works each season in each population. CDC will continue to innovate to make incremental improvements in vaccine effectiveness and vaccine coverage.

This week is National Influenza Vaccination Week, and it is a great opportunity to remind all of you to protect yourselves and your family by making sure that you and your families get the annual flu vaccine.

Thank you for the opportunity to speak, and I'm happy to take questions.

[The prepared statement of Dr. Messonnier follows:]

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Ms. DeGette. Thank you so much, Doctor.

And now, Dr. Fauci, you're recognized for 5 minutes.

TESTIMONY OF ANTHONY S. FAUCI, M.D.

Dr. Fauci. Chairperson DeGette, Ranking Member Guthrie, members of the committee, thank you for giving me the opportunity to speak to you today about the role of the National Institutes of Health in their research in addressing seasonal and pandemic flu.

If I could have the slide up, please.

As you've heard, and many of you have mentioned, the current seasonal influenza vaccines are not consistently effective, but I want to underscore what several people have said today, that it doesn't really matters if it's a hundred percent, 50 percent, or 20 percent, it is always, always better to get vaccinated than not.

Yet we need to do better. Both the seasonal flu and the fact that pandemics do occur -- we have experience that tell us it happens and will happen again. In addition, we tend to be able to chase after potential pandemics, like the H5N1, the H7N9.

This is a paper that we wrote just a little while ago, emphasizing the point that I'm -- oops, it disappeared. Sorry, there you go -- that we really need to do better. We need to do better in two aspects. We need to improve seasonal influenza vaccines, we need to prepare for pandemics, and we do need a universal vaccine. And that's what I want to talk about over the next couple of minutes.

As was mentioned just a while ago, we put together a strategic plan and a

research agenda to develop a universal influenza vaccine, and published this in February of 2018. This plan is what we call an iterative plan. By "iterative," meaning it would be a stepwise process. We are not going to get a universal flu vaccine next month or next year.

This particular slide shows what we call the two major groups of influenza vaccines -- influenza A vaccines -- not vaccines, but viruses.

The first group, as you see there, contains a number of influenza As, including H1 and the prepandemic H5. Group 2 contains H3 and the prepandemic H7. When we start developing a universal influenza vaccine, we will start with getting H3N2 or H1N1, all of the iterations, and then we'll move to the next one. And that's what that pyramid, that triangle there is on the right.

The first is a highly specific vaccine, what we have today, what we're giving to people in today's vaccine. As you go down, you get broader coverage. That's what we mean when we say a universal influenza vaccine.

You mentioned the issue of egg-based and the vicissitudes associated with that. These are various vaccine platforms. By "platforms" we mean a certain mechanism whereby we have a vaccine that does not require growing the egg -- growing the virus in eggs or even in cells. It's the recombinant DNA technology that you just mentioned.

Let me give you an example of how we're using that to develop a universal flu vaccine. This is a picture of the influenza virus on the left. On the right is a blowup of the hemagglutinin protein on the surface of that virus. As you can see here, there are two components of it: a head and a stem. The vaccine induces a response predominantly against the head, which is good news, because if it works, it protects you.

However, unfortunately, that particular component of the protein mutates

readily. So from season to season, it tends to drift. And that's the reason why all of us should get a vaccine every single year. When it changes a lot, we call that a shift, and that's when you get a pandemic. But note that the red dots, which mean mutations, are very few on the stem. That does not change very much.

And what investigators have done over the last few years is recognize that if you, for example -- and this is just one approach to a universal flu vaccine -- if you cut off the head and take that stem and put it on a nanoparticle, which is one of those platforms that I mentioned -- and I have an example of one of them blown up 4 million times. This is the first example of a true universal flu vaccine that are directed against the group 1. And this was just put into clinical trial last spring, a phase 1 trial. It is currently in phase 1. We're asking about safety and does it induce a good immune response.

Next year, we will try to cover the group 2. And I hope that as you continue to have these annual hearings, we'll be able to, year after year, come back to you and talk to you about the progress of going from the top of that pyramid all the way down to a true universal influenza vaccine.

Thank you.

[The prepared statement of Dr. Fauci follows:]

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Ms. DeGette. Thank you so much, Dr. Fauci.

Dr. Kadlec, now you're recognized for 5 minutes.

TESTIMONY OF ROBERT P. KADLEC, M.D.

Dr. Kadlec. Thank you, Chairwoman DeGette, Ranking Member Guthrie, and distinguished members of the subcommittee. Thank you for your continued commitment to flu preparedness and the opportunity to testify on our efforts to develop and rapidly manufacture effective medical countermeasures to treat influenza.

As noted, influenza is a serious threat to human health and poses a significant national security risk. Annually seasonal flu leads to hundreds of thousands of hospitalizations, tens of thousands of deaths, and costs $30 billion a year in lost productivity and healthcare costs. An influenza pandemic would be even worse, killing hundreds of thousands of Americans, costing up to $3.8 trillion.

Mitigating both seasonal and pandemic influenza is critical to saving lives, protecting Americans, and reducing the economic and healthcare burdens that result.

Before going further, I want to take a moment to thank you and your staff who worked on passing the Pandemic All-Hazard Preparedness and Advancing Innovation Act of 2019. It strengthens public health and readiness and healthcare readiness, bolsters response and recovery programs and increases transparency.

Specific and relevant to this hearing, it authorized an annual appropriation for pandemic influenza that will ultimately enhance the confidence of private partners to invest in research, development, and manufacturing activities.

We also appreciate the past congressional supplemental appropriations for pandemic influenza preparedness, with a 2005, 2006, and 2009 supplemental appropriations, we invested in new vaccines, antivirals, domestic manufacturing, and enhanced stockpiling. Continued effort and support and funding remains critical, however.

ASPR's role in pandemic influenza preparedness has defined multiple policy documents. The 2017 HHS Pandemic Influenza Plan outlines ASPR's initiatives to prevent, control, and mitigate the effects of the influenza virus to humans. More recently, in September of this year, the White House released an executive order on pandemic influenza preparedness. This EO identifies specific activities, many of which ASPR's already supporting with BARDA, to strengthen preparedness efforts.

Turning to preparedness initiatives, thanks to BARDA's investments, we've supported the development and approval of 23 influenza-related vaccines, antiviral drugs, devices, and diagnostics. Two significant items related to vaccine development is that now there is a licensed, cell-based influenza vaccine that can be administered to individuals 4 years and older, and a licensed recombinant DNA influenza vaccine available for persons 18 and older.

To enhance overall vaccine supply, we've supported development and licensure of adjuvanted and influenza vaccines, and during a pandemic, using adjuvants increase not only the limited vaccine supplies to protect more people, but do so faster.

To treat persons infected with influenza, we're also developing antiviral drugs. ASPR and BARDA has funded nine novel antiviral advanced development projects since 2007. To better detect the emergence of influenza, we're supporting the development of in-home and wearable diagnostics to enable patients to take responsible actions

towards earlier treatment to reduce the severity of the illness and nonpharmaceutical approaches like staying home to prevent spread of the disease.

While medical countermeasures will aid in the response and potentially limit the spread, there will be a strain on our healthcare infrastructure. Since 2002, investments administered through ASPR's Hospital Preparedness Program have improved individual healthcare entities' preparedness and have built a better coordinated system.

Beginning in 2018, ASPR has supported regional partnerships to enhance capabilities above what exists at the local coalition level. The intended goal is to enable multiple healthcare systems to leverage assets and support one another when needed.

A second issue that impacts response capabilities is our dependence on medical supplies, active pharmaceutical ingredients, and raw materials from overseas. When considering the global challenges of a pandemic, this dependence would become a matter of national security. ASPR is now incorporating new technologies to support innovation for preparedness and response. An example is alternative administration approaches such as microneedle patches that deliver vaccine through the skin that could limit our dependence on imported needles and syringes and allow for faster delivery and administration of vaccine. We'll continue to look for other innovative alternatives to address our reliance on foreign supplies.

An influenza pandemic poses a significant threat to national security that could result in a significant loss of life, negatively impact the economy, and place a tremendous strain on our healthcare infrastructure. Continued support from Congress is critical to push the needle forward to best protect and respond to emerging threats.

Thank you for your time, and I look forward to discussing how we can continue to work together on this important issue, and I'll be happy to answer any questions you may

have.

[The prepared statement of Dr. Kadlec follows:]

******** INSERT 1-3 ********

Ms. DeGette. Thank you, Doctor.

Dr. Marks, now I'll recognize you for 5 minutes for an opening statement.

TESTIMONY OF PETER MARKS, M.D.

Dr. Marks. Thank you, Chair DeGette, Ranking Member Guthrie, distinguished members of the subcommittee. I'm Peter Marks, director of the Center for Biologics Evaluation and Research at the Food and Drug Administration. Thank you for the opportunity --

Ms. DeGette. Dr. Marks, can you just move the microphone a little closer? Thanks.

Dr. Marks. Sorry.

Thank you for the opportunity to describe FDA's efforts, in close coordination and collaboration with its Federal partners, to ensure the development, approval, and availability of critical safe and effective medical products to address seasonal and pandemic influenza.

These products for influenza include drugs such as antiviral agents for its prevention and treatment, biologics including vaccine for prevention across the age spectrum, and devices for rapid diagnosis and supportive care.

FDA's involvement in these products spans the entire product life cycle, and the agency makes use of all of its available regulatory tools and expedited programs, including those provided by Congress, as appropriate, to help advance products critical for public health through toward approval.

Following approval, the agency monitors the safety of these products through post-market surveillance. Americans can rely on the fact that in approving a medical product, FDA has determined that it is both safe and effective. The confidence in safety and effectiveness can be particularly important in combatting increased vaccine hesitancy which can undermine the public health benefits of vaccination.

Influenza viruses continually undergo changes in their genetic makeup. These changes can occur from one season to the next. They can also occur during influenza season. Unlike other vaccines, the composition of influenza vaccines must be updated annually so that they're effective against the predominant circulating virus that's anticipated in the upcoming influenza season.

For the 2019-2020 season, there have been more than 160 million doses of influenza vaccine produced for use in the United States, and manufacturing demands for influenza vaccines are substantial. No other vaccine is produced, FDA-approved, and distributed every year across the Nation within an approximately 6-month timeframe.

Manufacturing of the antigens to be included in the vaccines usually occurs between December and May of each year. FDA then approves the updated seasonal influenza vaccines by the end of July, and in parallel with vaccine manufacturing, FDA develops and calibrates reagents that are provided to vaccine manufacturers and our regulatory counterparts across the globe. Manufacturers and the FDA use these reagents to test the vaccines for potency and identity before FDA provides approval of the new formulation of the licensed seasonal influenza vaccines for distribution in the United States.

Every year, FDA begins working with manufacturers at the earliest stages of influenza vaccine development, and we continue to assist them throughout the

production phase. During this period, we engage with companies on technical and manufacturing issues and conduct facility inspections, as warranted, to ensure compliance with current good manufacturing practices. The rigorous timelines currently required for vaccine production, including strain selection, reagent preparation, manufacturing of vaccine components, and formulation, fill, and distribution of the final product leave little room for error or for changes in vaccine composition after the initial strain selection process.

On the horizon are advances in manufacturing, as well as the adoption of different technologies for the production of antigen that could help compress the timeline for the production process and provide greater predictability. Certain technologies could offer more opportunity to adjust the composition of the vaccine closer in time to influenza season should a new influenza strain emerge after production has already begun.

In this regard, FDA scientists are collaborating with others to develop such needed advanced manufacturing technologies to more efficiently produce influenza virus or influenza antigen. The development adoption of such advanced manufacturing technologies has the potential to address the need for maximally efficient, agile, and flexible manufacture of both current and next-generation influenza vaccines produced according to the FDA's high standards for safety and effectiveness on which the American public relies.

Collaboration across the Federal Government is essential to meeting these challenges, and FDA looks forward to collaborating with BARDA, CDC, and NIH to implement the recent executive order on modernizing influenza vaccines and to further accelerating the adoption of improved influenza vaccine technologies.

As we continue to invest in the future of manufacturing and vaccine technology,

we also need to remember the importance of simply ensuring that more people are vaccinated, so please get your flu vaccine. And we also must work hard to ensure that products used to treat influenza, including antivirals and intravenous saline, are available and that we take steps to prevent and address shortages. As always, FDA remains committed to communicating and sharing updates with the public about all aspects of our flu response.

I look forward to answering your questions today. Thank you.

[The prepared statement of Dr. Marks follows:]

******** INSERT 1-4 ********

Ms. DeGette. Thank you, Doctor.

Apparently, they were getting ready for the Energy and Commerce holiday party early and they turned the lights down. They thought we should illuminate this important issue by turning the lights back up.

Okay. Now it's time for the members to ask questions, and the chair will recognize herself for 5 minutes.

And I just want to say it's really easy to forget about the dangers that even seasonal flu can pose. We worry about pandemic flu, of course -- I was telling Mr. Guthrie that keeps me up at night -- but the regular flu that occurs every year, people just dismiss it as like a cold or a stomach bug, but we shouldn't lose sight of the fact that the flu is consistently one of the 10 leading causes of death in the United States, and it leads to millions of illnesses every year. As many as 61,200 people died of seasonal flu just last year.

And so, Dr. Messonnier, I wanted to ask you, briefly remind us why the seasonal flu provides such a danger to public health.

Dr. Messonnier. Sure, thank you. And I think that's a really great point, that people dismiss the flu and confuse it with common colds that are also circulating this year. Anybody who's had influenza can tell you that it's nothing like that, and it can be incredibly serious.

The numbers for last year are preliminary, but I think they're a great place to start. Last year's season was one of the longest seasons on record, and our estimates are 40 million cases, 19 million office visits, 576,000 hospitalizations, 45,000 deaths, and importantly, 143 children died last year from influenza, and that's really a startling

number.

Ms. DeGette. Thank you.

Dr. Fauci, in my opening, and I know you referred to the fact that this virus mutates, sometimes even within one flu system -- or flu season. Why is it so critical for us to maintain vigilance in protecting against this really unpredictable virus?

Dr. Fauci. Well, I think you just said it, the fact that it is unpredictable means we need to be prepared, and the best way to be prepared from season to season is to develop a vaccine as closely matched to what you would predict the dominant circulating strain would be. In addition, there are other public health measures in addition that complement vaccine, such as treatment for influenza, particularly among those individuals who are at high risk for complications, such as the very young, the elderly, those with underlying conditions, pregnant women, et cetera.

We need to also do things that are public health measures. For example, if you do have the flu or your child has the flu, don't go to work, don't go to school. Make sure you don't spread it around the community.

Ms. DeGette. Right.

Dr. Kadlec, what keeps you up at night when you think about preparedness for the next flu -- big flu outbreak?

Dr. Kadlec. Pardon me. Thank you, ma'am, I appreciate the question. I mean, I sleep like a baby, I wake up every 2 hours screaming, but --

Ms. DeGette. Like me.

Dr. Kadlec. Yeah. But I think the key thing here is a pandemic. Quite frankly, I have unique background on this committee or this dais to have served 2 years on the Senate Intelligence Committee and looked at the many threats that face the United

States. But there is no singular threat that could devastate our country through our health and our economy and our social institutions than pandemic influenza.

Ms. DeGette. Yeah.

Dr. Kadlec. And we had four during the last century. And even though we've had a mild one in this first century, I think the risk is that we'll have another severe one, and that would devastate our country.

Ms. DeGette. And I know this panel has a lot more questions about that, but I'll throw that back to you, Dr. Fauci. I know this is why -- one of the reasons why it's so important that we continue to innovate and to advance the vaccines. What can Congress do -- what can Congress continue to do to help in these efforts to modernize and streamline the flu vaccine?

Dr. Fauci. Well, Madam Chairperson, what you can do is what you have been doing, and it really is very important. And all of us feel very strongly in a positive way how this committee continues to come back each year and emphasize publicly the importance of this.

With regard to support, the Congress has been extremely supportive of the research efforts at the NIH, as well as the work that the CDC and other agencies do. So my direct answer to your question is just keep it up, please.

Ms. DeGette. Okay. All right. Just because you said so.

Dr. Messonnier, I know that the chairman is going to ask you about what CDC is doing for public awareness, but maybe you can start giving me a brief answer to that.

Dr. Messonnier. Thank you. You know, Dr. Fauci and I were here previously talking in general about vaccines and the concerns about vaccine hesitancy in the United States. For flu, we have both concern from the public about the safety of vaccines, and

we need to reassure the public as well as emphasize the importance of their providers educating their patients about the safety and effectiveness of flu vaccine. But actually, if you ask people why they don't get the flu vaccine, what's different than other vaccines is, another reason that they really reflect on this, that they don't believe the flu vaccine works.

Ms. DeGette. All right.

Dr. Messonnier. I think we have to do a better job at educating people that, even if you can still get the flu with the flu vaccine, the flu is milder, and it can prevent hospitalizations and deaths. So it's worth getting it even for a year when it's not a great --

Ms. DeGette. Thank you.

The chair now recognizes the ranking member for 5 minutes for questioning.

Mr. Guthrie. Thank you.

I was going through trying to figure out where you've already answered some of my questions so we're all kind of on the same page on this area, which is great, but I'll -- so I may be repetitive, but it's important to repeat sometimes some of these things.

So, Dr. Kadlec, the September 19 executive order directs HHS to estimate the cost of expanding and diversifying domestic vaccine manufacturing capacity using innovative, faster, and more scaleable technologies. So putting that into real words, why is it important for us to improve our domestic vaccine manufacturing capacity for flu? And what faster and more scaleable technology would need to be used to expand and to diversify domestic capacity?

Dr. Kadlec. Well, thank you for your question, sir. And I think very simply is, the reason why domestic manufacturing is so critical, particularly for pandemics, is if

there's a pandemic, everybody will be taking care of themselves. And so the fact if we're reliant on foreign suppliers for vaccines or anything else, we're likely to be at the end of that line, because they're going to be taking care of that first.

The second issue is, quite frankly, sir, is there are technologies that exist today and some that Dr. Fauci's working on, like messenger RNA that will permit faster and more better matched vaccines to basically prevent flu, both seasonal and pandemic.

And specifically because of Congress' investments in the past, through the previous supplementals, we've developed two new vaccine technologies: One, recombinant cell culture, and the other one is recombinant DNA vaccines. And those are two very good and faster methods for producing. We have yet to know whether they are more effective than eggs. We believe so, but I think Dr. Messonnier can probably talk about some of the work that is ongoing in research, as well as Dr. Fauci to that. But those are two areas that I think we have leveraged it.

Unfortunately, those technologies do not have the capacity yet to overtake what we do with the egg-based flu vaccines.

Mr. Guthrie. Okay. Thank you.

And again, Dr. Fauci, in your statement, you noticed that alignment with the goals of the executive order, the National Institute of Allergy and Infectious Diseases is conducting and supporting research to develop state-of-the-art vaccine platform technologies that could be used to develop universal flu vaccines as well as improve the speed and agility of the flu vaccine manufacturing process.

So the question is, how are the vaccine platform technologies that the NIAID is currently researching different from flu vaccine production strategies?

Dr. Fauci. Well, the platforms that I showed on one of those slides are each

different way. All of them have a basis in recombinant DNA technology, but the critical issue about that is you don't need to grow the virus. And that is important, because when you grow the virus, it takes 5 to 6 months from the time you grow it, the way we do in eggs today and some in cells, and a number of things can happen when you do that. You can make a choice in February or March that this is the strain that you want to aim for for the following season, but by the time you get to the following season, it might have changed, number one.

Number two, there have been examples of when you put the virus in the egg, the virus tends to adapt to grow better in the egg, and it mutates. It's an RNA virus and it mutates readily. Most of those mutations don't mean anything. But every once in a while, it mutates to the point that it actually changes the virus enough that it's different from what you originally put in.

So all of the platforms, be they recombinant DNA, messenger RNA, DNA, nanoparticles, viral-like particles, vectors, they all are recombinant technologies that don't require your growing the virus, and that's very important.

Mr. Guthrie. Okay. Thank you very much. Appreciate that. That's good.

So, Dr. Marks, in March, Dr. Gottlieb testified as the commissioner at the time, using -- said that FDA scientists are using CMS data to look for differences in effectiveness in those receiving egg-based and cell-based vaccines, as well as differences in effectiveness in those that receive the standard dose versus a high-dose vaccine and the adjuvanted flu vaccine. What did CMS and FDA find by analyzing the Medicare data? And you can use that word if you'd like so we --

Dr. Marks. I thank you very much. The adjuvanted flu vaccines -- it took me about 4 years of medical school to learn how to pronounce that, so don't worry, it's okay.

So thank you for that question.

The FDA's recently finished a study and published a study that was done in conjunction with Centers for Medicare and Medicaid Services, using their large database. And they looked at six seasons' worth of standard dose versus high dose influenza vaccine. And from that, they were able to see that, particularly in the population of individuals over 85 years old, the high-dose vaccine, season after season, had better effectiveness, and even in the population over 65, there was a tendency towards better effectiveness in that population as well.

Mr. Guthrie. Okay. Thank you.

My time is expired. I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes Mr. Ruiz for 5 minutes.

Mr. Ruiz. Thank you, Madam Chair.

Compassionate prevention and care must be available to everyone in this country, and as has been alluded here, many people have died due to the flu virus. Just about a year ago, in fact, this Sunday marks 1 year when Jakelin Caal, a 7-year-old girl, died in CBP custody because she did not have appropriate access to medical care. Whether or not it was the flu, I don't believe it was, but there has been several children who have died in CBP custody since then, including some from the flu.

Following Jakelin's death, I visited the place where she had been held, and I was horrified by the conditions that I witnessed; facilities so crowded you couldn't even see the floor, bodies on top of one another, especially children with soiled diapers, coughing on one another. And there wasn't appropriate access to sanitation places to wash their hands, to bathe. And these are individuals whose immune systems were always down

due to the long trek and probably poor nutrition.

And as public health experts, I think you will all agree with me that such conditions create a breeding ground for a flu outbreak.

Following my visit, I wrote the Humanitarian Standards for Individuals in CBP Custody Act, which passed the House. It would ensure that individuals in CBP custody would have access to an initial health screening, to identify high-risk, vulnerable people, and provide appropriate intervention to prevent children and the elderly and others from dying. It would also put in place a baseline set of humanitarian public health standards such as access to clean water, proper sanitation, and personal hygiene.

I am concerned that despite urging from physicians and physician organizations and the CDC, CBP has refused to administer flu vaccines to protect children and families in their custody.

Dr. Messonnier, CDC submitted a report regarding its investigation of respiratory illnesses in U.S. Border Patrol facilities, including findings and recommendations to the Department of Homeland Security in January, this past January of 2019. And I would like to submit this report for the record.

Dr. Messonnier, do the children and adults detained in these facilities face heightened risk of contracting influenza?

Dr. Messonnier. As you've said, crowded conditions tend to be a breeding ground for respiratory infectious diseases. There's no specific information right now about the risk at the border compared to elsewhere. But I think it's important to remember that CDC recommends that everybody age 6 months of age or older --

Mr. Ruiz. Right, everybody.

Dr. Messonnier. -- be vaccinated.

Mr. Ruiz. However, this report does state that there was higher prevalence of influenza in December 2018, January 2019, than the national average. So --

Dr. Messonnier. Right. That's right. So --

Mr. Ruiz. -- in this report, it does, in 2019, January 2019, does show that there was higher. So --

Dr. Messonnier. Yes.

Mr. Ruiz. -- what recommendations does CDC make to DHS specific to influenza vaccine and other related care for those detained in Border Patrol facilities?

Dr. Messonnier. So as you said, CDC was asked by DHS for technical assistance in December of 2018 and January of 2019. We gave preliminary recommendations orally and then issued a written report. And the written report says that as consistent with our general infection control guidelines, priority should be given to screening and isolation of ill migrants, early antiviral treatment, and flu vaccination for all staff.

Mr. Ruiz. Great. In fact, I'll read it here, it says: Influenza vaccination should be implemented at the earliest feasible point of entry to allow maximum protection of migrant and potentially to reduce transmission in border facilities. Priority groups should include children aged 6 months through 18 years and pregnant women.

The term "earliest feasible point" is very important here. Are vaccines -- the success rate of vaccination, is it -- this is an obvious question, but is it more effective before they contract the influenza virus or after?

Dr. Messonnier. So it's obviously more effective when it's given before.

Mr. Ruiz. Exactly.

Dr. Messonnier. And I would also just point out perhaps that, you know, HHS' ORR program routinely vaccinates --

Mr. Ruiz. They do. ORR and ICE does. I'm specifically talking about CBP, and that's the point I'm making, because oftentimes, they stay there for 8, 14 days, when overcrowded conditions. So one of the reasons, perhaps they may say, oh, well, we want to get rid -- move the children or move the individuals to the next facility, but if they contract the flu vaccine at CBP, then receiving the vaccine at ICE or ORR is not going to be helpful. So that's why the recommendation was to vaccinate them at the earliest point of entry at CBP.

And I ran out of time. Thank you.

RPTR MERTENS

EDTR HUMKE

[11:27 a.m.]

Ms. DeGette. Without objection, the CDC report is entered into the record.

[The information follows:]

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

Ms. DeGette. The chair now recognizes the gentleman from West Virginia for 5 minutes.

Mr. McKinley. Thank you, Ms. Chairwoman.

I think maybe, Dr. Messonnier, maybe I will focus on you. Did I -- I want to make sure I heard your answer to the question why aren't -- why aren't more people getting a vaccine. And I thought your answer was something about the public's concern with its effectiveness. Am I -- did I state that correctly?

Dr. Messonnier. I think that there are three reasons why people don't get vaccinated, speaking generally. One is incorrect concern about the safety of the vaccine. A second is misunderstanding that the vaccine -- about vaccine effectiveness, and the third, frankly, is access. It --

Mr. McKinley. Okay. Let me focus more on that third because I think the first two, I don't agree with you at all. Mildred Smith. She's your neighbor, my neighbor. Mildred Smith has no idea about the effectiveness rate. None. You in academia, and maybe in the research, you understand that, but she doesn't understand that. I'd like to try to figure out more the third issue of access, to be able to get that and how we might do that, so that leads me to the next question.

A part of that is obviously, I'm just an engineer. I don't practice medicine, so I'm curious how we work in -- we seem to be working in a vacuum here in this conversation. What are they doing in Europe, for example? What's the outbreak? Do we have the same situation occur in Europe? Do they have a higher vaccination rate? Give me from a broader perspective than just the United States.

Dr. Messonnier. I think Europe is a broad set of countries, and different

countries have different vaccination coverage. But I think many countries struggle with vaccination coverage against flu. And a lot of countries actually don't have the routine recommendation that we do or the implementation recommendation.

Mr. McKinley. So you're telling me that if I were to, you know, Google something here on Europe, I would not find anything because it's limited, or the European Union does not pull together some data?

Dr. Messonnier. No. I'm sorry. I misunderstood. Of course, there's data. I don't have it on top of mind, but I'm happy to provide it. But I would like to add --

Mr. McKinley. Well, but I'd like to understand what they're doing in Europe about this because I know NIH is spending a significant -- maybe not enough but whatever. What are other countries doing about this? And what advances are they making towards this universal coverage, if that's a possibility?

And so what's Europe doing on universal coverage, the research in there, and then also, who are we partnering with? Who's the private sector group because NIH can only go so far. NIH is not going -- you don't take clinicals to market. Is there someone that -- are there different firms in the private sector that are showing some participation in this?

Dr. Messonnier. Maybe I'll just start with one fact and let Dr. Fauci go from there.

One thing just to point out is that the scientific community for influenza is incredibly collaborative. And the reason we have such great situational awareness about strains that are circulating is because countries all over the world, not only in Europe, but all over the world, gather strains of influenza, provide them to reference centers, sequence them, and that gives us the information globally about what's

circulating.

Mr. McKinley. Okay. Dr. Fauci.

Dr. Fauci. So with regard to the development of vaccines and the technology and the research, as with almost every aspect of medical research, the United States clearly dwarfs the other countries. However, the slide that I showed in my presentation about the strategic plan and research agenda that we put together was based on a meeting that we held in Rockville in the summer of 2017, and we had international participation.

So we have good input from people from the Far East, from China, from Europe, et cetera. But the actual work that's done, although not everything is done in the United States, an overwhelming proportion of the research and the production on the universal flu vaccine is done in United States. European countries make their own vaccine.

Mr. McKinley. I hope there's more data. I'm fascinated with that subject and how it might be able to get to that curve. Let's go back to the initial. If Messonnier did not have the answer, do any of you know what kind of rates? If we only have, what, 45 -- whatever the rates are.

I've got to admit. I'm one of the guys cheating this -- cheating death on this because as a senior citizen, I don't get the flu vaccine, and I know I should. I know my wife does it every year, and she lectures me on this, and I just haven't gotten around to doing it.

So what are the rates in Europe? Do any of you know?

Dr. Fauci. Yes, we do.

Mr. McKinley. I figured. I didn't ask the right person.

Dr. Fauci. In every single country, for example, I went to a meeting just a couple

of months ago on a different subject in France. In France, they do not have the type of recommendation that we have here which, as Dr. Messonnier said, that everyone 6 months of age or older should be vaccinated.

In several of the top European countries, they vaccinate those who are at highest risk for complications: the young children, the elderly, those with underlying conditions. It would be unusual for a European country to have the broad recommendation that we have of everyone 6 months of age or over to get a vaccine.

Mr. McKinley. Well, I'm just -- the reason I'm raising that question, and the time's up, I've gone over, is I want to understand a little bit. There in socialized medicine they have in Europe, I want to see, does that have an impact on it if we were to implement it?

Ms. DeGette. So the gentleman's time has expired.

Mr. McKinley. I yield back the balance of my time.

Ms. DeGette. The chair now recognizes Mr. Kennedy for 5 minutes.

Mr. Kennedy. Thank you, Madam Chair. I want to thank you for holding this important hearing and the witnesses for your testimony and your service.

It's clear from what we've heard so far this morning that public health surveillance tools are critical in monitoring and responding to infectious diseases such as influenza and other outbreaks across the country.

Unfortunately, a June 2019 report by the Massachusetts Special Commission on Local and Regional Public Health found that due to inconsistent funding for local public health agencies, my home State, like many others across the country, has limited capacity to collect and measure health data.

So beginning with Dr. Messonnier, how does CDC and its partners help States like

mine be able to track the spread of influenza from around the country as well as capture vaccination rates?

Dr. Messonnier. So as you point out, public health runs on data. It's an incredibly crucial part of our programs. We do provide funding to help health departments to enable them to work with us on surveillance, and we've been really innovative. In fact, we've worked with the American Public Health Lab Association -- sorry, Association of Public Health Labs to build a data system that's electronic so that the data goes from regional reference labs to the Cloud so that we can all have access to data sooner.

That being said, the flu program happens to be at the forefront of how we use data, and in general, the public health data systems are antiquated, and unfortunately, fragmented, and we really do need to think about new investments if we want the kind of solid systems that you're talking about.

Mr. Kennedy. So building on that, you said antiquated and fragmented. What gaps exist specifically in the collection of that data around the spread and severity of the flu virus?

Dr. Messonnier. Of course, what we'd all want is real-time, actionable data that can be used at every part of the public health and clinical system. We actually have a lot of data online now, and you can actually go to our flu site and look at electronic data that's posted every week that shows what the situation is in flu in every State. What you'd like to be able to do is use that same picture to click on your State and also understand vaccination coverage in every corner of your State and the capacity of the hospital system and whether hospital systems are overwhelmed.

And that's what we're working on is trying to integrate all of that big data to give

your State health officials the actionable data that they need.

Mr. Kennedy. Dr. Kadlec, do you have any ideas on the collection of flu and pandemic data as well?

Dr. Kadlec. Sir, none beyond that has been identified for Dr. Messonnier, but I think the key thing is to what has been pointed out is that the systems are antiquated and fragmented. And there is a need to basically enhance those systems so that there is better real-time data to Dr. Messonnier's point to be actionable.

Mr. Kennedy. And just to be a little more blunt then, if I can, are you suggesting that Congress -- what actions would you like Congress to take? Is that funding, or is that additional structures that need to be put in place in order to flush out the system the way you would want to see it?

Dr. Kadlec. So I think for the purposes of this conversation, I would just note that there is a multi-year budget that has been put together that looks at pandemic influenza that's required by Congress. It's a multi-year for the public health emergency medical countermeasure which identifies that we probably need about $5.7 billion to support efforts by NIH, FDA and ASPR. But it doesn't include what CDC needs to do for surveillance and its other programs, important programs for vaccine acceptance.

So I think there's a way to capture this in a way going forward that I think would holistically represent what is needed to address this challenge broadly. We are responding to what Congress has identified in one area of this, but I think to Dr. Messonnier's point, there is a need to basically include these other very important supporting activities as part of that.

Mr. Kennedy. So it's my understanding, Doctor, that during the 2009 H1N1 outbreak, local health departments did play a key role in the distribution of the vaccine.

According to the National Association of County and City Health Officials, since 2008, local health departments have eliminated a cumulative total of more than 56,000 jobs, a decrease of about 25 percent of the public health workforce.

Doctor, how do you think ASPR is working with State and local health departments to prepare for that next flu pandemic?

Dr. Kadlec. Well, I think critically speaking, CDC has an important role to play, a principal role, and we play a supporting role. There are two grant programs that are administered by the department, one by CDC dealing specifically with local public health departments, and the one that ASPR basically administers which is really about hospital preparedness. And those two things are critically linked in doing that together. And so we really need to work together to make sure that we capitalize on the public health infrastructure.

But you have highlighted, I think, a critical reality in the trends of local public health departments which is not only the graying out of public health departments but certainly the support they need, subsidies at the State and local level as well as the Federal level to do this. And I think jointly through CDC and ASPR, we can do better to do this, but I think quite honestly, that's an area that you've highlighted that is a vulnerability.

Mr. Kennedy. Thank you, sir. I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes the gentlelady from Indiana for 5 minutes.

Mrs. Brooks. Thank you, Madam Chairwoman, and thank you again for holding this very important hearing and thank you all for your work.

I'd actually like to go back and allow Dr. Messonnier to answer. Is there anything

further you'd like to say that Dr. Kadlec -- and then I have some questions for Dr. Kadlec because you were nodding quite a bit. But is there anything else you would like to add?

Dr. Messonnier. I was nodding. I think Dr. Kadlec said most of it, but you know, it is CDC's step program that provides direct funding to States and then from States to local health departments to specifically work on preparedness capacity.

You can see this capacity used every day at local and State health departments, both to respond to the everyday emergencies, also to respond to the unexpected emergencies. And if we fail to invest in those departments, we'll obviously always come to regret it if we have to rely on them in an emergency.

Mrs. Brooks. Thank you. Thank you.

Dr. Kadlec, I'd like to talk with you. Committee staff recently participated in a pan flu table top exercise with ASPR, and thank you for that participation. One of the biggest takeaways was that the U.S. lacks sufficient domestic manufacturing capacity and/or raw materials for almost all pan influenza medical countermeasures. This is very concerning.

Further, that global manufacturing capacity would not be sufficient to meet the demand, so specifically, we have concerns about the United States' supply of needles, syringes, surgical masks. That was raised during the exercise. We learned that -- and I think we saw this during Ebola. Surgical masks are not made in the United States, and so there was a run on masks and other supplies during Ebola.

Can you discuss the challenges we face with respect to those supplies regarding the lack of domestic manufacturing and the volume we need versus what we currently have access to in the event of a pandemic?

Dr. Kadlec. Thank you, ma'am, for your question, and yes, it is a significant

vulnerability as we look at particularly for pandemic preparedness. Eighty percent of the materials that we're counting on for, not only just for pandemic support, but generally in our healthcare system emanate from China and India. So that's both raw materials, finished products and active pharmaceutical ingredients.

If you had to look specifically at a couple of areas of particular concern around pandemic influenza preparedness, you would have to look at the antiviral drug supply. Again, we have about 67 million courses of about 80 million person requirement that we have in our stockpile, and the active pharmaceutical ingredient comes from Asia at the present time.

So once we would expend that immediate supply during a pandemic, in order to manufacture more, there a number of generic manufacturers here domestically in the United States, but that active pharmaceutical ingredient is -- it would be found in Asia and would be a critical supply material for any country, much less us.

Mrs. Brooks. What are we doing as the Federal Government to work to address our domestic manufacturing capacity, whether for the API or --

Dr. Kadlec. Ma'am, on the issues of vaccines alone, I think the key thing is is -- I can't give you the particulars, but we're going to have an announcement here shortly that will indicate some investments domestically to expand some of our new technology -- newer technologies for vaccine manufacturers. And I think the key thing there is that we're actively pursuing this in accordance with the executive order.

Obviously it's going to be a resource limited kind of activity, but significantly beyond, that we're really trying to put our arms around this vulnerability in terms of our supply chain to the other things that you mentioned, surgical masks, latex gloves, other personal protective equipment, as well as active pharmaceutical ingredients.

Mrs. Brooks. Is it fair to say that if we're better prepared for seasonal flu preparedness that that would help us in the event of a pandemic?

Dr. Kadlec. Yes, ma'am.

Mrs. Brooks. And is the H7N9 flu strain still a potential pandemic threat? And you're all nodding yes, I suppose. And is our prepandemic stockpile adequate right now relative to that?

Dr. Kadlec. Ma'am, I believe that -- and I would turn to Dr. Messonnier and Dr. Fauci for their answer, but my understanding is that it's not a good match with the current circulating strains, so its utility would be limited.

Mrs. Brooks. Dr. Fauci?

Dr. Fauci. I agree. It's another example of the virus changing. We made a vaccine back in 2013, and we get to 2018, 2019, and it's a bit different, so it would not be a good match.

Mrs. Brooks. And given ASPR's support for developing new antiviral products, how would adding new antivirals to the stockpile increase our preparedness? And how -- what is the -- what's the time that it takes and the money that it takes to add new antivirals to our stockpile?

Dr. Kadlec. Ma'am, very briefly, I think the risk that you're trying to mitigate is the risk that over time, circulating flu strains will be resistant to what we have in our stockpile which is Tamiflu. And currently, there is evidence of that in the world today.

The real reality is how much does it cost. Newer classes of antibiotics tend to be more expensive, and so it would be a much more significant investment in terms of replacing our existing stockpile.

And we're evaluating what's the mix that we need to have which gives us the

advantage over what we have in our stockpile, what do we need to buy or purchase that would basically minimize or mitigate our risk to future strains.

Mrs. Brooks. Thank you.

I yield back.

Ms. DeGette. Dr. Kadlec, I just wanted to follow up on something Mrs. Brooks asked you. You said a big announcement about domestic production is going to be made. When will that announcement be made, do you expect?

Dr. Kadlec. Ma'am, I'm hopeful by next week.

Ms. DeGette. By next week. Okay. That will be -- that will be ready good. Thank you.

The chair now recognizes Ms. Kuster for 5 minutes.

Ms. Kuster. Thank you very much, and thank you, Madam Chair, for holding this timely hearing this week during National Influenza Vaccination Week.

In my home State of New Hampshire, 40 people lost their lives in the last flu season, and of particular concern to me is the impact on seniors. You can imagine in the winter driving through rural New Hampshire is hard enough, but if you're an ill senior, that is really difficult. So I want to thank you all for being with us.

I want to focus in on the seasonal flu vaccine last year was more effective for the first primary strain, but its effectiveness rate dropped significantly later in the season when the dominant strain in the United States changed. And unfortunately, the longer season and the shift in flu strain, as I mentioned, led to 40 deaths in my State.

Dr. Fauci, what do you mean when we talk about vaccine effectiveness, and how is it measured?

Dr. Fauci. Vaccine effectiveness is really a percent of protection based on a

comparison to people who are not vaccinated. So if you have 100 percent effectiveness which you almost never have, that would be essentially everybody gets protected who gets vaccinated. The percentage goes down as you have people who are vaccinated but who actually do get infected.

Ms. Kuster. Have flu symptoms?

Dr. Fauci. Right.

Ms. Kuster. All right. And how does the effectiveness of last year's vaccine compare to those in the past? And will we -- when we will know how effective this year's vaccine is?

Dr. Fauci. Well, if you look at last year's effectiveness, you have to be careful to make sure that you can pick -- that you look at H3N2 compared to H1N1 because when we vaccinate, we vaccinate against H3N2, H1N1, and B, actually two Bs. So when you look at the H3N2, I believe it was 29 percent, if I'm not mistaken. It was 29 percent effective against H3N2.

And if you look at the chart -- I'm speaking, but Nancy has it. If you look at the chart that the CDC puts out, they give each year what the effectiveness is. It really is a wide range. There's a very good year where you can get 60 percent.

The average is somewhere between 40, 50 percent or so. On a very bad year, you could go down to around 10 percent. When I say that, I say it with some degree of nervousness. It's still always better to get vaccinated regardless of what that percent is.

Ms. Kuster. Well, I want to get to that with Dr. Messonnier. Why is it so important for people for whom the vaccine may currently be less effective such as seniors to get the flu vaccine each season?

Dr. Messonnier. Thank you. Maybe just to go back to a question that you

asked, this one strain, the H3N2 strain which was the strain that caused that second peak last year, happens to be a particularly difficult strain in terms of vaccine effectiveness. But if you look historically, the range of the effectiveness of that strain is always harder because of the reasons that Dr. Kadlec and Dr. Fauci mentioned earlier. We'll have preliminary estimates of the vaccine effectiveness, this season's vaccine, in February, and then our final estimates should be available in the summer.

The larger issue is when Dr. Fauci referred to vaccine effectiveness, but we have to remember that even if the vaccine is not perfectly effective against any influenza, it still can be effective against more severe influenza and against death. And so even in a year where the overall vaccine effectiveness is not as great, vaccine effectiveness against more severe illness can actually be high. It's always better to get vaccinated than not.

Ms. Kuster. So we should be encouraging our constituents to get the vaccine. The symptoms will be milder, and we should --

Dr. Messonnier. Everybody should get the vaccine because today I can't totally predict what the season is going to be like, and my kids are vaccinated. My parents are vaccinated. Of course, I'm vaccinated.

Ms. Kuster. And I will be as well. Thank you.

Dr. Marks, you stated in your testimony that the FDA conducts, quote, applied scientific research to address current challenges in season and pandemic influenza vaccine production, including improving their effectiveness. What specific research efforts is the FDA currently engaged in to improve vaccine effectiveness rates, particularly for those populations less protected by recent flu vaccines.

Dr. Marks. Thank you for that question. So we are engaged in research that's looking mainly to try to improve the ability to produce influenza vaccines on a rapid basis.

We have some work that's going on that essentially builds off of NIH's work on trying to make a more effective vaccine.

But one of our major -- the major thrusts of work from FDA's perspective is trying to be able to be agile in our manufacturing, to look at things like advanced manufacturing technologies such as continuous manufacturing which could allow us to actually have seasonal influenza or pandemic influenza vaccines produced at a much greater quantity, in a much smaller footprint, on U.S. soil in the event of a pandemic which I think is one of the things that, as Dr. Kadlec mentioned, is important for national security.

Ms. Kuster. Great. Thank you.

My time is up. I yield back.

Ms. DeGette. The chair now yields 5 minutes to the gentleman from Texas, Mr. Burgess.

Mr. Burgess. Thank you, and thanks to the panel for being here. I apologize. I've been upstairs at a cosmetics hearing. That's why I look so youthful.

Since I haven't been here, I haven't heard all of the questions that have been asked, so if I do something that's duplicative, I apologize about that. But Dr. Messonnier and maybe Dr. Kadlec, the issue of the vaccination at facilities for Customs and Border Protection has apparently come up. We had a hearing, I think we held a subcommittee in September, and also addressed this. I've traveled to many of the Customs and Border Protection facilities on the border in Texas, specifically Clint and the Ursula facility down at McAllen. I actually went to the Ursula facility at McAllen with a DHS physician who was on that trip.

So when this issue came up, I called that person and said hey, does DHS not do this, and he said no, DHS has given -- and I forget the figure, and Dr. Kadlec, you may be

able to supply it, but tens of thousands of doses of flu vaccine are administered by the Department of Homeland Security.

I guess the issue is if they are in a facility that's only going to retain them for 12 to 72 hours, and then they're going to a Health and Human Services facility, and we're prominently talking about children here going to a Health and Human Services facility or an ORR facility where they will be for perhaps several weeks, I think it makes sense to do the vaccination at the ORR facility.

Now, I know there was an issue because Congress was late in supplying some supplemental funding for Department of Homeland Security. They got backed up with the number of people that were coming across the border in May and the early part of June, so people were held at CBP facilities for longer than what was ideal.

But if the difficulty is we weren't providing DHS with the funding to do their primary job in the first place, I don't know where they were supposed to get the money to buy additional flu vaccine, but I suppose that's a separate story.

But can you talk at all about how you've coordinated with Customs and Border Protection and the Department of Homeland Security more specifically about your recommendations and what they see as their role?

Dr. Messonnier. Sure. And I apologize for repeating myself, but we were contacted by DHS last December, and we provided technical consultation in December and January that led to an oral report out and then a written report which was entered into the record. And what we recommended was what we would generally say, that the priority be given to infection control, identification, and isolation of the migrants, early provision of antivirals, and priority to vaccination of the DHS staff.

Our report goes on to say as consistent with our general recommendations for

everybody in the United States, we would recommend a flu vaccine for everybody 6 months of age and older at the earliest operationally feasible time.

Mr. Burgess. So children that are held in Office of Refugee Resettlement facilities are going to receive the full complement of childhood vaccines as just part of the course. I think that's one of the things that's evolved since 2014.

Dr. Messonnier. That's right.

Mr. Burgess. Because we don't know the vaccine history, we just provide the vaccines. It seems like it would make sense to provide the flu vaccine at that interval because that's done relatively early in their stay in an HHS facility.

Dr. Messonnier. That's correct. Children within ORR are given both the childhood vaccines and their flu vaccines, and my understanding is coverage is high. Another complication of this, as you point out, is the medical records which don't come with those children.

Mr. Burgess. Right.

Dr. Messonnier. They err on the side of protecting them with the vaccine.

Mr. Burgess. And, of course, what they do come with is the flu sometimes because they are held in less than ideal facilities referred to as stash houses on the other side of the border and then brought over when it's convenient with the coyotes or the cartels. They don't provide vaccination services on their side, and so they end up in our facilities oftentimes very, very ill.

Well, I'd like to see us do -- if we're not doing a good job with coordinating between the two agencies, I'd like to see that as part of the exercise that comes out of this. Once again, my thanks to everyone who is on the panel.

Some of my favorite people in the world are on this panel, so I appreciate you

being here and participating in our hearing today.

Thank you, and I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes the gentlelady from Florida for 5 minutes.

Ms. Castor. Well, thank you, Chairwoman DeGette, for calling this hearing.

Dr. Messonnier and Fauci, we had the benefit of your testimony before the subcommittee earlier this year, the measles hearing where you both stressed the importance of vaccinations for infectious diseases. And I wanted to talk a little bit about that in regards to the flu, but looking at the CDC's statistics over the last, 50, 60 years.

I think for measles, what was remarkable was that in the 1950s and 1960s where you had hundreds of thousands of people dying from that disease, the measles vaccine practically eradicated measles, and the big concern was now that people were skipping that vaccine, and it could make a comeback.

With flu, what really stands out are the high numbers still of people who come down with the illness, who are hospitalized and even die because -- and that's largely because the flu strains change over time. Is that right?

Dr. Fauci. Yes. Well, you compared measles with flu which is something we discussed at the last hearing. So the measles that I, unfortunately, got infected with when I was a child is not particularly different from the measles that we have circulating right now. It just doesn't change. And that's the reason why a highly effective vaccine like measles which is 97 percent, at least, effective can essentially eliminate measles from certain parts of the world.

But influenza, we're constantly chasing it. It continually evolves. It continually mutates. And that's really the reason why we need to do better with seasonal flu

vaccines, but we also need to get a universal vaccine that would cover those kinds of changes that occur.

Ms. Castor. And it's so heartening to hear about the progress being done there, but the current vaccines are safe and effective. I think you've all testified to that. So I'd like to focus on the availability. Dr. Messonnier, is the flu vaccine widely available currently?

Dr. Messonnier. Yes. Flu vaccine is widely available currently and we watch carefully across the United States to make sure that consumers aren't experiencing any shortages. You know, the last thing we want is for someone to show up in a doctor's office asking for the flu vaccine and be turned away because --

Ms. Castor. Right. And you said one of the reasons that people often skip it is the-- skip the flu vaccine is because they're skeptical it's effective, and some people skip it because maybe they do run into a barrier. But I think working together over time, we've made a lot of progress on that.

Now under the Affordable Care Act, the vaccine is covered, so it should be free if you have a policy under healthcare.gov. Most standard insurance policies cover this because everyone realizes, boy, it's a whole lot less expensive to get the flu vaccine than to miss a week or 10 days of work or something even more serious.

I looked up for the State of Florida, the Florida Department of Health, floridahealth.gov. You can find, you can locate where your -- where to get your vaccine, but it's fairly easy now. The Veterans Administration, you can get a free flu shot there. Community health centers all over your neighborhoods, you can get your flu vaccine.

Oftentimes your employers, colleges and universities do that because that's the last thing they want is students and professors being infected. Most grocery stores and

pharmacies now, you can walk right in because I think sometimes it's a convenience. People are busy with their lives.

Are there any other barriers that we need to be working on to ensure that people -- that there's not a cost barrier or just the access?

Dr. Messonnier. Thank you for those comments, and I think, you know, in addition to the issue with the vaccine effectiveness that Dr. Fauci talked about, certainly a big difference between where we are with measles and influenza is vaccination coverage.

And as you point out, it is a good buy for people as individuals and businesses to keep their employees safe. And health systems, we can actually show that, for example, in people over 65, it's much more effective from a cost perspective to prevent the flu than it is to take care of people once they get sick.

And I think the final thing that you were mentioning is really important which is we need to make it easy for people to make the healthy choice for themselves and their families by making it easy for them to get the flu vaccine.

Half of adults are actually getting vaccinated outside their medical -- their doctor's office. They're getting vaccinated at pharmacies and drug stores and supermarkets, and they're getting vaccinated in the workplace. Children, some States have actually had a lot of success in school-based vaccination programs where kids are vaccinated while they're in school, making it much more convenient for parents.

And one of the things that we're doing is exploring all of those strategies to see what we can do again to make it easy for people to make healthy decisions.

Ms. Castor. Well, I've had my flu shot, and everyone in my office, we have a let's get our flu shot day, and everyone -- we apply a little peer pressure for those that might need it because it's so important. We want everyone to be healthy and well. And if

you haven't gotten your flu shot yet, you better go out today and go ahead and do that.

Thank you.

Ms. DeGette. I thank the gentlelady.

The chair now recognizes the gentleman from Virginia for 5 minutes.

Mr. Griffith. Thank you very much, Madam Chair.

Congresswoman Castor set up one of my questions very well, Dr. Messonnier. She said that, you know, you can go to the VA and get your shot. Most of the studies that have been done on the -- let me make sure I get the wording correct -- the high dose vaccine have shown that it's much more effective for people over the age of 65 which was a part of your answer back to her. But because the CDC has not made that a preferred -- let me make sure I get -- a preferred recommendation, the VA hospitals can't give that to people over 65, so they have to go somewhere else. A lot of doctors are giving it, but the VA can't give it.

So that being said, with the studies out there, what do we need to do to get the CDC to make this a preferred recommendation for the high dose flu vaccine because it looks like we're -- you know, she mentioned it, not knowing I was going in this direction, that a lot of people go to the VA Hospital, and a lot of our veterans do.

But if you're over the age of 65, you probably ought to be getting this not yet CDC preferred treatment, but the high dose vaccine, but you're not able to get it there.

Dr. Messonnier. Actually, thank you for the opportunity to comment on this. There are actually nine different flu vaccines available this season, and eight of those are licensed for people over 65. So the complication is the comparison of every single one of those products to know which ones are better and which ones are not.

CDC, as I expect you would not be surprised, understandably cautious about

making preferential recommendations because we need to be sure that a vaccine that we're going to prefer is not just effective this season but is effective, is preferential, better, every season. And since every flu season is so different, we tend to be cautious.

That being said, we're taking this issue very seriously. Since last year, we've launched new, more robust studies to examine the vaccines that are available in this age group, and we have an interagency working group with our Federal partners so that we can make sure that we're covering all the watershed of all the studies that need to be done.

We've also put this back to our advisory committee to ask them to look again at the available data and consider this issue. The issue will be considered as all of these issues are in our public meeting where folks can see the debate and see how they come -- you know, what conclusions they come to.

So we take the issue very seriously, but again, understandably cautious about making a recommendation like that.

Mr. Griffith. But you said eight of the nine are actually considered preferred.

Dr. Messonnier. No, licensed. Of the nine available vaccines, eight of them are licensed for people over 65.

Mr. Griffith. Okay. But this is dealing with the high dose vaccine, and according to the data I have here, there have been 14 studies over nine consecutive seasons, 14 million study participants, and only one of those studies did not say that it was preferred or that it was better for people over the age of 65 to get the high dose vaccine.

Dr. Messonnier. So that is a comparison of one company's high dose vaccine against the same company's regular dose vaccine.

Mr. Griffith. Uh-huh.

Dr. Messonnier. The problem is that there are more than one high dose vaccine and also adjuvanted vaccines in that age group. The other issue, back to the issue Dr. Fauci was talking about, is that we need to make sure that it's preferential -- that it's more effective against every one of the potential strains of flu vaccine which means we need more robust data, not just effectiveness against H1N1 but against H3N2 and both types of B, be confident that a preferential recommendation will be right every single season.

Mr. Griffith. Well, in the absence of a preferential recommendation, can you work with the VA? Will you work with the VA to ensure that our veterans over age 65 can receive the high dose vaccine if their doctor thinks that's appropriate?

Dr. Messonnier. We're obviously always happy to work with the VA, and they are a part of this interagency working group where we're really robustly trying to get the data together to look at this issue really seriously.

Mr. Griffith. Because outside of the VA, a lot of doctors are recommending that for their patients.

All right. Switching gears because I've just got a few seconds left, and I'm just going to make a comment. If we have time, Dr. Kadlec and Dr. Fauci, you all can respond, but we keep waiting. I've been here now 9 years which is not nearly as long as some of the members of this committee, and every year we hear that we're almost there. We're getting there. We hear -- we see great slides, and you all do great work.

And Dr. Burgess said you are all some of his favorite people. I would agree with that. You all are doing great work, but you know, is this year going to be any different? Are we going to come back next year, and again, we still won't have something that's a non egg-based vaccine?

Dr. Fauci. We certainly are better off this year than we were last year in our quest for a universal flu vaccine. Last year we didn't even have a candidate.

This year, we're now 8 months in phase one, and by early 2020, we'll know clearly is it safe, and does it induce the kind of response that you would predict would be protective. So clearly, there's a difference between the last time we spoke at the hearing.

Mr. Griffith. Yeah. And there's always advancement. I'm just looking for that day when there's -- coming from a family with a lot egg-based vaccine problems because of the egg-based situation, I'm really looking forward to the day when we can say that we have more than 50 percent of the vaccine out there is non-egg based.

I yield back, Madam Chair.

Ms. DeGette. I thank the gentleman. The gentleman missed the slide presentation, and so we will be --

Mr. Griffith. No. I saw the slide presentation, or I would have had a much more biting question. But the presentation was great. I saw it. It was good.

Ms. DeGette. We'll get you a copy.

The chair now recognizes the gentlelady from New York for 5 minutes.

Ms. Clarke. Thank you, Madam Chair, and I thank our Ranking Member Guthrie for convening this very important hearing on the influenza virus and what can be done across the Federal Government to improve and protect public health as we near peak flu season here in the United States.

I want to thank our expert witnesses for being here today to testify on behalf of the CDC, NIH, HHS, and the FDA.

And while the national targets for vaccination rates for the past decade have

ranged from 70 to 90 percent, depending on the population, it appears as though we are falling woefully short of these goals. Last season, only 43 percent of adults and 63 percent of children received their annual flu vaccine.

I'd like to better understand why these vaccination rates continue to be so low and what we can do to improve these numbers overall, also, specifically, what underserved populations. So Dr. Messonnier, what trend has CDC identified in recent years with regard to flu vaccination rates, and where are we making progress? Where are we falling short?

Dr. Messonnier. So I share your concern and your frustration that vaccination rates for influenza are lower than we want them to be. There has been a 5 to 8 percent increase in coverage from one year to the next, so the recent trends are optimistic, but history has shown us that, you know, that may not hold true.

And I think as you've said, we have studied this issue. When we survey people to ask why they don't get the flu vaccine, what they say is that they don't think it works, they're concerned that it's not safe, and oh, well, flu isn't that serious.

We definitely also know that we see lower vaccination coverage rates in rural areas, in people of lower socioeconomic status, and the data really does indicate that especially when people aren't convinced of the value of a flu vaccine, how easy it is to get the vaccine matters.

Ms. Clarke. Are there particular populations who face barriers to accessing the flu vaccine, resulting in coverage disparities?

Dr. Messonnier. I think that our data suggest people of lower socioeconomic status, people without health insurance, people in rural areas, this is data in children, have lower vaccination rates. I'm especially concerned with the issue for children

because the vaccines for children's program provides a safety net for children who can't afford vaccines. Those children should be able to get vaccines easily, and yet, vaccination coverage for children is still unacceptably low.

Ms. Clarke. Dr. Marks, you've already attested to the safety of the flu vaccine. Unlike other vaccines, however, the flu vaccine is recommended every season over the course of a person's life. What can you tell us about the studies that have looked into the long-term effects of the flu vaccine to calm concerns people may have? And I know you've said some of it already here today, but I think it's worth reiterating.

Dr. Marks. Thanks very much for that question.

So both for childhood vaccines and for adult vaccines, there have been numerous studies that have looked at the vaccination schedules and at repeated vaccination, and FDA continues to use its large database surveillance systems to look at the safety of vaccines. All indications are that the current vaccine regimens are safe and effective for their -- in their intended schedules and there's really no reason not to get vaccinated routinely and that the benefits greatly outweigh any risks.

Any medical intervention has small risks, but vaccines are among the most amazing health interventions of the 20th century and of the 21st century, that is, in terms of being public health interventions that have reduced illness and prevented deaths.

Ms. Clarke. And, Dr. Fauci, according to your testimony, over the last 15 years, the effectiveness of seasonal influenza vaccines have ranged from 10 to 60 percent. Why does NIH, along with your fellow public health agencies, still recommend the flu vaccine each season?

Dr. Fauci. Thank you for that question, and it's really an important question. When you talk about effectiveness, you've got to understand that even if a vaccine is not

effective in preventing infection, it can clearly mitigate the seriousness of the illness, prevent hospitalization, and certainly prevent death.

And that's the reason why you've heard all of us say regardless of what the percent efficacy is on a chart, it is always better to get vaccinated than not to get vaccinated because some degree of protection, either against infection or the complications of infection are very important and advantageous. So many lives are saved, many, many lives, even with a vaccine that is not optimally protective.

Ms. Clarke. Very well. It is clear that more needs to be done to increase the number of people who get vaccinated, particularly for those more vulnerable to the flu and marginalized from care.

And improving the vaccination rate will not only serve public health in the broad sense, it would also save lives. And I think there's an appointment at the attending physician with my name on it.

I yield back, Madam Chair.

Ms. DeGette. I thank the gentlelady.

I want to thank the witnesses for coming today. In case there's any mistake, the unified, bipartisan message from this hearing is get your flu shot. This week's a good time to do it because it's the flu shot week, and we don't know how bad this season's going to be, so everybody needs to get their flu shot.

It's hard to get such bipartisanship that we were up here saying the members felt like we could all exchange opening statements and give each other's opening statements, and they would still have the same impact. So it's really important that people get their flu shots.

I want to remind members that pursuant to the committee rules, they have 10

business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee. I ask the witnesses to respond promptly to any such questions should you receive any, and with that, the subcommittee is adjourned.

[Whereupon, at 12:13 p.m., the subcommittee was adjourned.]