

**PATHWAY TO A VACCINE: ENSURING A SAFE  
AND EFFECTIVE VACCINE PEOPLE WILL TRUST**

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**VIRTUAL HEARING**  
BEFORE THE  
SUBCOMMITTEE ON OVERSIGHT AND  
INVESTIGATIONS  
OF THE  
COMMITTEE ON ENERGY AND  
COMMERCE  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED SIXTEENTH CONGRESS  
SECOND SESSION

WEDNESDAY, SEPTEMBER 30, 2020

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<sup>1</sup>The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF02/20200930/111063/HHRG-116-IF02-20200930-SD004.pdf>.

<sup>2</sup>The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF02/20200930/111063/HHRG-116-IF02-20200930-SD010.pdf>.

<sup>3</sup>The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF02/20200930/111063/HHRG-116-IF02-20200930-SD009.pdf>.

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<sup>6</sup>The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF02/20200930/111063/HHRG-116-IF02-20200930-SD005.pdf>.

# **PATHWAY TO A VACCINE: ENSURING A SAFE AND EFFECTIVE VACCINE PEOPLE WILL TRUST**

**WEDNESDAY, SEPTEMBER 30, 2020**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 11:34 a.m., via Cisco Webex online video conferencing, Hon. Diana DeGette (chairman of the subcommittee) presiding.

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

Also present: Representatives O'Halleran, Dingell, Bucshon, Carter, and Bilirakis.

Staff present: Kevin Barstow, Chief Oversight Counsel; Jeseca Boyer, Professional Staff Member; Jeffrey C. Carroll, Staff Director; Austin Flack, Staff Assistant; Waverly Gordon, Deputy Chief Counsel; Perry Hamilton, Deputy Clerk; Chris Knauer, Oversight Staff Director; Joe Orlando, Policy Analyst; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Benjamin Tabor, Policy Analyst; C.J. Young, Press Secretary; Mike Bloomquist, Minority Staff Director; S.K. Bowen, Minority Press Secretary; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Clare Paoletta, Minority Policy Analyst, Health; Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations and Everett Winnick, Minority Director of Information Technology.

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

Today, the Subcommittee on Oversight and Investigations is holding a hearing entitled, Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust. The purpose of today's hearing is to examine the safety, efficacy, and accessibility of protective COVID-19 vaccines.

Due to the COVID-19 vaccine emergency, today's hearing is being held remotely. All members and staff will be participating via video conferencing, and as part of our proceeding, microphones will be set on mute for the purposes of eliminating inadvertent back-

ground noise. Members and witnesses, you will need to unmute your microphone any time you speak.

If at any time during the hearing, I'm unable to chair the hearing, the chairman of the full committee, Chairman Pallone, or the vice chairman of the committee, Congressman Kennedy, will serve as chair until I'm able to return.

Documents for the record can be sent to Benjamin Tabor at the email address we've provided to staff. All documents will be entered into the record at the conclusion of the hearing.

The Chair will now recognize herself for an opening statement.

**OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO**

Today, the Energy and Commerce Committee continues its oversight of the Nation's COVID-19 pandemic response, examining the pursuit of a safe and effective COVID-19 vaccine that the American people can trust.

In the eight months that we've battled COVID-19, over 7 million Americans have had the virus, and, tragically, over 200,000 of them have lost their lives. Millions of people face unemployment and have lost their health insurance, and families are still juggling childcare and virtual classrooms.

The list of those most vulnerable to COVID-19 is especially—especially on the line as the virus continues to spread around the country. We know that a safe and effective and trusted COVID-19 vaccine will be a critical tool to stem this pandemic. I believe that I am joined by everybody in this hearing and everybody in this country in hoping that a vaccine is available as quickly as possible.

This summer, we held a hearing with five of the leading companies who are working to develop a COVID-19 vaccine. The companies assured us that while the pace of the vaccine is really unprecedented, safety and science are not going to be sacrificed for speed.

Last month, these companies joined four other manufacturers in a rare joint pledge, stating that they would stand with science and not put forward a vaccine until it had been thoroughly vetted. Honoring this commitment will be critical as the future success of a COVID-19 vaccine depends on the American public's confidence that it will be safe and effective.

Alarmingly, the public's trust in a future COVID-19 vaccine has declined dramatically in just a few months. Nearly two-thirds of Americans worry that political pressure will rush approval of a COVID-19 vaccine, and more than half say that even if it were free, they would not get vaccinated before election day.

One does not have to search far to find the source of the public's distrust. Time and again throughout the pandemic, the Trump administration has politicized science, undermining its own public health experts at every turn. And in fact, just last night in yesterday's Presidential debate meltdown, President Trump called the process a, quote, very political thing.

The White House and the HHS leadership have interfered with CDC guidance and other scientific publications for political purpose. The White House has publicly pressured FDA to issue emer-

agency use authorizations for prospective COVID-19 treatments, despite objections from FDA scientists.

And the President, unfortunately, has attacked the credibility of his own public health leaders. For example, just hours after CDC Director Redfield testified on the effectiveness of wearing face coverings and the potential timeline for a vaccine, President Trump told the press that Dr. Redfield was, quote, confused, and had made, quote, a mistake.

The President has politicized the pursuit of a COVID-19 vaccine repeatedly by claiming it will be available in October before a, quote, special day, obviously referring to election day, and he did that again last night. The President has even accused his own FDA of being part of the, quote, Deep State, suggesting it was slow-walking a vaccine to hurt his political prospects. And just last week, following that—reports that the FDA would be publishing additional standards for emergency use authorization of a COVID-19 vaccine, President Trump falsely claimed that the guidance was politically driven. The reported guidance was praised by external experts, but it may not ever see the light of the day because of the President's political whims.

The committee, this committee, the Oversight Subcommittee, has been sounding the alarm on the administration's dangerous politicization of science for months. And frankly, we're not alone in our concern.

Last week, the National Academy of Medicines and Sciences took the unusual step of issuing a statement warning that the repeated politicization of science, quote, undermines the credibility of public health agencies and the public's confidence in them at a time when we need most.

Fortunately, as we will hear from our witnesses, there are ample reasons to be optimistic. The search for a COVID-19 vaccine is, and will continue to be, driven by science, and I believe there are steps that we can take to restore the American public's confidence.

Namely, the administration must allow the career scientists at the FDA to do their jobs free from political interference, such as allowing the time necessary to conduct robust review of clinical trial findings. And it must let FDA release the additional standards for emergency use authorization of a COVID-19 vaccine once it's developed.

All of us on this committee, Democrats and Republicans, are rooting for a safe, effective, and trusted COVID-19 vaccine, accessible to all Americans, and we will continue our oversight until these goals are met. We will also continue to call for a comprehensive COVID-19 vaccine plan.

I look forward to hearing from the panel today. Hopefully, our wonderful experts can help guide us on ways to ensure that the public has full confidence in a COVID-19 vaccine once it's made available. I also hope that they can provide additional solutions and suggest guardrails that will ensure that science and not politics guides the way, because the health of our Nation depends on it.

[The prepared statement of Ms. DeGette follows:]

## PREPARED STATEMENT OF HON. DIANA DEGETTE

Today, the Energy and Commerce Committee continues its oversight of the nation's COVID-19 pandemic response, examining the pursuit of a safe and effective COVID-19 vaccine that the American people can trust.

In the eight months we have battled COVID-19, over seven million Americans have had the virus and more than 200,000 of them have lost their lives.

Millions of people face unemployment and have lost their health insurance, and families are juggling childcare and virtual classrooms. The lives of those more vulnerable to COVID-19 are especially on the line as the virus continues to spread around the country.

We know a safe, effective, and trusted COVID-19 vaccine will be a critical tool to contain this pandemic. I believe I am joined by everyone in hoping that such a vaccine is available as soon as feasible.

This summer, we held a hearing with five of the leading companies who are working to develop a COVID-19 vaccine. The companies assured us that, while the pace of vaccine development is unprecedented, safety and science are not being sacrificed for speed.

Last month, these companies joined four other manufacturers in a rare joint pledge stating they would “stand with science” and not put forward a vaccine until it had been thoroughly vetted. Honoring this commitment will be crucial as the future success of a COVID-19 vaccine depends on the American people having confidence that it is safe and effective.

Alarming, the public's trust in a future COVID-19 vaccine has declined dramatically in just a few months.

Nearly two-thirds of Americans worry that political pressure will rush approval of a COVID-19 vaccine and more than half say that even if it were free, they would not get vaccinated before Election Day.

One doesn't have to search far to find the source of the public's distrust. Time and again throughout the pandemic, the Trump Administration has politicized science, undermining its own public health experts at every turn.

The White House and HHS leadership have reportedly interfered with CDC guidance and other scientific publications for political purposes. The White House has publicly pressured FDA to issue emergency use authorizations for prospective COVID-19 treatments, despite objections from FDA scientists.

And, the President has attacked the credibility of his own public health leaders. For example, just hours after CDC Director Redfield testified on the effectiveness of wearing face coverings and the potential timeline for a vaccine, President Trump told the press that Dr. Redfield was “confused” and had made “a mistake.”

The President has politicized the pursuit of a COVID-19 vaccine by repeatedly claiming it will be available in October, before, a “special date,” obviously referring to Election Day.

The President has even accused his own FDA of being part of the [quote] “deep state” suggesting it was slow walking a vaccine to hurt his political prospects.

And, just last week, following reports that FDA would be publishing additional standards for emergency use authorization of a COVID-19 vaccine, President Trump falsely claimed that the guidance was politically driven. The reported guidance was praised by external experts, but it may never see the light of day—all because of President Trump's political whims.

The Committee has been sounding the alarm on the Administration's dangerous politicization of science for months, and we are not alone in our concern.

Last week, the National Academies of Medicine and Sciences took the unusual step of issuing a statement warning that the repeated politicization of science “undermines the credibility of public health agencies and the public's confidence in them when we need it most.”

Fortunately, as we'll hear from our witnesses, there are reasons to be optimistic that the search for a COVID-19 vaccine is, and will continue to be, driven by science. And, there are steps we can take to restore the American people's trust in a COVID-19 vaccine.

Namely, this Administration must allow career scientists at FDA do their jobs free from political interference—such as allowing the time necessary to conduct robust review of clinical trial findings. And it must let FDA release the additional standards for emergency use authorization of a COVID-19 vaccine it has already developed.

The Committee is rooting for a safe, effective, and trusted COVID-19 vaccine that is accessible to all Americans, and we will continue to conduct oversight to ensure these goals are met. We will also continue to call for a comprehensive COVID-19

vaccine plan—something the Trump Administration has failed to develop in the four months since this Committee first urged them to do so.

I look forward to hearing from our panel today. Hopefully, these experts can help guide us on ways to ensure that the public has full confidence in a COVID-19 vaccine once it is made available. I hope they can also provide additional solutions and suggest guardrails that will ensure that science, and not politics, guide the way.

The health of our nation depends on it.

Ms. DEGETTE. And now I'm very pleased to recognize our ranking member, Mr. Guthrie, for 5 minutes, for the purposes of an opening statement.

**OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY**

Mr. GUTHRIE. Thank you, Chair DeGette, for holding this important hearing about the COVID-19 vaccine pathway.

Ultimately, it will be a vaccine that offers us the best chance to finally end this pandemic, allowing our Nation to fully reopen. But it is not just the vaccine itself. In addition to an improved or authorized vaccine, we will need widespread acceptance, distribution, and immunization to successfully combat this virus.

The purpose of this bipartisan hearing should be to increase public confidence in the Food and Drug Administration and its processes for authorizing and approving vaccines through science-based decisions that are there—that there is greater vaccine acceptance and confidence among Americans.

Congress, through this committee, created the emergency use authorization pathway as part of Project BioShield Act in 2004, and later expanded that pathway in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 on a bipartisan basis. Through those efforts, we provided special authority to the FDA to be used in a public health emergency prior to a full approval when the scientific evidence is available to support such use.

To receive an emergency use authorization, or EUA, a drug company must demonstrate that based on the total totality of scientific evidence, the drug's known or unknown potential benefits outweigh the known and potential risks. The FDA can apply that standard appropriately to different settings, such as requiring more rigorous evidence for treatments used on healthier populations than for seriously ill, hospitalized patients.

For COVID-19 vaccines, the FDA has announced it is using an "EUA-plus approach" through a guidance setting, a much more stringent standard than for other EUAs. Unfortunately, I have grave concerns that some are trying to score political points by irresponsibly criticizing the FDA and its vaccine review and approval process, potentially undermining trust in the FDA-authorized vaccine, especially during this global pandemic and national health emergency.

It is understandable in this politicized environment that many in the public would be concerned or confused about the vaccine development and approval process, whether the corners are being cut and whether these unfounded—with these unfounded criticisms circulating.

The truth of the matter is that the review and approval stages of the vaccine will be controlled throughout the process by non-

political, independent, scientific experts, not politicians. The data produced during the vaccine clinical trials are reviewed and evaluated by a Data Safety Monitoring Board, which is composed of independent scientific experts. In addition, there is an FDA Vaccines and Related Biological Products Advisory Committee, composed of independent leading medical experts, who are expected to review and evaluate data on the vaccines in public meetings.

Indeed, even Congress has contributed getting assurances on a scientific decision from the FDA. It was this committee's full committee hearing in June and other committee hearings over the past few months where Congress and the American people received assurances from FDA Commissioner Stephen Hahn that he would support his career scientists and the FDA would not cut corners on the safety or efficacy of COVID-19 vaccines.

The intense scrutiny has led to other extraordinary pledges from the highly respected public health officials. Dr. Peter Marks, the director of FDA's Center for Biologics, said he will resign his position if the FDA were to green-light an unproven coronavirus vaccine. In addition, the director of National Institutes of Health, Dr. Francis Collins, and the director of National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci, have said they will only back a vaccine that has science behind it.

Further, nine drug companies have already pledged they will not submit vaccine candidates for FDA review until their safety and efficacy is shown in large clinical trials. In addition, each of the four companies who are now in Phase 3 clinical trials have published their clinical trial protocols.

For vaccine distribution, two independent committees will provide guidance: the National Academies of Science and Engineering and Medicine, and CDC's Advisory Committee on Immunization Practices.

I urge each of us to put politics aside—I know we're a few weeks from election, but put politics aside in order to deliver one unified, life-saving message, that Americans can trust the FDA's vaccine approval process, and it will be driven by the science and will result in science-based decisions.

And, lastly, a reminder for everybody to get your flu shot. It has been—this year, it will be more important than ever. I've already received my flu shot.

I look forward to the testimony from these esteemed witnesses and welcome them to this hearing. And I yield back.

[The prepared statement of Mr. Guthrie follows:]

#### PREPARED STATEMENT OF HON. BRETT GUTHRIE

Thank you, Chair DeGette, for holding this important hearing about the COVID-19 vaccine pathway.

Ultimately, it will be a vaccine that offers us the best chance to finally end this pandemic, allowing our nation to fully reopen. But it is not just the vaccine itself. In addition to an approved or authorized vaccine, we will need widespread acceptance, distribution, and immunization to successfully combat this virus.

The purpose of this bipartisan hearing should be to increase public confidence in the U.S. Food and Drug Administration (FDA) and its process for authorizing and approving vaccines through science-based decisions so that there is greater vaccine acceptance and confidence among Americans.

Congress, through this Committee, created the emergency-use authorization pathway as part of the Project BioShield Act in 2004, and later expanded that pathway

in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 on a bipartisan basis. Through those efforts, we provided special authority to FDA to be used in a public health emergency prior to a full approval, when the scientific evidence is available to support such a use.

To receive an Emergency Use Authorization (EUA), a drug company must demonstrate, that based on the totality of scientific evidence the drug's known or potential benefits outweigh the known and potential risks. The FDA can apply that standard appropriately to different settings, such as requiring more-rigorous evidence for treatments used on healthier populations than for seriously ill hospitalized patients. For COVID-19 vaccines, the FDA has announced it is using an "EUA plus approach," through a guidance setting a much more stringent standard than for other EUAs.

Unfortunately, I have grave concerns that some are trying to score political points by irresponsibly criticizing the FDA and its vaccine review and approval process, potentially undermining trust in an FDA-authorized vaccine, especially during this global pandemic and national health emergency. It is understandable in this politicized environment that many in the public would be concerned or confused about the vaccine development and approval process and whether corners are being cut with these unfounded criticisms circulating.

The truth of the matter is that the review and approval stages of the vaccine will be controlled throughout the process by non-political, independent, scientific experts, not politicians. The data produced during the vaccine clinical trials are reviewed and evaluated by a Data Safety Monitoring Board, which is composed of independent scientific experts.

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Indeed, even Congress has contributed to getting assurances on a science-based decision from the FDA. It was this Committee's full Committee hearing in June, and other Committee hearings over the past few months, where Congress and the American people received assurances from FDA Commissioner Stephen Hahn that he would support his career scientists and that FDA would not cut corners on the safety or efficacy of COVID-19 vaccines.

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Further, nine drug companies have already pledged that they will not submit vaccine candidates for FDA review until their safety and efficacy is shown in large clinical trials. In addition, each of the four companies who are now in Phase 3 clinical trials have published their clinical trial protocols.

For vaccine distribution, two independent committees will provide guidance: The National Academies of Sciences, Engineering and Medicine; and CDC's Advisory Committee on Immunization Practices.

I urge each of us to put politics aside in order to deliver one unified, life-saving message that Americans can trust that the FDA's vaccine approval process and that it will be driven by the science and will result in a science-based decision.

And lastly, a reminder for everybody to get your flu shot. It has never been more important.

I look forward to the testimony from these esteemed witnesses and welcome them to this hearing. I yield back.

Ms. DEGETTE. I thank the gentleman.

I got my flu shot too, and I echo what you say, everybody should get their flu shot.

The Chair will now recognize the chairman of the full committee, Mr. Pallone, for 5 minutes.

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. PALLONE. Thank you, Chairwoman DeGette.

Today we're going to hear from some of the Nation's leading public health experts on one tool that could help put an end to the pandemic and the suffering, and that's a safe, effective, and trusted COVID-19 vaccine. And I'm pleased that you're all with us today so that expertise and science have their rightful place in these discussions.

We all want a COVID-19 vaccine to be developed as soon as possible, but first and foremost, we must confirm that it's safe and effective, and we must ensure it is trusted and accessible to all who need it. But as I said in our July hearing with vaccine manufacturers, my fear is that the Trump administration might force the FDA to approve a vaccine before proven to be safe and effective in an effort to boost the President's political fortunes. I hope that doesn't happen, and I'm grateful that career FDA officials have repeatedly stated the importance of putting science first.

Now, let me just say that since January, the President has consistently placed politics over science in the Nation's COVID response, and he's undermined, in my opinion, the independence and integrity of our public health agencies and scientific experts. His words have created confusion amongst the American people, eroding their trust in our public health institutions, and so it's little wonder that polling now shows the public trust in the future COVID-19 vaccine has declined drastically over the past few months. That's why we have to build back the confidence of the American people as we work to ensure a safe and effective vaccine is developed.

Now, we're going to probably vote on an updated HEROES Act that was introduced yesterday, and included in that is a billion dollars in funding for an evidence-based, public awareness campaign to outline the importance of vaccine and combat misinformation, some of which is unfortunately coming from the President.

In this new bill, updated HEROES Act, there is also \$20 billion added to authorize the Secretary to provide grants or contracts for vaccine and therapeutic development; \$7 billion to conduct activities to enhance, expand, and improve vaccine distribution and administration; and also, language to provide grants to State and local public health departments for procurement of vaccines and data and facility enhancements.

And I would also remind everyone that the HEROES Act, as will this updated HEROES Act, provides free treatment, drugs, and vaccine with no copay, similar policy that we had in CARES for testing and contact tracing with, you know, free testing, in this case free vaccine, and no copay.

Now, of course, I regret that Mitch McConnell and President Trump have not—I mean, really stood in the way of the HEROES Act that the House passed back in May, and I continue to call on Mitch McConnell and the President to come to the table to negotiate real help. And maybe, you know, hope springs eternal, maybe before we leave this week, we will have a consensus bill to follow up on the CARES Act that has this language and funding for vaccines that I just mentioned. But, unfortunately, what we continue to see from this administration is political calculations and not science guiding its decisions.

And now, of course, the Trump administration is attacking a potential COVID vaccine in court because they want to strike down the Affordable Care Act, and they have asked the Supreme Court to do that. And remember, the ACA requires that health insurance plans cover all recommended vaccines without cost-sharing for patients. So if it's struck down, then we'll lose access to healthcare, including a potential vaccine for those who lose their coverage under the ACA. And that, to me, is an outrage.

So I look forward to hearing from the witnesses today. While I think the Trump administration's actions, if left unchecked, could actually hamper the effort to develop and administer a successful COVID vaccine, so for that reason, I hope our witnesses can advise the panel on what guardrails they hope to see in place to keep that from happening. That's one of the main reasons I want to hear from all of you, to see what you think we can do to prevent a situation where we don't have a safe and effective vaccine, people don't want to take it, all the other concerns that I've expressed.

So thank you, again, Madam Chair, and I yield back.

[The prepared statement of Mr. Pallone follows:]

#### PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today, we will hear from some of the nation's leading public health experts on one tool that could help put an end to the pandemic and the suffering—a safe, effective, and trusted COVID-19 vaccine. I am pleased that you are all with us today so that expertise and science have their rightful place in these discussions.

We all want a COVID-19 vaccine to be developed as soon as possible. First and foremost, we must confirm that it is safe and effective. And we must ensure it is trusted and accessible to all who need it.

But as I said in our July hearing with vaccine manufacturers, my fear is that the Trump Administration might force the Food and Drug Administration (FDA) to approve a vaccine before proven to be safe and effective, in an effort to boost the President's political fortunes.

I hope this does not happen, and I am grateful that career FDA officials have repeatedly stated the importance of putting science first.

But, since January, President Trump has consistently placed politics over science in the nation's COVID-19 response, undermining the independence and integrity of our public health agencies and scientific experts.

His words have created confusion among the American people, eroding their trust in our public health institutions. It is little wonder then that polling shows that public trust in a future COVID-19 vaccine has declined drastically over the past few months.

That is why we must build back the confidence of the American people as we work to ensure a safe and effective vaccine is developed.

In the updated Heroes Act introduced earlier this week, we included funding for an evidence-based public awareness campaign to outline the importance of vaccines and combat misinformation—some of which is unfortunately coming from the President himself.

In this new bill, there's also \$20 billion to authorize the Secretary to provide grants for vaccine and therapeutic development, \$7 billion to conduct activities to enhance, expand and improve vaccine distribution and administration and also language to provide grants to state and local public health departments for procurement of vaccines, public health data and facility enhancement.

I would also remind everyone that the updated Heroes Act provides free treatment, drugs and vaccines, which builds on a similar policy that we included in the CARES Act.

While I regret that Mitch McConnell and President Trump have stood in the way of the Heroes Act, which the House passed in May, I continue to call on Mitch McConnell and President Trump to come to the table to negotiate real help for American families and our public health system.

Unfortunately, in addition to blocking relief for families and fueling concerns that political calculations—and not science—guide its decisions, the Trump Administration is attacking access to a potential COVID-19 vaccine in court. As you know,

Madam Chair, the Affordable Care Act required that health insurance plans cover all recommended vaccines without cost sharing for patients.

Should the ACA be struck down completely, as the Administration is trying to do at the Supreme Court in just a few weeks, millions of American families will lose access to health care, including a potential COVID-19 vaccine. This is a national outrage that should concern all Members of this Committee.

I look forward to hearing from the witnesses today. While I think the Trump Administration's actions, if left unchecked, could actually hamper the effort to develop and administer a successful COVID-19 vaccine, I hope our witnesses can advise the panel on what guardrails they hope to see in place to keep that from happening.

Thank you, I yield back.

Ms. DEGETTE. The Chair now is pleased to recognize the ranking member of the full committee, Mr. Walden, for 5 minutes.

**OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON**

Mr. WALDEN. Thank you very much, Chair DeGette, and I appreciate you having this hearing.

Americans should have high confidence that any COVID-19 vaccine that's approved or authorized by the U.S. Food and Drug Administration, the FDA, will have gone through the most rigorous, independent, and transparent trials, testing and review in the world.

In fact, the scientific and public attention focused on COVID-19 vaccine's process is itself unprecedented. For example, FDA has issued rigorous guidance for these vaccines, and each of the Phase 3 trials is enrolling at least 30,000 participants.

In addition, the FDA has multiple existing safeguards in place to ensure science-based decisions. These include standards for the vaccine review process, the emergency use authorization review process, and the necessary evidence required to receive an approval that meets FDA's gold standard.

Further, there are multiple safeguards outside of the FDA. For example, each of the Phase 3 trials will be overseen by the Data and Safety Monitoring Board, the DSMB. Now, that's an independent, multidisciplinary group, which includes individuals who are experienced with clinical trials, biostatisticians, bioethicists, immunologists, vaccinologists, and virologists.

The purpose of the DSMB is to oversee and monitor clinical trials to ensure participant safety and validity and the integrity of the data. In addition, all four companies in Phase 3 trials have published their clinical trial protocols to provide even more transparency. There are also independent experts who serve on an FDA advisory committee who will scrutinize safety and efficacy data of the vaccine candidates.

The evidence required of these vaccines is consistent with the FDA's gold standard and has made the vaccine supply in the U.S. reliable, safe, and effective.

Separately, the U.S. Centers for Disease Control and Prevention, the CDC, Advisory Committee on Immunization Practices, or ACIP, is comprised of medical and public health experts who are responsible for developing recommendations on the use of FDA-approved vaccines for Americans, including how, when, and to whom a vaccine should be given.

It's critical that a life-saving, approved coronavirus vaccine gets to those most at risk to this deadly virus and without delay, once the FDA's independent scientists have cleared it for safety and for efficacy. However, some States now have indicated that they plan to withhold distribution of vaccines while they conduct their own unprecedented review of the data. I think that potentially risks the lives of their own citizens.

It will be the first time some of these governors have done that. Such reckless actions dangerously undermine the FDA. They lead to greater vaccine hesitancy, delay, and obstruct vaccine distribution. They create public confusion with inaccurate and misleading information about vaccine safety and efficacy, and worst of all, they will jeopardize American lives.

These States have not provided any evidence of any expertise to conduct such a review, nor have they cited any legal authority to prevent their citizens from accessing a vaccine approved by the FDA, especially during a national public health emergency.

The scientific collaboration throughout the COVID-19 vaccine research and development effort is extraordinary. That collaboration must continue through the complex vaccine distribution process, including the appropriate prioritization for distribution and all the logistics involved in distributing an approved or authorized vaccine.

American scientists are making remarkable progress toward a COVID-19 vaccine. Experts such as Dr. Anthony Fauci are optimistic that these efforts will lead to a life-saving vaccine that will benefit public health in our country and around the world. So, it's essential that all of us involved in public policy in this space stick to the facts and not falsely denigrate those doctors, scientists, and public health officials who are working around the clock to save lives.

Madam Chair, in addition, I'd like to ask unanimous consent request to submit some documents for the record.

The Energy and Commerce Committee Republicans have worked over the last several months to develop recommendations to address an uptick in cases or a potential second wave of COVID-19 infections in the U.S. The results of these efforts released a series of working documents, and I've asked unanimous consent to include the vaccine and therapeutic second-wave document that we just released in July into the record.

In addition——

Ms. DEGETTE. As noted, this will happen at the end of the hearing.

Mr. WALDEN. OK. In addition, I ask the following documents be entered into the record. First, the clinical trial protocols recently released by Moderna, Pfizer, AstraZeneca, and Janssen. Second, the letter signed by nine companies developing COVID-19 vaccines, pledging to uphold the integrity of the scientific process. Third, the FDA Guidance for Industry with recommendations for entities developing COVID-19 vaccines with the goal of licensing the vaccine candidate which was released in June. And fourth, the pledge by senior FDA career executives to follow the science to protect public health in the pandemic.

And I understand these documents have already been shared with the majority and at the appropriate time would ask that they all be entered into the record.

Ms. DEGETTE. They sound great to me, and we'll do it at the end of the hearing. Thank you.

Mr. WALDEN. All right. And with that, Madam Chair, thanks again for the hearing, and I yield back the balance of my time.

[The prepared statement of Mr. Walden follows:]

#### PREPARED STATEMENT OF HON. GREG WALDEN

Americans should have high confidence that any COVID-19 vaccine that is approved or authorized by the U.S. Food and Drug Administration (FDA) will have gone through the most rigorous, independent and transparent trials, testing and review in the world.

In fact, the scientific and public attention focused on the COVID-19 vaccine process is itself unprecedented. For example, FDA has issued rigorous guidance for these vaccines, and each of the Phase 3 trials are enrolling at least 30,000 participants. In addition, FDA has multiple existing safeguards in place to ensure science-based decisions. These include standards for the vaccine review process, the Emergency Use Authorization review process, and the necessary evidence required to receive an approval that meets FDA's gold standard.

Further, there are multiple safeguards outside of FDA. For example, each of the Phase 3 trials will be overseen by the Data and Safety Monitoring Board (DSMB). The DSMB is an independent, multidisciplinary group which includes individuals who are experienced with clinical trials, biostatisticians, bioethicists, immunologists, vaccinologists, and virologists. The purpose of the DSMB is to oversee and monitor clinical trials to ensure participant safety and the validity and integrity of the data. In addition, all four companies in Phase 3 trials have published their clinical trial protocols to provide even more transparency.

There are also independent experts who serve on an FDA Advisory Committee who will scrutinize safety and efficacy data of the vaccine candidates. The evidence required for these vaccines is consistent with the FDA's gold standard that has made the vaccine supply in the U.S. reliable, safe, and effective.

Separately, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who are responsible for developing recommendations on the use of FDA approved vaccines for Americans, including how, when, and to whom a vaccine should be given.

It is critical that a life-saving, approved coronavirus vaccine gets to those most at risk to this deadly virus without delay once the FDA's independent scientists have cleared it for safety and efficacy.

However, some states have indicated that they plan to withhold distribution of vaccines while they conduct their own, unprecedented reviews of the data, potentially risking the lives of their own citizens.

Such reckless actions dangerously undermine the FDA, lead to greater vaccine hesitancy, delay and obstruct vaccine distribution, create public confusion with inaccurate and misleading information about vaccine safety and efficacy, and worst of all, jeopardize American lives.

These states have not provided any evidence of any expertise to conduct such a review nor have they cited any legal authority to prevent their citizens from accessing a vaccine approved by the FDA, especially during a national public health emergency.

The scientific collaboration throughout the COVID-19 vaccine research and development effort is extraordinary. That collaboration must continue through the complex vaccine distribution process, including the appropriate prioritization for distribution and all the logistics involved in distributing an approved or authorized vaccine.

American scientists are making remarkable progress towards a COVID-19 vaccine. Experts such as Dr. Anthony Fauci are optimistic that these efforts will lead to a life-saving vaccine and will benefit public health in our country and the world.

It is essential that all of us involved in public policy in this space stick to the facts and not falsely denigrate those doctors, scientists and public health officials who are working around the clock to save lives.

Ms. DEGETTE. I thank the ranking member.

The Chair asks unanimous consent that the members' written opening statements be made part of the record, and without objection, they will be entered into the record.

I'd now like to introduce our witnesses for today's hearing. Dr. Mark McClellan, who is the former commissioner of the Food and Drug Administration and founding director of Duke-Margolis Center for Health Policy at Duke University; Dr. Ali S. Khan, dean of the public health center at the University of Nebraska Medical Center; Dr. Paul Offit, director of the Vaccine Education Center at the Children's Hospital in Philadelphia; Dr. Helene Gayle, co-chair of the National Academies of Sciences, Engineering, and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus; and Dr. Ashish K. Jha, dean of the School of Public Health at Brown University.

I really want to thank all of you for joining us today in this really important hearing. And I know all of you have been advised by staff. The committee is holding an investigative hearing, and when doing so, we have the practice of taking testimony under oath. Do you have any objections to testifying under oath?

Seeing no objection, let the record reflect that the witnesses have responded no.

The Chair then advises you that under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Does any of you desire to be accompanied by counsel today?

Let the record reflect that the witnesses have reflected no.0

So if you would, please raise your right hand so I may swear you in.

Do you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth?

Let the record reflect the witnesses have responded affirmatively.

All of you are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code.

We'd now like to recognize our witnesses for a 5-minute summary of their written statement. There's a timer on your screen, you can see it, and it will count down your time. It will turn red when your 5 minutes has come to an end.

And so I'd like to first recognize you, Dr. McClellan, for 5 minutes.

**TESTIMONY OF DR. MARK MCCLELLAN, M.D., PH.D., FOUNDING DIRECTOR, DUKE-MARGOLIS CENTER FOR HEALTH POLICY DUKE UNIVERSITY; DR. ALI S. KHAN, M.D., MPH, MBA, DEAN, COLLEGE OF PUBLIC HEALTH UNIVERSITY OF NEBRASKA MEDICAL CENTER; DR. PAUL A. OFFIT, M.D., DIRECTOR, VACCINE EDUCATION CENTER, CHILDRENS HOSPITAL OF PHILADELPHIA; DR. HELENE GAYLE, M.D., MPH, CO-CHAIR, COMMITTEE ON EQUITABLE ALLOCATION OF VACCINE FOR THE NOVEL CORONAVIRUS, NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE; AND DR. ASHISH K. JHA, M.D., MPH, DEAN, SCHOOL OF PUBLIC HEALTH, BROWN UNIVERSITY**

**STATEMENT OF MARK McCLELLAN, M.D.**

Dr. McCLELLAN. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, I'm Mark McClellan, director of the Duke-Margolis Center for Health Policy. I previously had the privilege to serve as Commissioner of the FDA from 2002 to 2004, and I also serve on the board of directors of Johnson & Johnson.

The development of a safe and effective vaccine, in conjunction with other treatments and nonmedical measures like masks and testing, represents our best path for containing and moving beyond the pandemic. The impact of a vaccine depends on its safety and effectiveness and also on public confidence in the vaccine.

Guided by the healthcare providers they trust, Americans will need to choose to get a vaccine to protect themselves and reduce the spread to people around them. Critical to achieving the benefits of safe and effective vaccination are actions of our Federal Government, public health scientists, and regulators, in particular, the expert staff of the FDA. The FDA has set the global gold standard on issues of medical product safety and effectiveness and has unparalleled experience and expertise in regulating vaccines that are used safely and effectively by hundreds of millions of Americans.

Throughout my career, I've experienced the firsthand—I have firsthand experienced the integrity, expertise, and commitment of the FDA's career staff, particularly in responding to public health emergencies. The vaccine experts in the Biologics Center are globally respected for their decades of experience in overseeing all aspects of vaccine development, manufacturing, and post-market monitoring.

I appreciate the FDA staff's explicit commitments to the public that these processes are followed, FDA's approach to COVID, vaccines as part of a well developed system of independent checks that have been put in place over decades to build a reliable and robust infrastructure for assuring vaccine safety and effectiveness.

There's great urgency in a pandemic. Speed matters, given the lives being lost daily. During my time as FDA Commissioner, we worked on a bipartisan basis with this committee to enact FDA's authority for emergency use authorization, which has since been used and augmented based on experience with the H1N1 pandemic.

The administration deserves credit for the work of Operation Warp Speed, which has led to extraordinary progress in advancing multiple promising vaccines, converting what's typically a long and uncertain, sequential development process to a much shorter par-

allel process, including conducting clinical trials at scale at the same time as scaling up manufacturing.

The assurance of clinical safety and effectiveness as part of these steps is imperative, including if an emergency use authorization is applied. The FDA has provided industry and researchers with early and frequent guidance in this process, including written guidance documents for preclinical and clinical development, as well as safe manufacturing practices.

Some recent statements from the White House have implied that FDA's plan to release additional written guidance on its expectations for EUA of a vaccine is unnecessarily raising the bar. That's not the case. FDA standards are based on these decades of experience and with the experience and development of urgently needed countermeasures during public health emergencies.

The FDA has been sharing its regulatory guidance directly with manufacturers and researchers, and its guidance is reflected in the design and conduct of the large-scale clinical trials and other development activities underway now. Vaccine manufacturers have committed to following FDA's guidance.

The FDA has been clear in public statements, as recently as yesterday, that its emergency use authorization standards for vaccines are different and much higher than those for therapeutic products already on the market, like convalescent plasma, and are generally the same as for the safety and effectiveness of other vaccines. Consequently, the FDA has required very large, randomized clinical trials. It's requiring the trials to produce large safety databases to monitor for side effects that extend past a month or two during which most serious side effects typically occur. The FDA has also made clear it intends to use its emergency use authorization to require substantial post-market data collection, all to augment evidence available on the vaccine.

Congress designed the emergency use authorization process to provide the FDA with exactly this flexibility to set standards that are appropriate for the different contexts that arise during the pandemic.

All of these well established systems for vaccines' safety and effectiveness are hard to disrupt, and they have kept the COVID vaccine development process robust and on track. This is despite a range of political actions, including proposed actions by some governors to set up new and untested vaccine review processes, despite the fact that vaccine development continues to follow FDA's long-held standards and guidance. While the concern is understandable, these political actions create uncertainty for the public that diminishes confidence in the FDA and vaccine development.

Over the years, this committee has provided strong bipartisan support and resources for an effective FDA and science-based development process for products that address unmet medical needs. We need that today more than ever to avoid ending up prolonging the pandemic and all of its health and economic consequences.

And if you could put the remainder of my statement, a longer statement, into the record, I'd appreciate it.

[The prepared statement of Dr. McClellan follows:]

PATHWAY TO A VACCINE: ENSURING A SAFE AND EFFECTIVE VACCINE PEOPLE WILL TRUST

Witness appearing before the House

Energy and Commerce Subcommittee on Oversight and Investigations

Mark B. McClellan, MD, PhD

Director, Margolis Center for Health Policy

at Duke University

Chairwoman DeGette, Ranking Member Guthrie, and members of the House Energy and Commerce Subcommittee on Oversight and Investigations: I'm Mark McClellan, Director of the Robert J. Margolis, MD, Center for Health Policy at Duke University. I previously had the privilege to serve as Commissioner of the U.S. Food and Drug Administration, and I currently serve on the board of directors of Johnson & Johnson, which is engaged in an effort to develop a vaccine to COVID. I appreciate the opportunity to join you today to discuss the path forward as we work together to develop, approve, and distribute safe and effective vaccines to overcome the global COVID-19 pandemic.

The development of safe and effective vaccines, in conjunction with other therapeutic interventions and non-medical measures like masks and physical distancing, represents our best path for containing and moving beyond the pandemic. The impact of a vaccine depends on its safety and effectiveness, and also on public confidence in the vaccine. Guided by the health care providers they trust, Americans will need to choose to get a vaccine, both to protect themselves and to reduce spread to people around them. Critical to achieving the benefits of safe and effective vaccination are the actions of our Federal government's public health scientists and regulators, in particular the expert staff at the U.S. Food and Drug Administration (FDA). The FDA has set the global gold standard on issues of medical product safety and effectiveness, and has unparalleled experience and expertise in regulating vaccines that are used safely and effectively by hundreds of millions of Americans.

It was my privilege to serve as FDA Commissioner from 2002 to 2004. During that time, among many other issues, the agency dealt with containing the Severe Acute Respiratory Syndrome (SARS) coronavirus outbreak. We also worked on a bipartisan basis with this committee to enact FDA's authority for emergency use authorization (EUA), which has since been augmented based on experience with the H1N1 pandemic. While at the agency, and subsequently in our work related to FDA issues at Duke University, I have experienced first-hand the integrity, expertise, and commitment of the FDA's career staff – particularly in responding to public health emergencies with timely and science-based

actions. The vaccine experts in FDA's biologics center are globally respected for their decades of experience in overseeing all aspects of vaccine development, manufacturing, and post-market monitoring, and I appreciate the FDA staff's explicit commitments to the public to ensure that these processes are followed. I continue to have full confidence in FDA's guidance of the COVID-19 vaccine development process, as reflected in the agency's actions to date and its expectations for the path forward for vaccine development from here. FDA's approach to COVID-19 vaccines has been scientifically sound and remains on track.

I would like to describe that path for the committee, with an emphasis on key steps that FDA is taking to support the science-based assessment of candidate COVID-19 vaccines, as part of the well-developed systems of independent checks that have been put in place over decades to build a reliable and robust infrastructure for assuring vaccine safety and effectiveness.

The approach is designed to ensure that any vaccine that is approved or authorized will be safe and effective for use, which is the only basis for the trust needed for patients and providers to use it. There's great urgency in a pandemic. Speed matters given all of the lives lost daily. We must make sure that we are doing everything that can safely be done in parallel, like scaling up manufacturing and assuring its quality even as we conduct clinical trials. But when it comes to the assurance of clinical safety and effectiveness as part of these steps, there are no shortcuts. The fastest way to success is through good science that delivers a confident result.

The Administration deserves credit for launching Operation Warp Speed, which has led to extraordinary progress in advancing multiple promising vaccine platforms by converting what is typically a long and uncertain sequential development process to a hyper-parallel process. FDA has provided industry and researchers with early and frequent guidance in this process, including written guidance documents for preclinical and clinical development, as well as safe manufacturing practices. The National Institutes of Health (NIH) has similarly helped to set up and monitor well-designed, very large-

scale randomized clinical trials. Manufacturers supported by the Biomedical Advanced Research and Development Authority (BARDA) are taking financial risk to produce hundreds of millions of doses before we know whether the vaccines work. And the Centers for Disease Control (CDC) has initiated collaborative planning with state, local, and private sector partners for the extensive operational steps needed to support timely distribution and administration of any vaccines that prove safe and effective.

Some recent statements from the White House have implied that FDA's plan to release additional written guidance on its expectations for emergency use authorization of a vaccine is unnecessarily raising the bar on regulatory standards for authorization. That is not the case. FDA's standards are based on decades of experience with vaccines routinely used by millions of Americans as well as extensive experience with the development of urgently needed countermeasures during public health emergencies. FDA's guidance to product developers is intended to help them develop the totality of evidence needed for FDA to support a decision about benefits and risks of using a treatment or vaccine. FDA has been sharing its regulatory guidance directly with vaccine manufacturers and researchers, and its guidance is reflected in the design and conduct of the large-scale clinical trials and other development activities already underway. The agency's further written guidance in development on expectations for an emergency use authorization for a vaccine simply reflects FDA's ongoing feedback to sponsors. Vaccine manufacturers have already committed to following FDA's guidance, including in writing and in statements to Congress. Releasing the written guidance doesn't change that but would add to transparency about it. Indeed, manufacturers routinely request written guidance from FDA to reduce the time and increase clarity around the development process.

Written guidance or not, FDA has been clear in public statements that its emergency use authorization standards for vaccines are different and much higher than those for currently-available therapeutic products like convalescent plasma. Convalescent plasma has been used for a century as a treatment for many infections, and it has already been used in tens of thousands of seriously ill COVID-

19 patients without evidence of any significant safety problem. It may not have much or any benefit – clinical trials are underway now to help answer that question – but this is a very different context from vaccine use in people who aren't sick. COVID-19 vaccines in development are entirely new products intended for use by potentially hundreds of millions of healthy Americans to prevent them from developing infections and serious complications. Consequently, FDA is requiring very large, well-designed, randomized clinical trials that have meaningful clinical endpoints of significant reductions in infections and serious COVID-19 complications. FDA is also requiring the trials to produce large safety databases to monitor for side effects that extend past the month or two during which most serious side effects from a vaccine generally occur. In addition, FDA has also made clear that it intends emergency use authorization powers to require substantial postmarket data collection on any populations who get relatively early access to an authorized vaccine. Such data would further augment the evidence collected in the clinical trials.

Vaccine use is a very different context for the application of emergency use authorization compared to convalescent plasma, requiring a much higher evidence standard on safety and effectiveness. Congress designed the emergency use authorization process to provide FDA with exactly this flexibility to set standards that are appropriate to the different contexts that arise in a pandemic.

Whether or not any further guidance is published, FDA's current guidance coupled with well-established clinical development processes and supports provide a very clear idea of what we should expect in the coming weeks to assure safe and effective vaccines. In particular, we should expect multiple independent checks and public review opportunities built into a well-developed approach that generates the needed evidence on vaccine safety and effectiveness.

First, the large randomized clinical trials underway now, or getting underway soon, must continue until they establish whether the vaccines cause a meaningful reduction in the likelihood and severity of COVID-19 infections without significant safety problems. It is well-established practice for

such pivotal trials to be monitored by independent experts who make up a data safety monitoring board (DSMB). They, and not politicians, should determine when there is sufficient evidence from the trial, leading to a report on the trial's findings. These independent advisors backed by FDA's established standards on good trial practices are also critical to identifying potential safety issues during a trial. FDA has already demonstrated its willingness to use its authority to suspend a vaccine trial, if the trial's safety monitoring suggests a concern.

Second, in consultation with FDA, companies will need to submit their evidence to the FDA in an application for emergency use or approval. The FDA scientific staff will review this evidence and provide a written assessment, which will be shared publicly at a meeting of the FDA's independent expert advisory committee on vaccines, the Vaccines and Related Biological Products Advisory Committee (VRBPAC). This committee will independently review the evidence and answer questions from FDA staff as to whether the standards for an emergency authorization have been met. The FDA has committed to such a public advisory committee meeting for each new vaccine.

Next, the FDA will take what it has learned from this public airing of evidence to make a decision about emergency authorization or approval. The decision will be reflected in a detailed written report. The report should include a specific plan for learning more about the vaccine's safety as it begins to be used. This plan will include Federal and state vaccine databases to track who has been vaccinated, and mechanisms for drug manufacturers, clinicians, and patients to report whether they had a significant health issue or other adverse event arise following vaccination. Such systems for monitoring infections and potential vaccine side effects in early-use populations should be augmented using secure linkages to electronic databases from medical records, insurance claims, and other sources for timely detection and analysis of further data related to safety. In addition, health care workers who may be first to receive the vaccine could participate in a registry to assess infections and side effects, such as the HERO registry

supported by the Patient-Centered Outcomes Research Network (PCORNet) that is tracking other COVID-related data on health care professionals who volunteered to share it via a secure mobile app.

Finally, the Advisory Committee on Immunization Practices (ACIP) at the CDC will publicly review the evidence and the FDA's authorizations to recommend how the vaccine should be distributed. If the FDA expands its authorization, the CDC's independent advisers will likely meet again to provide a basis for updating their guidance.

Given all of these steps and the FDA's high bar for authorizing a vaccine, it has never been likely that a vaccine would be approved before the election. We shouldn't use that single point in time as a yardstick to measure success. The bottom line is that this process is proceeding at a historic pace, and if we are able to deliver a safe and effective vaccine sometime this fall or winter, it will be a monumental achievement for all of those who supported these endeavors, including the patients who entered trials, the providers on the frontlines, the sponsors who developed products, the administration that stood up Operation Warp Speed, and the members of Congress who had the foresight to provide the foundational regulatory authorities, research infrastructure, and funding and impetus to make it possible.

If this process stays on track, it is possible that one or more vaccines may be authorized for initial use in certain populations before the end of the year. Unless a clinical trial shows overwhelming evidence of effectiveness, and especially since the supply of a vaccine will initially be limited, it's likely that this vaccine access will occur in a staged process. This would start with the people most likely to benefit from a vaccine based on available evidence – potentially including health care workers, high-risk essential workers, older individuals and those with comorbidities. The data on infections and potential adverse events collected from the early-use groups would add substantially to the evidence collected in the clinical trials, including longer-term follow-up on additional patients to address more remote

potential long-term safety risks. Additional studies might also be conducted in groups not well represented in the current trials, such as children and young people.

The EUA allows FDA to enable this very staged market entry of a product like a vaccine, where the vaccine can initially be made available to a smaller group of patients based on their much higher risk of contracting COVID, suffering a bad outcome, or transmitting it to others at high risk. In such a group, the benefits may outweigh the risks, even in a setting where the long-term uncertainties aren't as well understood. As more data is collected, and more and longer-term follow-up is completed, access can be expanded to other groups of patients based on their risk and their likelihood of achieving benefits that outweigh any rare and theoretical safety issues. These further steps would provide the foundation for a broader emergency authorization or approval, and broader use of a vaccine, which is more likely to happen in the second quarter of 2021 or perhaps later.

Given everything I have outlined here - the well-established practices for good clinical trials; independent expert review and public transparency; written commitment of companies to follow the FDA-guided process; and particularly the FDA's experience and commitment to a well-developed, science-based process - I am confident in the path ahead for developing safe and effective vaccines - so long as FDA's expert staff continues to guide it. Science-based decisions like those coming for COVID-19 vaccines are complex, and there will always be some differences of scientific viewpoints among experts and the broader public. But with more than a century of experience in making science-based decisions, a long-established culture of independence and professionalism, independent advisory groups, and the best collection of expertise on COVID-19 vaccines in the world, the FDA is the best equipped place to consider the evidence and views and make these decisions. We're lucky to have such resources in the midst of this public health emergency, so that we can develop and make available safe and effective vaccines at a rapid pace.

All of these well-established systems are hard to disrupt, and they have kept the COVID-19 vaccine development process robust and on track. This is despite a range of political actions, including steps from the White House to influence FDA's process as well as proposed actions by governors to set up some kind of new and untested vaccine review process. Despite the fact that vaccine development continues to follow FDA's long-held standards and guidance, such political actions have created uncertainty for the public that has diminished confidence in the FDA and in vaccine development. Recent public opinion surveys have shown a concerning shift in American attitudes toward potential COVID-19 vaccination. A [recent Pew Research Center](#) poll found 49% of respondents unwilling to be vaccinated today if a new vaccine were available. That's a 22% increase in unwillingness to be vaccinated since Pew surveyed vaccine attitudes in May. For COVID-19 vaccines to have an impact, they must be safe and effective – and Americans must be confident in using them progressively more widely. So it's particularly important for Americans to know that the FDA and the other public health agencies involved in vaccine development and use are following their well-established science-based processes.

Thanks to the instrumental steps in Operation Warp Speed to accelerate vaccine development, coupled with the hard work and professionalism of the FDA, academic experts, industry scientists, public health experts, and others, it is possible that we will have safe and effective vaccines available on a limited basis later this year and much more widely during 2021. But vaccines are only effective to the extent they are used. Over the years, this committee has provided strong bipartisan resources and support for an effective FDA and a science-based development process for products to address unmet medical needs. We need that today more than ever, to avoid ending up prolonging the pandemic and all of its health and economic consequences.

Finally, it's worth emphasizing that for some time to come, we will need to rely on the entire playbook of steps to contain this pandemic. Vaccines will not provide a short-term silver bullet under any plausible circumstances but will hopefully soon become an increasingly important component of

that response. Even as we begin to use vaccines, we will still need the other proven steps that work – masks, distancing, avoiding large groups especially indoors, and personal hygiene like hand washing and sanitizing. We also need to keep working on potential therapeutics, another critical part of Operation Warp Speed and the NIH’s ACTIV trial network.

The return to normalcy will happen gradually. We will still be grappling with COVID-19 next year. But with the right tools, we can accelerate this return, allowing us to significantly reduce the burden of COVID-19 while reopening more effectively and saving lives. To achieve these shared goals, we need to agree on some common principles. These include supporting the steps to efficiently advance the development and use of a safe and effective vaccine, based on FDA’s trusted and scientifically sound guidance. Thank you for your time and continued efforts to address the challenges to the health of the nation and the world.

Ms. DEGETTE. That will be done. Thank you so much, Doctor. Next, I'm pleased to recognize Dr. Khan for 5 minutes.

**STATEMENT OF ALI S. KHAN, M.D.**

Dr. KHAN. Good morning, Chair DeGette, Ranking Member Brett Guthrie, and members of the subcommittee. I'm Ali Khan, a physician, infectious disease epidemiologist, and dean of the College of Public Health at the University of Nebraska Medical Center. I was formerly the assistant surgeon general at the Centers for Disease Control and Prevention with responsibility for national preparedness.

We are currently witnessing the greatest public health failure in our Nation's history, from a sluggish and shortsighted government response, combined with a disregard for scientific expertise that has undermined trust in public health.

I'm pleased to be here today to discuss my experience with preparedness planning and to reinforce that we must heed the lessons learned from prior vaccination campaigns, such as the 2009 H1N1 pandemic, including addressing the challenges with trust. I also want to remind that with 750 preventable deaths occurring every day in the United States, we cannot wait for a vaccine to contain this COVID-19 pandemic.

Now, while the preliminary data is hopeful, the prediction of an election day COVID-19 vaccine has raised numerous concerns in the scientific and vaccine development community, as well as among the public about trust for the vaccine. Trust for the vaccine will be as important, if not more so, than the safety and efficacy which are much easier to manage.

The lessons of the 2009 H1N1 experience may be helpful as the Nation undertakes its most ambitious vaccination campaign ever. That response uncovered communications, operational, and policy challenges across the Federal Government regarding the distribution of vaccines.

The H1N1 vaccine was initially available in the United States in October 2009, about four months after the WHO declared a pandemic, but the vaccine did not become more broadly available until December of 2009. By that time, the peak of H1N1 had passed and many individuals were no longer interested in getting vaccinated. And this diminished the credibility at all levels of government when the amount of vaccine available to the public did not meet expectations set by the government.

In addition, State leaders had poorly defined initial target groups for vaccination, with unexplained variation between entities, and despite significant outreach efforts and provision of free vaccine, difference persisted between Blacks and Whites and vaccination rates.

And, finally, logistics challenges included 100-dose minimum orders, and many States were forced to break down and repackage the vaccine to efficiently serve smaller vaccination sites.

Now, there are a myriad of strategic and operational challenges with potential COVID-19 vaccine, including the probable need for two doses of the same vaccine given 21 to 28 days apart, multidose vials, complex storage requirements, and others. So it's really going to be critical to leverage our Nation's existing public health system

and vaccine distribution infrastructure to ensure the efficient, effective, and equitable access to these vaccines.

Unified planning and priority setting at the State, local, Tribal, and territorial level is a must, and we also need to assure the interoperability and timeliness of the numerous data systems to manage and evaluate the effectiveness of the distribution and administration of the vaccine and monitor the adverse events.

Now, while vaccine demand will likely be the immediate issue for any potential licensed vaccine, we must acknowledge that public acceptance of a COVID-19 vaccine is not a given. There's evidence of existing vaccine hesitancy, even before any actual or even perceived rare potential complication identified in post-licensing monitoring. To increase vaccine uptake, we must avoid the use of predictions in our messaging and provide clear, consistent, and fact-based messages. Lessons learned from H1N1 reinforce that we need to underpromise and overdeliver.

In conclusion, there's no guarantee that vaccine efficacy and vaccine coverage will be sufficient to contain the COVID-19 pandemic. So, right now, while we wait for the vaccine, we have the ability to implement an evidence-based playbook that will reduce the number of cases and deaths, and this will require unified local, State, and Federal leadership that is evidence-based and uses metrics.

Thank you. I will be ready to answer any questions. And if you may, Madam Chair, include my longer testimony in the record.

[The prepared statement of Dr. Khan follows:]



**University of Nebraska Medical Center  
College of Public Health**

**Hearing on Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust**

**Witness appearing before the  
116<sup>th</sup> Congressional House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Ali S. Khan, MD MPH MBA  
Dean and Professor of Epidemiology  
Assistant Surgeon General, USPHS (retired)**

**September 30, 2020**

**TALKING POINTS****Introduction**

- Good afternoon, Rep. Diana DeGette, Chair of the Subcommittee, ranking member Brett Guthrie, and members of the subcommittee.
- I'm Ali S. Khan, a physician, former Assistant Surgeon General at the Centers for Disease Control and Prevention responsible for national preparedness, and currently dean of the College of Public Health at the University of Nebraska Medical Center.
- I am pleased to be here today to offer testimony to examine the future safety, efficacy, and accessibility of COVID-19 vaccines and the challenges with trust.

**Problem Statement – General**

- We are currently witnessing the greatest public health failure in our nation's history.
- A sluggish and shortsighted government response combined with a disregard for scientific expertise has undermined public health and allowed a novel coronavirus to gain a foothold in the U.S.

**Solution – General**

- I am here to discuss my prior experience with preparedness planning and to reinforce that we must heed the lessons learned from prior vaccination campaigns like 2009 H1N1p
- However, with ~750 preventable deaths occurring each day in the U.S., we cannot wait for a vaccine to contain this outbreak.
- We can take evidence-based steps to drive down the number of new cases and deaths today with the public health tools we already have available.

**Problem Statement – Vaccine Timeline**

- While the preliminary data is hopeful, the prediction of an election day COVID19 vaccine has raised numerous concerns in the vaccine scientific and development community as well as in our communities.
- I would like to remind members of the subcommittee that we have been waiting 30 years for an HIV vaccine and we still do not have effective vaccines for dengue, RSV, noroviruses, and numerous other viral diseases.
- Please note that going back to my earlier comment of we cannot wait of a vaccine to use public health measures to contain this disease, if the FDA finally mandates 2 months of post-vaccine monitoring in Phase 3 trials before approval, that will equate to at least more 30K additional deaths.

**Problem Statement – Trust**

- In line with getting the messaging right, public acceptance of a COVID-19 vaccine is not a given.
- Trust of the vaccine will be as important if not more so than the safety and efficacy which are much easier to manage.
- A recent study and poll from the Associated Press-NORC Center for Public Affairs Research suggest that a 1/4 to a 1/2 of the U.S. population would not be willing to receive it.<sup>1</sup>
- Some people may legitimately fear that if a vaccine is developed too quickly and corners were cut, there won't be time to adequately test it.
- If you recall, in 1976, a failed political campaign to mass-vaccinate the public against a strain of the **swine flu** virus negatively influenced the public's perception of the flu vaccine in this country.
  - 45 million were vaccinated in 10 weeks.
  - However, there was no swine outbreak and, instead, the vaccine resulted in over **450 people developing the paralyzing Guillain-Barré syndrome at a rate above baseline of ~1 per 100,000.**
  - Political expediency and self-interest of government health bureaucracy were attributed to this fiasco although it reflected the precautionary principle.
- Again, in 1998, the FDA approved a new recombinant **Lyme vaccine**, LYMERix™, which reduced new infections in vaccinated adults by nearly 80%.
  - Just 3 years later, the manufacturer voluntarily withdrew its product from the market amidst negative media coverage, the public's fear of the side-effects, and declining sales.

**Problem Statement – 2009 H1N1p experience**

- In 2009, **H1N1p influenza** uncovered communication, operational and policy challenges across the federal government with regard to the distribution of vaccines.
  - Similar to COVID-19, H1N1p was novel, with the majority of the U.S. population lacking immunity to the virus, and an understanding of its virulence was unknown.
  - The H1N1 vaccine was initially available in the United States in October 2009, almost four months after the World Health Organization's (WHO) pandemic declaration but did not become more broadly available until late December 2009.
  - By the time a vaccine was available, the peak of H1N1 had passed, and many individuals were no longer as interested in getting vaccinated.

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<sup>1</sup> The Associated Press-NORC Center for Public Affairs Research. Expectations for a COVID-19 Vaccine

- “By the end of 2009, approximately 61 million persons had been vaccinated. By January 29, 2010, approximately 124 million doses had been distributed.”<sup>2</sup> By May 31, 2010, an estimated 90 doses had been administered or 27% of the population above 6 months of age.
- Vaccine distribution was delegated to state and local jurisdictions, which were provided flexibility in deciding the best methods for distribution.
- The distributor (McKesson) required a 100-dose minimum order and many states were forced to break down and repackage the vaccine to efficiently serve smaller vaccination sites, such as nursing homes, rural doctors’ offices, and schools.<sup>3</sup>
- State leaders had poorly well-defined, initial target groups for vaccination with unexplained variations between entities.
- Accurate communication for the H1N1 vaccine and response was a challenge.
  - The credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials.
  - Vaccine administration plans varied across the nation which required time clarifying information to ensure local accuracy.
  - The availability of multiple vaccine formulations with varying contraindications for various priority groups complicated vaccine administration plans even further, which in turn had to be shared with the public.

#### **Problem Statement – Challenges of Vaccine Distribution**

- While the Federal Distribution Strategy outlines that each state will develop its own COVID-19 immunization program, the guidance leaves open many issues critical to successful vaccine distribution.
  - Transportation and storage – Different types of vaccines need different transportation and storage conditions. One of the biggest distribution challenges is temperature control.
    - The two vaccines that seem most likely to be ready first are from Pfizer and Moderna.
    - These vaccines are stored at different temperatures (Moderna -20 degrees, Pfizer -94 degrees) and require different kinds of preparation by the health care provider.
    - According to The IQVIA Institute for Human Data Science, the biopharma industry loses 35 billion dollars each year due to temperature-control failures across their supply chains.

<sup>2</sup> Interim Results: Influenza A (H1N1) 2009 Monovalent Vaccination Coverage --- United States, October–December 2009. MMWR, January 22, 2010 / 59(02):44-48. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5902a4.htm>

<sup>3</sup> Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning GAO-11-632: Published: Jun 27, 2011. <https://www.gao.gov/assets/330/320176.pdf>

- State Health Departments may be required to allocate half of their allotted vaccine which may pose storage challenges.
- State Health Departments may need to break down 975 – dose shipments of the Pfizer vaccine for smaller jurisdictions.
- Tracking – product security and traceability is critical when managing temperature sensitive vaccines on a global scale.
  - CDC is already rethinking an untested vaccine registration system [Vaccine Administration Management System (VAMS)] and potentially relying on state immunization registries. However, linkages will be essential.
  - The CDC will require vaccinators to provide dose-level accounting and reporting for vaccinations, so we know where every dose of COVID-19 vaccine is at any point in time.
  - Although the sophistication of our tracking systems have improved dramatically in the past decade many states will still face major challenges meeting the necessary tracking and reporting expectations.
  - We have a limited window of just months to fully assess and implement a tracking solution.

#### Problem Statement – Equity

- COVID-19 Amplifies existing racial health disparities.
- Non-white, socioeconomically disadvantaged, and non-English-speaking populations shoulder disproportionate COVID-19 burdens.
- As of April 15, 2020, case data from CDC show that in COVID-19 cases where race was specified, Blacks, who comprise 13 percent of the total U.S. population (U.S. Census Bureau, 2018), make up 30 percent of COVID-19 cases; Latinos, who make up 18 percent of the population (U.S. Census Bureau, 2018), account for 17 percent of COVID-19 cases.<sup>4</sup>
- However, a survey of the U.S. adult population in May 2020 found that Black Americans reported lower influenza vaccine uptake and lower COVID-19 vaccine acceptance than all other racial groups.<sup>5</sup>
- Despite outreach efforts to minimize disparities for the 2009-H1N1p Influenza vaccine uptake and free vaccine, a difference persisted between Blacks and Whites (13.8% vs 20.4%); Whites and Hispanics had similar 2009-H1N1 vaccination rates.<sup>6</sup>

<sup>4</sup> Double Jeopardy: COVID-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S. SAMHSA; 2020. <https://www.samhsa.gov/sites/default/files/covid19-behavioral-health-disparities-black-latino-communities.pdf>

<sup>5</sup> Malik, A.; McFadden, S.; Elharake, J.; Omer, S. Determinants of COVID-19 vaccine acceptance in the US. *The Lancet*; 2020. <https://doi.org/10.1016/j.eclinm.2020.100495>

<sup>6</sup> Uscher-Pines, L., Maurer, J., & Harris, K. M. (2011). Racial and ethnic disparities in uptake and location of vaccination for 2009-H1N1 and seasonal influenza. *American journal of public health, 101*(7), 1252–1255. <https://doi.org/10.2105/AJPH.2011.300133>

- Vaccination coverage is significantly lower among non-Hispanic blacks, Hispanics, and non-Hispanic Asians compared with non-Hispanic whites adults for 6 vaccines, with only a few exceptions.<sup>7</sup>

#### **Solution – Leverage Our Existing Distribution Infrastructure**

- When the time comes, we can leverage our nation’s existing vaccine distribution infrastructure to ensure efficient, effective, and equitable access to COVID-19 vaccines.
  - CDC has worked for decades with state, local and tribal health departments to develop plans for vaccine distribution and administration.
  - Each state can leverage this past preparedness work and refine their plans to ensure public health systems are prepared with trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a COVID vaccine program.
- Thanks to congressional support, state preparedness efforts for **anthrax and smallpox attacks** provides an additional framework that we can leverage for effective COVID vaccine distribution.
  - The mass prophylaxis protocols for anthrax and smallpox provide models of government-led vaccination targeted at rapidly protecting large segments of the population.
  - States have planned to receive countermeasures directly and then dispensed to the public, either directly to Points of Dispensing (PODs) or through intermediate receiving, staging, and storage (RSS) centers, which may be operated by state, county, or local agencies.
  - PODs can be administered by both public and private sector agencies and may provide useful models for the distribution of the COVID vaccine.
  - This includes for outbreaks of measles, mumps, and meningitis
- The **Vaccines for Children (VFC) program** can be and has been leveraged to provide federally purchased vaccines to children; adults who are uninsured or underinsured; and fully insured individuals during public health emergencies.
- During H1N1, we leveraged this infrastructure and partnerships between federal officials and their state and local counterparts to increase vaccine uptake.
  - Pandemic vaccine shipments finally hit their stride in December, reaching the 100 million-dose milestone by the middle of the month.
  - Sebelius, at a December 17 2009, press briefing, told reporters that partnerships between federal officials and their state and local counterparts would yield long-term

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<sup>7</sup> Lu, P. J., O'Halloran, A., Williams, W. W., Lindley, M. C., Farrall, S., & Bridges, C. B. (2015). Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S. *American journal of preventive medicine*, 49(6 Suppl 4), S412–S425. <https://doi.org/10.1016/j.amepre.2015.03.005>

benefits. "One of the key lessons we learned is you can't mount a public health response only from the beltway," she said.<sup>8</sup>

- States set up immunization clinics in nontraditional venues such as shopping malls, airports, subway stations, and sporting events.
- Also, 40 states used school-based vaccinations to some degree and the CDC reported that three of the four states that had the highest vaccine uptake were among those with school-based vaccine clinics.
- Additionally, the 2019 measles outbreak driven by 1) pockets of low vaccination coverage and variable vaccine acceptance; 2) relatively high population density and closed social nature of the affected community; and 3) repeated importations of measles cases among unvaccinated persons traveling internationally and returning to or visiting the affected communities.<sup>9</sup>
  - Robust responses in New York city and New York state leveraged multiple partners for their vaccination efforts, including administration of approximately 60,000 MMR vaccine doses in the affected communities; locally tailored communication campaigns; partnerships with religious leaders, local physicians, health centers, and advocacy groups; and use of local public health statutory authorities.
  - These combined efforts ended transmission before the 12-month elimination deadline.

#### **Solution – Trust**

- Getting trust and safety issues wrong with a COVID-19 vaccine could both jeopardize containment of COVID-19 and set the United States back for years or even decades when it comes to public acceptance of vaccines.
- To ensure the public adopts evidence-based prevention steps and to increase vaccine uptake, we must avoid the use of predictions in our messaging.
- Lessons learned from H1N1 and Measles reinforce that we need to under promise and over deliver and ensure we meet complex demands with rapidly evolving, fact-based messaging.
- Embrace clear, consistent, and fact-based messaging
- We also need to make sure we include appropriately targeted messaging to reach diverse populations, such as those disproportionately affected.

<sup>8</sup> Schnirring, L. H1N1 Lessons Learned: Vaccination campaign weathered rough road, paid dividends. CIDRAP; 2010. <https://www.cidrap.umn.edu/news-perspective/2010/04/h1n1-lessons-learned-vaccination-campaign-weathered-rough-road-paid>

<sup>9</sup> Patel, M., Lee, A. D., Clemmons, N. S., Redd, S. B., Poser, S., Blog, D., Zucker, J. R., Leung, J., Link-Gelles, R., Pham, H., Arciuolo, R. J., Rausch-Phung, E., Bankamp, B., Rota, P. A., Weinbaum, C. M., & Gastañaduy, P. A. (2019). National Update on Measles Cases and Outbreaks - United States, January 1-October 1, 2019. *MMWR. Morbidity and mortality weekly report*, 68(40), 893–896. <https://doi.org/10.15585/mmwr.mm6840e2>

**Solution – Efficient and Equitable Vaccine Distribution**

- We cannot wait 3 months for distribution to pharmacies after the first orders like we did with the H1N1 vaccine.
- Couple free vaccine with reimbursed costs of administration.
- And since 660 million doses will not be immediately available, we must follow the National Academy of Medicine’s four-phased approach<sup>10</sup> guided by evidence and criteria for equitable distribution.

**Solution – Unified Planning and Priorities**

- Drive informed and evidence-based development and execution of vaccine distribution plans.
- Planning efforts cannot be undertaken by a single individual, healthcare system, city, or state.
- We are currently seeing the siloed development of plans for hospitals, corporations, cities, and states all with different priorities and rationales, some of them in contradiction of the other, which will impact the success of our response.
- Instead, development of a locally tailored plan needs to include collaboration, expertise, and input from many partners within the community to be effective to include well documented priority groups and phases.

**Solution – Data for Action**

- We will need to scale up, test, assess upgrades, and ensure data linkages for:
  - HHS’s Vaccine Tracking System (VTrckS)
  - Vaccine Administration Management System (VAMS)
  - Vaccine Adverse Event Reporting System
  - State Immunization Registries
- Supplement surveillance and administrative data with survey data

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<sup>10</sup> Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine. NAP; 2020. <https://www.nap.edu/read/25914/chapter/4#56>

**Conclusion**

- Lives—and a normal way of life—are at stake.
- Right now, while we wait for the vaccine, we have the ability to implement an evidence-based playbook that will reduce the number of cases and deaths. This will require unified local, state, and federal leadership that is evidence based and uses metrics to:
  - Create a comprehensive testing, solitary isolation, and contact tracing program
  - Reinforce community engagement prevention practices like wearing a mask, handwashing, physical distancing, and avoiding crowds, and
  - Continue our exemplary efforts in reducing deaths of those who do get infected.
- Clear, Consistent, and Fact-Based Messaging can start today in conjunction with equitable vaccine distribution planning to ensure trust in an eventual safe and effective vaccine(s).
- With unified leadership at the federal level, the implementation of evidence-based practices, and funding, the federal government can heed the lessons from previous pandemics and other nations to conquer this pandemic and set the stage for a healthier future.

Thank you, Rep. DeGette and members. I will try to answer any questions you might have.

Ms. DEGETTE. We will do that, and thank you very much.  
Dr. Offit, you're now recognized for 5 minutes.

**STATEMENT OF PAUL A. OFFIT, M.D.**

Dr. OFFIT. I too would like to thank the Energy and Commerce Committee for allowing me to be part of this hearing. My name is Paul Offit. I am an attending physician in the Division of Infectious Diseases At the Children's Hospital of Philadelphia, and a professor of pediatrics at the Perelman School of Medicine at the University of Pennsylvania. I'm also the co-inventor of the rotavirus vaccine, RotaTeq, which was recommended by the CDC for use in all infants in the United States in 2006 and by the World Health Organization for all infants in the world in 2013.

I've been a member of the Advisory Committee on Immunization Practices at the CDC, and am currently a member of the FDA's vaccine advisory committee, VRBPAC, as well as the NIH's ACTIV group, assembled by Dr. Francis Collins, to facilitate the development of COVID-19 vaccines.

The American public is skittish about the speed with which vaccines to prevent COVID-19 are being developed, and it's understandable. The language surrounding this effort is a little frightening. Phrases like warp speed, the race for a vaccine, and vaccine finalists, have caused some to wonder whether critical phases of vaccine development are being skipped, or worse, that safety guidelines are being ignored.

Further, the administration's politicization of science in areas like mask hygiene and social distancing, as well as the push to approve drugs such as hydroxychloroquine or biologicals such as convalescent plasma through an EUA without clear evidence of safety or efficacy, have caused some to wonder whether the same low standards will be applied to COVID-19 vaccines. Indeed, recent polls have shown that more than half of all Americans would choose not to receive a COVID-19 vaccine if offered, which would make it difficult to achieve herd immunity by vaccination and eventually gain control of this pandemic. Despite these understandable concerns, I'm optimistic that what happened with hydroxychloroquine and convalescent plasma will not be repeated for vaccines for several reasons.

First, the Data Safety Monitoring Boards that are supervising COVID-19 vaccines have been charged by the NIH ACTIV group with holding them to the same standards of safety and efficacy that would be found for any vaccine, which makes sense, given that most of those who will initially receive these vaccines will be healthy young people unlikely to die from this infection.

Second, FDA Commissioner Hahn stated in a recent op-ed in the Journal of the American Medical Association, that he would, quote, rely on transparent discussions by the FDA's VRBPAC committee prior to vaccine authorization or licensure, end quote. This committee is composed of academicians and researchers who are not associated with either industry or government and can be counted on to give an unvarnished appraisal of COVID-19 vaccines prior to approval.

Third, while the development of COVID-19 vaccines has been faster than any vaccine ever produced, one aspect of that develop-

ment process is identical to the way vaccines have been developed for the past 70 years, specifically, the Phase 3 trials.

Phase 3 trials for COVID-19 vaccines are large, prospective, placebo-controlled trials of about 30,000 people. The size of these trials is typical. For example, the human papilloma virus vaccine Phase 3 trial included about 30,000 participants, and the conjugate pneumococcal vaccines, about 35,000. As long as these Phase 3 trials are allowed to proceed until there is clear, statistically robust evidence that the vaccines work and are safe in the groups who will soon receive them, then they will have been held to the same standards as previous vaccines.

Finally, during my service on FDA's vaccine advisory committee, I've come to know the people at the FDA who are involved in vaccine licensure. These people are exactly who you would want them to be, dedicated to protecting the public from products that are unsafe or ineffective. If COVID-19 vaccines are released before they're ready to be released, you will hear from these people. And you will also hear from people like Drs. Francis Collins and Tony Fauci, both of whom are trusted by the American public, as well as many other academicians and researchers who wouldn't stand for this.

The public is already nervous about these vaccines. If trusted health officials stand up and decry a premature release, the celebration by the administration will be short-lived.

In summary, while people are understandably nervous about soon-to-be-released COVID-19 vaccines, I think they can take comfort in the fact that many people in supervisory positions, as well as a cadre of independent academic scientists standing behind them, are monitoring this process and looking out for the public's best interest.

Thank you.

[The prepared statement of Dr. Offit follows:]

**Testimony of Paul A. Offit, MD**

**The Children's Hospital of Philadelphia before the:**

**Energy and Commerce Committee**

**Investigations Subcommittee**

**September 30, 2020**

My name is Paul Offit. I am an attending physician in the division of Infectious Diseases at the Children's Hospital of Philadelphia and a Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. I am also the co-inventor of the rotavirus vaccine, RotaTeq, which was recommended by the CDC for use in all infants in the United States in 2006 and by the World Health Organization for all infants in the world in 2013. I have been a member of the Advisory Committee on Immunization Practices at the CDC and am currently a member of the FDA's Vaccine Advisory Committee, VRBPAC, as well as the NIH's ACTIV group, assembled by Dr. Francis Collins to facilitate the development of COVID-19 vaccines.

The American public is skittish about the speed with which vaccines to prevent COVID-19 are being developed. And it's understandable. The language surrounding this effort is a little frightening. Phrases like "Warp Speed," "the race for a vaccine," and "vaccine finalists," have caused some to wonder whether critical phases of vaccine development are being skipped or, worse, that safety guidelines are being ignored. Further, the administration's politicization of science in areas like mask hygiene and social distancing, as well as the push to approve drugs such as hydroxychloroquine or biologicals such as convalescent plasma through an EUA without clear evidence of safety or efficacy, have caused some to wonder whether the same low

standards will be applied to COVID-19 vaccines. Indeed, recent polls have shown that more than half of all Americans would choose not to receive a COVID-19 vaccine if offered, which would make it difficult to achieve herd immunity by vaccination and eventually gain control of this pandemic.

Despite these understandable concerns, I am optimistic that what happened with hydroxychloroquine and convalescent plasma will not be repeated for vaccines, for several reasons:

First, the Data Safety Monitoring Boards that are supervising COVID-19 vaccines have been charged with holding them to the same standards of safety and efficacy that they would for any vaccine, which makes sense given that most of those who will initially receive these vaccines will be healthy, young people, unlikely to die from this infection.

Second, FDA Commissioner Hahn stated in a recent op-ed in the *Journal of the American Medical Association* that he would “rely on transparent discussions by the FDA’s VRBPAC Committee prior to vaccine authorization or licensure.” This committee is composed of academicians and researchers who are not associated with either industry or government and can be counted on to give an unvarnished appraisal of COVID-19 vaccines prior to approval.

Third, while the development of COVID-19 vaccines has been faster than any vaccine ever produced, one aspect of the development process is identical to the way vaccines have been developed for the past 70 years; specifically, the phase 3 trials. Phase 3 trials for COVID-19 vaccines are large, prospective, placebo-controlled trials of about 30,000 people. The size of these trials is typical. For example, the Human Papillomavirus Virus (HPV) vaccine phase 3 trial included about 30,000 participants and the conjugate pneumococcal vaccine trials about

35,000. As long as these phase 3 trials are allowed to proceed until there is clear, statistically robust evidence that the vaccines work and are safe in the groups that will soon receive them, then they will have been held to the same standards as previous vaccines.

Finally, during my service on the FDA's Vaccine Advisory Committee, I have come to know people at the FDA who are involved in vaccine licensure. They are exactly who you would want them to be—dedicated to protecting the public from products that are unsafe or ineffective. If COVID-19 vaccines are released before they are ready to be released, you will hear from these people. And you will also hear from people like Drs. Francis Collins and Tony Fauci, both of whom are trusted by the American public, as well as the many other academicians and researchers who wouldn't stand for this. The public is already nervous about these vaccines; if trusted health officials stand up and decry a premature release, the celebration by the administration will be short lived.

In summary, while people are understandably nervous about soon-to-be-released COVID-19 vaccines, I think they can take comfort in the fact that many people in supervisory positions, as well as a cadre of independent, academic scientists standing behind them, are monitoring this process and looking out for the public's best interests.

Ms. DEGETTE. Thank you, Doctor.

The Chair is now pleased to recognize Dr. Gayle for a 5-minute opening statement.

**STATEMENT OF HELENE GAYLE, M.D.,**

Dr. GAYLE. Thank you very much, and good morning to chairs, the ranking members, and the members of the subcommittee. Thank you very much for having this and then for inviting me and my other panelists. My name is Helene Gayle, and I am testifying today in my capacity as the co-chair of the National Academies' Committee on Equitable Allocation of the Vaccine for the Novel Coronavirus, having spent 30 years in public health, including 20 years with the Centers for Disease Control.

In July, the NIH and the CDC asked the National Academies to develop an overarching framework for COVID-19 vaccine allocation to assist policymakers and inform the work of national health authorities and other advisory bodies in the development of national and local guidelines.

On September 1st, our committee released a discussion draft of that framework to be able to get input from the public. The discussion draft presented lessons learned from other allocation efforts, our draft allocation framework, and how this framework might be applied in various scenarios. Our final report will be released to the public this Friday, so today I will be talking only about that discussion draft.

Now, as mentioned previously, this is not the first time the Nation has faced allocating scarce resources during a public health emergency. So in developing a draft framework for the equitable vaccine allocation, our committee was informed by lessons from previous allocation efforts for vaccines, as well as strategies set forth in other allocation frameworks that were being developed in the United States and around the world.

Our committee proposed six foundational principles that informed our deliberations about allocation criteria. First, we focused on the principle of maximization of benefits, and that led us to adapt an overarching framework—or overarching goal of maximizing societal benefit through the reduction of morbidity and mortality caused by the transmission of the novel coronavirus.

Second, the higher rates of COVID-19 infections, serious disease, and death among people of color, linked to the longstanding impact of systemic racism and inequity led us to a principle of mitigation of health inequities.

Our third principle of equal regard directs attention to the equal worth and value of every person.

The fourth principle of fairness highlighted the importance of impartiality.

Our fifth principle of transparency emphasized the importance of open disclosure of the principles, criteria, and priority groups that determined our allocation framework and who would get the vaccine sooner than others.

And the final principle is that all decisions must be evidence-based.

To determine the population groups that comprised each allocation phase, our committee used four risk-based criteria to charac-

terize population groups by the risk faced by their typical members in each of these groups. The risk category include the risk of acquiring or transmitting the infection, the risk of severe morbidity and mortality, and the risk of negative societal impact.

Our committee proposed a four-phased approach to COVID vaccine allocation. Within the population groups included in each of these four phases, our committee also recommended that vaccine access should be prioritized by geographic areas identified as vulnerable through CDC's Social Vulnerability Index.

We had four phases, the first included a jumpstart phase, and that included frontline health workers, not defined by professional titles but by their actual risk of exposure, and it also included first responders.

The jumpstart phase is followed by a phase 1b, which includes older adults living in congregate settings, individuals with select high-risk underlying conditions that were—were also included in this phase.

The second phase, with an expansion of vaccine supply, would allow for immunization of additional individuals with underlying conditions that put them at an increased risk, all older adults not identified in the first phase, and then also teachers and school staff, people who are incarcerated or detained or living in group homes, or homeless shelters or other congregate settings. And, additionally, the first group of critical workers who are in industries essential to the functioning of society and at high risk of exposure. All of those were included in the second phase.

The third phase, when vaccine supply would become more widely available, allowed for broader immunization of workers who were important to restoring the full economic activity and broad immunization of children and young adults.

And, finally, once vaccine supply became more broadly available in phase 4, vaccines would become available to any of those who were not part of the first three phases.

While uncertainty about the COVID vaccine existed, our committee approached our draft framework with the best available evidence today, understanding that this would continue to evolve.

So with that, I just want to thank you for the opportunity to testify. This is only a brief summary of our discussion draft. The complete and final report will be released this Friday, October 10th, and that report will, in addition to having our final allocation framework, will also discuss topics related to implementation, risk communication, community engagement, vaccine acceptance, and global consideration.

Thank you, and I am happy to answer questions.

[The prepared statement of Dr. Gayle follows:]

Good morning, Chair DeGette, Ranking Member Guthrie and members of the subcommittee. Thank you for the opportunity to testify today. My name is Helene Gayle, and I am president and CEO of The Chicago Community Trust. I am speaking to you today in my capacity as co-chair of the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus of the National Academies of Sciences, Engineering, and Medicine.

The National Academy of Sciences was chartered by Congress in 1863 to serve as an independent, authoritative body outside the government that could advise the nation on matters pertaining to science and technology and later expanded to include the National Academies of Engineering and Medicine. The National Academies do not advocate for specific policy positions. Rather, they enlist the best available expertise across disciplines to examine the evidence, reach consensus, and identify a path forward. National Academies reports, proceedings and other publications are available via the web in PDF form without charge.

In July, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) asked the National Academies to convene an ad hoc committee to develop an overarching framework for COVID-19 vaccine allocation in order to assist policymakers and inform the work of national health authorities and additional advisory bodies, including CDC's Advisory Committee on Immunization Practices (ACIP), during the development of national and local guidelines.

On September 1, our committee made available a discussion draft of its framework, *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*, to obtain input from members of the public and to inform our final report. The discussion draft presented lessons learned from other allocation efforts, our draft allocation framework, and how this framework might be applied in various scenarios. I have been asked to summarize this

discussion draft today. Our final report will be released to the public this Friday, October 2. Therefore, it is important to keep in mind that the information I present here today reflects our discussion draft, which is subject to change in response to public comment and peer review. Furthermore, the final report will address topics related to implementation, risk communication, community engagement, vaccine hesitancy, and global considerations. I will not be speaking on these issues today.

This is not the first time the nation has been faced with the issue of allocating scarce resources in the midst of a public health emergency. In developing our draft framework for equitable COVID-19 vaccine allocation, our deliberations were informed by practical lessons from previous efforts to allocate vaccines for the 2009 H1N1 influenza pandemic and for Ebola virus disease, as well as by the goals, ethical principles, and prioritization strategies set forth in other allocation frameworks—including several that have recently been developed to distribute scarce inpatient medications for COVID-19. Guiding principles from these allocation frameworks for scarce inpatient medications for COVID-19 include:

- Ensure that allocation maximizes benefit to patients, mitigates inequities and disparities, and adheres to ethical principles.
- Promote the common good through fairness, transparency, accountability, and trustworthiness.
- Save the greatest number of lives possible—while respecting rights and fairness—to maximize benefit to the community as a whole.
- Use the best available evidence to assess benefit to communities and address uncertainty.
- Allocate scarce resources responsibly to reduce risk while providing benefit.

- Provide clear and transparent criteria for prioritization strategies.
- Ensure that allocation policies are flexible, responsive to the concerns of the affected population, and proportionate to the epidemiological situation and the vaccine supply relative to need.

Drawing on prior work, our committee proposed six foundational principles (consisting of ethical and other principles) which informed our deliberations about allocation criteria. Our committee immediately invoked a principle of *maximization of benefits* that sets a **primary goal of maximizing societal benefit through the reduction of morbidity and mortality caused by the transmission of the novel coronavirus**. While spread throughout the society, the pandemic's damage has more significantly harmed some populations more than others, particularly causing higher rates of infection, serious illness, hospitalization, and death among people of color due to the longstanding impact of systemic racism and inequity. This reality led us to formulate a principle of *mitigation of health inequities* to address the higher risks faced by such persons in work environments and living arrangements that correspond to higher risk of transmitting and acquiring infection and with having a higher prevalence of certain health problems that make it more likely that they will suffer severe outcomes and even die from COVID-19. In difficult choices about vaccine allocation, the principle of *equal regard* directs attention to the equal worth and value of every person, protecting each one from discrimination, while the principle of *fairness* requires impartiality and the engagement and participation of affected populations in setting allocation criteria and determining priority groups. Furthermore, the principle of *transparency* ensures the disclosure of the principles, criteria, and priority groups that will determine people's chances of getting a vaccine sooner rather than later. Finally, none

of these principles can accomplish its goals without the principle that all decisions must be *evidence-based*.

The ethical principle of transparency, as well as the practical requirement of efficient, consistent administration of the framework led us to develop and propose four risk-based criteria for operationalizing the foundational principles to achieve its primary goal.

- **Risk of acquiring infection:** Individuals have higher priority to the extent that they have a greater probability of being in settings where COVID-19 is circulating and exposure to a sufficient dose of the virus.
- **Risk of severe morbidity and mortality:** Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- **Risk of negative societal impact:** Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.
- **Risk of transmitting disease to others:** Individuals have higher priority to the extent that there is a higher probability of their transmitting the disease to others.

To determine the population groups that comprise each allocation phase, our committee operationalized the above criteria by characterizing certain population groups in terms of the risks faced by their typical members and the ability of a vaccine to reduce those risks.

Our committee proposes a four-phased approach to COVID-19 vaccine allocation.

**Within the population groups included in each of these four phases, our committee recommends that vaccine access should be prioritized for geographic areas identified as**

**vulnerable through CDC’s Social Vulnerability Index.** It is also important to note that within each phase, all groups have equal priority.

The first phase includes a “jumpstart” phase, Phase 1a. Included in Phase 1a would be “frontline” health workers—health professionals who are involved in direct patient care, as well as those in transport, environmental services staff, or other health care facility services, who risk exposure to bodily fluids or aerosols. Under conditions of such scarcity, access should not be defined by professional title, but rather by the individual’s actual risk of exposure to COVID-19. The rationale for including “frontline” health workers in the first phase is manifold: their contact with patients with SARS CoV-2 (despite the use of PPE, which can be limited in some settings); the fact that they work in an essential industry, but may be precluded from performing their professional duties if not adequately protected; and the reality that many who are in low wage jobs may also contribute to further transmission due to living in crowded, often multi-generational living situations where social distancing is unrealistic. The latter is especially true for many of those who work in nursing homes and as home health aides. In addition to frontline health workers, first responders are included as well. The “jumpstart” phase is followed by Phase 1b—which includes those older adults living in congregate settings, such as nursing homes, skilled nursing facilities, and other similar settings. Last, individuals with select high-risk comorbid and underlying conditions are included in Phase 1b.

In Phase 2, expansion of vaccine supply would allow for the immunization of another cohort of individuals with comorbid and underlying conditions that put them at increased risk, as well as all older adults not already included in Phase 1. Current knowledge of the relative risks stemming from specific underlying risk factors is evolving quickly and will be better known by the time vaccines actually become available. This may allow decision makers to target those at

greatest risk of serious morbidity and mortality more effectively than is possible today. This could also allow the identification of younger people who are at high risk of infection or serious morbidity/mortality so that they can also be prioritized.

Recognizing the importance of education and child development, teachers and school staff are included in Phase 2. It is important to include this group relatively early to facilitate the reopening of schools, and to protect the most high-risk adults present when this occurs given current knowledge about morbidity and mortality due to COVID-19.

People who are incarcerated or detained and people who live in group homes and homeless shelters are also included in Phase 2 along with the staff who work in such settings. With respect to these groups, our committee stressed the importance of recognizing their reduced autonomy and the recognized difficulty of preventing spread in such settings should COVID-19 be introduced. Last, the first cohort of critical workers who are both in industries essential to the functioning of society and at high risk of exposure are included in Phase 2.

In Phase 3, vaccine supply will become more widely available and allow the broader immunization of workers essential to restoring full economic activity. In this phase, the broad immunization of children and young adults is included. An important caveat here is that broad immunization of children will depend on whether new COVID-19 vaccines have been adequately tested for safety and efficacy in childhood age groups.

Finally, once vaccine supply becomes more broadly available (Phase 4), vaccines would be made available to healthy adult individuals who would be interested in receiving the vaccine for personal protection.

It is important to acknowledge that uncertainties about the COVID-19 vaccine and the nature of the pandemic itself persist, but our committee approached its draft framework under the best available evidence today.

There are many uncertainties regarding if and when vaccines against COVID-19 will become available, under what regulatory framework they will be approved for first use, what their ultimate product profiles will be (e.g., in terms of efficacy among different age groups, dosage schedule(s), and safety/adverse reactions), as well as the schedule and timelines for expanding vaccine supply availability (e.g., when doses will become available and how quickly supply will expand). Our committee's discussion draft also discusses how the framework will adapt in the face of these uncertainties.

This is only a brief summary of the our committee's discussion draft work—the complete and final report will be available for free download in PDF format from the National Academies Press website on Friday, October 2. The discussion draft is available at <https://www.nap.edu/catalog/25914/discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine>.

Thank you for the opportunity to testify. I would be happy to address any questions that you might have.

Ms. DEGETTE. Thank you, Dr. Gayle. We'll look forward to seeing your report on Friday.

Dr. Jha, now pleased to recognize you for 5 minutes for an opening statement.

**STATEMENT OF ASHISH K. JHA, M.D.**

Dr. JHA. Great. Thank you, Chairwoman DeGette, Ranking Member Guthrie, members of the committee. It is my honor to be with you here today.

We are nine months into the worst pandemic in a century. More than a million people around the world and more than 200,000 Americans have succumbed to this disease. While we have identified a series of public health measures and therapies that, if used effectively, can keep the disease at bay, in order to bring the pandemic under control, we will need safe and effective vaccines.

Now, while it usually takes years, often decades, to build a vaccine, unprecedented collaboration among the global scientific community means we have multiple candidates in Phase 3 trials just nine months after we identified the virus. This is incredible progress.

But here's the problem. While the process so far has been carried out with great scientific integrity, as we near the end zone, we need to ensure we don't fumble the ball. We have seen large declines in Americans' willingness to get a vaccine. And if we fumble the ball, the cost to our lives and to our treasures will be enormous.

And so as has been already stated, here is the key point. We need to ensure that we have vaccines that are safe and effective and perceived to be so by the American people.

So why are Americans worried? They're worried because of the politicization of the scientific Federal agencies like the FDA. Whether it was the emergency use authorization of hydroxychloroquine or the unfortunate hyping of convalescent plasma, physicians and nurses and the American people increasingly worry about the integrity of the FDA decisionmaking process.

The decision to issue an EUA for a vaccine must be based on scientific timetable, not on a political one. And the unease has grown recently as the Pfizer CEO has repeatedly suggested that he is moving to get their vaccine out before the election.

This, on top of the landscape of vocal, science-denying anti-vaxxers, has created a dangerous situation that, if allowed to fester, could cause loss of faith in vaccines for years. We must not let this happen.

I believe there are three things we must do. First, we must let prespecified, scientific standards drive whether a vaccine receives an EUA or not. Last week, FDA scientists put out guidance about the requisite followup time period and the impact of any vaccine on disease severity. These are right, and they are a minimum, and we must ensure that we let the FDA use their standards for an EUA approval.

Second, we need a lot more transparency in the process. While I was heartened to see vaccine companies make their protocols public, we need more transparency about safety signals in their trials

and how they're addressing them. Unprecedented times like these call for unprecedented transparency.

And, finally, it is critical that when an EUA is issued by the FDA, we hear directly from the great career scientists at the agency. This will ensure—or this will assure the American people that science is driving this process, not politics.

These are critical steps, but they alone will not be enough. We need a strong communication plan that engages with clinical and public health leaders, religious leaders, and others about the process. Americans will turn to these individuals to get advice.

Next, we need a plan for a fair distribution. This is a source of immense concern for many Americans. We cannot repeat the mistakes we are making with testing where the well-connected are able to get tested on a regular basis but regular testing is not available for schoolteachers and nurses and first responders. We need to ensure that vaccines are available for all of us, not just those who are well connected.

And, finally, we need to eliminate all financial barriers to getting vaccinated. One in three Americans report that they will skip the vaccine because of financial concerns. We can't possibly let this be the case.

2020 has been a very hard year for all of us. 2021 can be better. In order to get some semblance of a new normal, we need a vast majority of Americans to get vaccinated with a safe and effective vaccine. The vaccine development process so far has been done with great scientific credibility. It's now time to let science finish the job, and let's use good science communication to help people understand the integrity of the scientific process, and let's eliminate financial barriers and implement smart distribution plans to ensure that we can turn vaccines into vaccinations. If we do all of that, we can finally bring the pandemic under control, heal our economy, and let Americans get back to their lives.

Thank you.

[The prepared statement of Dr. Jha follows:]

Written Testimony of Ashish K. Jha  
Dean, Brown University School of Public Health

Testimony to the Subcommittee on Oversight and Investigations of the Committee on Energy  
and Commerce

September 30, 2020

**Introduction**

As we enter the fall of 2020, the number of cases of COVID-19 across our nation is starting to grow, a certain degree of fatigue is setting in, and we could be heading into a difficult fall and winter. Unfortunately, more than 200,000 Americans have already died of this disease and many more could die if we are not careful in managing the outbreak. We have to continue to focus our efforts on key public health measures, such as avoiding indoor gatherings, wearing masks, and building up testing and tracing. And we have to focus our attention on protecting lives and livelihoods until a safe and effective vaccine is widely available.

While we all acknowledge that our nation's public health response to COVID-19 has fallen far short of expectations, there is one area where our efforts have been superb. And that is in the effort to identify, test, and scale-up a vaccine for COVID-19. While that effort is hardly finished, we have much to be proud of. But there are very serious challenges ahead in ensuring that these remarkable efforts are not undermined and, ultimately, made less effective. There are three areas that we must focus on to ensure that we turn vaccines into vaccinations – and that we are able to save lives and bring the pandemic under control.

**Current Status:**

The Administration's COVID-19 vaccine program, known as Operation Warp Speed, is committed to scaling up the production and distribution of a set of vaccines if they receive approval from the Food and Drug Administration. The scientific progress behind the development of the vaccine has been unprecedented. While it generally can take decades (and even in the best of circumstances, years) to build a vaccine, the scientific community has worked effectively and collaboratively

across the globe to launch a series of products into clinical trials. As of September 28, at least 11 vaccine candidates are in Phase III clinical trials, several of which are the candidates identified by OWS. Critically, this initiative has not only invested substantially in the development of vaccine candidates but has directed investments toward manufacturing and distribution. While the approval of a COVID-19 vaccine will certainly mark a turning point in our battle against this virus, it is unlikely to be a silver bullet in ending the pandemic. Should a safe and effective vaccine be approved in the coming months, its success will hinge upon our collective ability to promote its widespread distribution and adoption, turning vaccines into vaccinations. This will undoubtedly be a massive undertaking, and it will require transparent and accessible communication to address vaccine hesitancy, an economic strategy that reduces financial barriers to vaccination, and a comprehensive distribution plan that prioritizes high-risk populations.

#### **Hesitancy and the Need for a Clear Communication Strategy**

Many Americans are hesitant about receiving a COVID-19 vaccine and unsure if it will be safe. This concern goes well beyond the baseline vaccine hesitancy present before the pandemic. As the key agency running the evaluation process for vaccine candidates, the Food and Drug Administration is the institution Americans need to be able to trust the most when it comes to assessing if a vaccine is safe. Yet the FDA has made several critical mistakes in this pandemic that have been extremely costly to its credibility and trust with the American people. A fundamental part of reducing vaccine hesitancy will be ensuring that the American people can trust the FDA's decision making.

While several mistakes by the FDA have eroded its credibility with the public, none is worse than the handling of convalescent plasma, which was approved through an Emergency Use Authorization on August 23, 2020, in a highly advertised and widely televised announcement including the president. Some in the scientific community were wary of this approval because there was no randomized-controlled trial, typically the gold standard needed to demonstrate the efficacy of a treatment. A more nuanced view allows us to appreciate the trade-offs: Given the extraordinary circumstances in this pandemic, trying out a new treatment based on preliminary research showing some potential is a reasonable step, as long as there are oversight and follow-up. What made the convalescent plasma EUA so detrimental to our vaccine efforts was the way in which it was announced, and the discredit it brought to the chief of the FDA, Dr. Stephen Hahn. Holding a press conference in which the president announced a miracle treatment (which convalescent plasma is not) and Dr. Hahn backed him up by exaggerating the evidence of its benefits, downplaying the data that failed to show benefit, and dramatically overstating the size of the benefit (in a way that would suggest that either the FDA doesn't understand basic epidemiology or was choosing to mislead the American people) all contributed to most physicians and many Americans assuming that the FDA and its leader were not being straightforward with the American people. That Dr. Hahn then followed up with interviews and tweets suggesting that he did not need to follow the advice of the FDA's scientific advisors and that he was looking to approve the vaccine before the election further eroded his credibility.

The announcement solidified in the public conversation the impression that, increasingly with this administration, politics are taking over trusted, non-partisan scientific institutions – those

institutions that we desperately need to stay free of politics so people can trust that an approved vaccine is becoming available for only one reason: it is scientifically proven to be ready and safe.

At this point in the pandemic, there is a pattern to these announcements. Months ago, we saw the same forces at work when the FDA approved another experimental COVID-19 treatment, hydroxychloroquine, which showed an even worse scientific promise than convalescent plasma but was a favorite of the president. It was approved through an EUA on March 28, 2020, only to be revoked by mid-June.<sup>5</sup> What happened between March and June is well-known: Hydroxychloroquine was found to be more harmful than helpful, and the president's continued support of the treatment further divided the nation instead of building trust among all Americans. Instead of praising an unproven treatment, the FDA could have used this moment to build a common understanding of how we best use limited evidence in a pandemic and how to weigh the risk of death or prolonged suffering from the virus against the risk of death or prolonged suffering from treatments.

These failures and mishaps surrounding EUAs for treatments are concerning, given that an EUA for a vaccine presents even higher stakes. While we sometimes accept a certain level of potential harm in experimental treatments for those who are severely ill, vaccines are given to *healthy people* and therefore need to have a substantially higher measure of safety and effectiveness. When it comes to intervening with vaccines for the healthy, even a mild risk of harm needs to be weighed carefully.<sup>6</sup> Let's remember that an EUA for a COVID-19 vaccine would be unprecedented. The FDA has only once before used this process, approving a vaccine for inhaled anthrax that was mostly distributed only to high-risk soldiers and civilians in war zones.<sup>7</sup>

The fact that an EUA has never before been issued for a vaccine intended for broad distribution to the American public is one more reason our approval process must remain anchored in rigorous analysis to validate safety and efficacy – and our leaders must present decisions and steps along the way with scientific accuracy and utmost clarity. There is no room for ambiguity in an agency leader’s commitment to evidence or to admitting what we know and do not know at any point in time. In this pandemic, we cannot afford our scientific institutions to communicate misinformation and publish confusing or misleading guidance due to political pressure (as we have also seen from the CDC and HHS), only to later apologize and try to correct the record. Research on misinformation repeatedly shows that once the seeds of doubt are sown, the damage is done. A confused public is a public feeling out of control, out of trust, and out of tools to assess evidence. It is a public that is open to polarization and that is increasingly unreachable for those who hope to share the latest science and evidence on a pathway to vaccine acceptance.

As a nation today, this is the struggle we will face once we try to turn approved COVID-19 vaccines into vaccinations: A distrusting public wary of anything and everything coming from the government, regardless of political affiliation. While vaccine hesitancy itself has been growing in recent years – as highlighted by the 2019 measles outbreak in New York City and other metropolitan areas<sup>9</sup> – the problem has taken on new and unseen proportions in recent months. While in May, 72% of American adults indicated that they would be willing to receive a COVID-19 vaccine, that number has dropped substantially to only 51% indicating their willingness in September (polls by Pew Research Center).<sup>10</sup>

Recent polls confirm why this is happening: 77% of Americans worry that the vaccine development process is moving too quickly to identify all of the risks of a new vaccine.<sup>10</sup> A STAT poll further reveals the belief that the approval process has been co-opted and is being driven by politics more than science.<sup>11</sup> This belief spanned party lines, with 72% of Republicans and 82% of Democrats expressing worries that politics will influence decisions about the approval of a vaccine.

Patterns of increasing hesitancy regarding a COVID-29 vaccine have also persisted across gender, racial and ethnic groups, and levels of education. In September, only 32% of Black Americans indicated in the Pew poll that they would get a COVID-19 vaccine if one were available today, compared with 52% of White Americans.<sup>10</sup> This level of mistrust amongst people of color is unsurprising, considering the long history of structural racism and unethical medical experimentation on this population. Even over the past few months, efforts by the Trump administration to expand testing in retail locations have largely ignored Black neighborhoods.<sup>12</sup> Given the disproportionate impact that COVID-19 has had on Black, Latino, and Indigenous communities, however, it is especially critical that we work to cultivate confidence within these communities.

To address these significant challenges and work towards broad acceptance of a vaccine, we must start today with rebuilding trust within all segments of the American population. A few key steps that can get us there are:

**1) Transparency.**

People have to trust that the vaccine is developed without cutting corners for political gain.

Ensuring this trust requires an unprecedented level of transparency. While some trial

materials have been made available by companies in recent weeks, there remains a lack of candor on some essential vaccine safety topics. For example, the Astra-Zeneca Phase III trial was recently paused following an unexpected safety event, a normal procedure in clinical trials. Through a transparent explanation of what had occurred and what their investigation had found, Astra-Zeneca and agencies including the FDA could have reassured the public and strengthened confidence by demonstrating that their protocols to evaluate safety were working. Instead, Astra-Zeneca released a brief and veiled statement that acknowledged the pause without providing any information on what had occurred or why.<sup>13</sup> Though at first, it appeared this was simply an example of waiting to gather complete information before making it public, Astra-Zeneca soon provided more information on the pause to investors on a private call while continuing to withhold this information from the public. Such behavior reinforces concerns that companies and government organizations are hiding safety risks in the interest of profit or political gain.<sup>14</sup> Though Astra-Zeneca is a private company, it has received a large amount of support from the U.S. government and is dependent on the FDA for permission to market and distribute its vaccine. Astra-Zeneca should be far more transparent about these pauses and issues at hand – and the FDA should signal to Astra-Zeneca and all manufacturers that they need to be more forthcoming with side-effects and other concerns that might arise during the trials. This new level of transparency is a critical step we can take today to combat vaccine hesitancy.

**2) Value independent experts and allow for a robust scientific debate.**

Most members of the public will not be concerned with details such as the intricacies of trial designs and outcomes, but they have come to trust independent scientific experts.

Throughout this pandemic, public health experts and independent scientists have fact-checked research, framed FDA, HHS, and CDC decisions for diverse audiences, and served as trusted voices in the midst of a chaotic response to the pandemic. These experts are key to regaining the public's confidence that the process has not been corrupted. Several pharmaceutical companies recently took positive steps by releasing their designs of the Phase III clinical trials currently underway. Trial design is critical to defining what goals we are aiming for and ensuring that any effect seen in the resulting data is legitimate. Able to review these trial designs, many in the public health community have expressed concern regarding the differences in endpoints between these trials, noting that in some cases they are focused more on whether the vaccines can prevent mild cases of COVID-19 than whether they can prevent the severe and sometimes fatal cases that are of most concern. Drs. Topol and Doshi outlined this problem in a recent New York Times Op-ed, for example, and many others have commented on social media platforms.<sup>15</sup> Physicians from Brigham and Women's Hospital have similarly questioned the criteria the FDA has established for reviewing the trial data.<sup>16</sup> This is a healthy process that does not undermine but rather builds trust: By allowing transparency and outside feedback, the FDA can improve its process and gain trust at the same time. It is crucial now that the FDA engages with this feedback and works to improve the trial designs. Ignoring these experts would further deteriorate trust in the agency.

**3) Engage with local community leaders and identify trusted messengers now.**

With trust in government voices at a historic low, identifying and engaging community leaders, religious and civil society leaders, and other trusted messengers is essential to combating vaccine hesitancy. To succeed with broad public acceptance of a COVID-19

vaccine, we must not just rebuild trust in the process of vaccine development but also rebuild the strained relationship between governments and the people they serve. We can do so by engaging with community leaders in hearing their concerns, and in offering vaccines as a way to keep their communities safe. This is especially true for communities of color, as fewer than 1 in 5 Black Americans trust the federal government, and the numbers look similar for Latinx and immigrant communities. Lifting up and empowering local voices is a valuable asset to help reassure populations whose personal and learned experiences in healthcare settings have led them to question scientific and medical advice. It is especially critical at a time when minority communities have faced considerably higher rates of COVID-19 infection and mortality than the overall population.

**4) Act to stop the spread of misinformation.**

The pandemic has radically sharpened our understanding of the tremendous cost to lives and livelihoods of allowing misinformation to spread freely online. Congress can act to increase platform accountability in this crisis, and members of Congress must consider their own role as key communicators who can bring a focus on evidence and accuracy to the public conversation.

**Pricing and Payment**

While hesitancy and distrust from the American people is perhaps the greatest barrier to widespread COVID-19 vaccine adoption, there are potentially substantial financial barriers as well. A vaccine against COVID-19 will only be effective if a large majority of the United States population gets vaccinated, and therefore every vaccination benefits the public good. As such, we must seek to remove all barriers to vaccination and that includes ensuring that there is no direct cost of COVID-19 vaccination to individuals. This is essential, whether people have health

insurance or not. The U.S. government has indicated broadly that they intend to make the vaccine free for all Americans, but it is imperative that policies and procedures are instituted to ensure that this is the case. Further, it is critical that this information is incorporated into the overall vaccine communications strategy to ensure that Americans are aware that they will not need to pay for a vaccine. According to a recent Pew survey, 32% of those who indicated they did not intend to get vaccinated cited financial barriers as a factor in their reticence.<sup>10</sup> Even among those who indicated they were planning to get vaccinated, one in five said that they would be considerably less likely to follow through if they ended up having to pay out of pocket.

There have already been major steps in guaranteeing that the American people will not have to pay out of pocket for a COVID-19 vaccine. In addition to mandating that insurers cover the costs of COVID-19 testing, the CARES act included language which will require all private insurers to cover the costs of a COVID-19 vaccine within fifteen days of when one is made available.<sup>18</sup> However, our political leaders must make sure that this commitment is true for all Americans and not solely those with private insurance. Medicare does not generally cover drugs approved through the emergency use pathway.<sup>19</sup> This is easily remediable and should be done quickly. We must also not forget the millions of Americans who do not currently have health insurance. Setting aside any debates regarding insurance coverage in this country, a vaccination campaign targeting widespread immunity benefits from maximizing the number of people who receive vaccines. Thus, the American people stand to benefit from removing financial barriers to vaccination for all people who currently reside in the country. Lastly, we must remember that the cost of a vaccine is not the only financial barrier Americans may face in seeking to get vaccinated. If physicians and health systems charge fees for the service of providing a vaccination, that could result in out-of-pocket spending even in a situation where there was no cost for the vaccine itself.

Given that one-third of those who do not plan to get vaccinated are concerned about cost, it is clear that the commitment to removing out-of-pocket costs and the steps taken in the CARES act have not been communicated effectively. Our political and civic leaders must clearly, widely, and repeatedly remind the American people that there will not be out-of-pocket costs associated with a COVID-19 vaccine. If policies cannot be put in place to avoid costs associated with receiving the vaccine and independent of the vaccine itself, then this must be honestly and transparently communicated in order to avoid a situation in which people receive an unexpected bill after getting vaccinated. This would result in the spread of misinformation about vaccine costs, further weakening trust in the government's management of a COVID-19 vaccine. Ideally, though, we will be able to establish policies that can indeed eliminate out-of-pocket spending on COVID-19 vaccinations and spread awareness of this to the American people, removing a formidable barrier to widespread vaccination.

**Distribution**

A final critical piece in guaranteeing the success of a COVID-19 vaccine is establishing an equitable and transparent distribution strategy. We must focus on first vaccinating the highest risk individuals. Our allocation of COVID-19 testing over the course of the pandemic is a great example of what not to do. It has taken us over 8 months to perform 100 million tests – and testing is substantially easier than vaccinations. Further, testing has been done largely inequitably, ensuring that the wealthy and the well-connected get testing before those who are at highest risk. Our vaccination strategy must be different – and better. Our strategy should ensure that the allocation of vaccinations (as well as other resources) in this pandemic is structured around

maximizing benefit and promoting equity.<sup>20</sup> Given the unequal burden of the pandemic borne by minority populations, the goals of maximal benefit and of promoting equity often overlap.

Recently, the National Academy of Medicine (NAM) assembled a committee of U.S. health experts to develop a framework for the equitable distribution of a COVID-19 vaccine. This committee has since released a clear framework for vaccine allocation to guide policymakers and the public health community in determining priorities for vaccination.<sup>21</sup> The framework works to comprehensively account for the many factors that determine COVID-19 risk by considering health disparities, occupation, living conditions, health status, and local levels of viral spread. The NAM framework puts healthcare workers at the top of their list, followed by individuals with comorbidities and elderly individuals living in congregate living facilities.<sup>22</sup> By recognizing and prioritizing groups that are at higher risk, such as incarcerated individuals, the elderly, health care workers, those with underlying health conditions, and more, this framework will hopefully provide the pathway for a vaccine distribution process that has the maximum impact on disease spread and reduces health disparities in our nation that have been exacerbated by this pandemic. Not only has the panel been tasked with determining who to prioritize when it comes to vaccine distribution, but it has also been key in guiding how to transparently communicate these decisions to the broader public. NAM published the preliminary framework early in September for public feedback.

There are, obviously, other critical organizations whose advisory role to the U.S. government is vital, including the Advisory Committee on Immunization Practices (ACIP), a panel that has, in the past, advised the CDC on vaccination priorities. While the ACIP supports the NAM recommendations that healthcare workers should be first priority, followed by essential workers,

those with high-risk comorbidities, and the elderly, the ACIP has yet to formalize their recommendations.

The bottom line is this: There is relatively broad agreement in the public health and scientific community that vaccine distribution should be guided by risk – that those who are at highest risk of getting infected as well as those who are highest risk of suffering complications from COVID-19, should be prioritized first. This is clearly the right approach.

It is essential to get a detailed map from the Administration outlining the plan for vaccine distribution as well as a clear communication strategy of how that will be shared with the American people. This will be critical in ensuring that Americans know when they might expect to be eligible to be vaccinated. An uncoordinated, poorly communicated strategy would not only reduce the population-level benefits of vaccination, but it would breed further mistrust. The creation of a successful distribution strategy for a COVID-19 vaccine will require coordination across multiple government agencies, in which each group has a clear and distinct role. It will rely upon priority recommendations that reflect guidance from the top trusted public health experts, and it must not be swayed or thwarted by political interference.

### **Conclusion**

As expectations grow for an approved vaccine in the coming months, we are preparing to undertake one of the largest and most complex vaccination campaigns in history. Success could help us bring the pandemic under control, allow us to reboot our economy, and enable us to return to our lives. Failure to vaccinate a sufficient fraction of our population could instead bring a false sense of

security, lead to ongoing infections and deaths, and further damage our economy. As preparation for a vaccine continues, there are three main goals we should be targeting.

The first is to ensure the safety and efficacy of the vaccines through careful, complete, apolitical, and highly transparent Phase III trials and scientific review. We cannot afford to vaccinate hundreds of millions of Americans with a vaccine that could cause harm, nor can we afford to grant the public a sense of false confidence from a vaccine with inadequate efficacy, leading to a breakdown of the masking, distancing, and other public health measures that continue to be critical to effectively combatting this pandemic.

Second, we must introduce policies that guarantee that there will be no financial barriers to getting vaccinated. We must make sure that this policy extends to every American, regardless of insurance status.

Lastly, we must establish a distribution plan for an eventual vaccine that recognizes the elevated risks and burdens faced by certain populations and communities and works to avoid previous missteps, and instead ensures an equitable allocation of vaccines.

Hovering above each of these three areas is the need for a comprehensive, clear, and transparent communications strategy. We have brought unprecedented resources and the energy of the U.S. government to get us to where we are. This has been superb work. We must continue by partnering with state and local officials, civil society and religious leaders, and the scientific community to ensure that we make available vaccines that are safe and effective and that we do so in a way that

poses no financial burden to the American people and that maximizes health and well-being for all Americans.

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Ms. DEGETTE. Thank you so much, Dr. Jha.

Thank you to all of our panelists for your excellent testimony.

Now it is time for the members to ask questions, and the Chair will recognize herself for 5 minutes.

So when I was watching the debate last night, I suddenly realized that the President, who has been politicizing this whole vaccine approval process, is actually trying to blame the Democrats for that. And I don't think it should be politicized by anybody. All of our panelists today testified that we need to rely on the scientific integrity of our agencies and our scientists. I believe so strongly in that, and I believe that that's what we need to do.

And so that's the impetus for my questioning, because I think that the career scientists have been systematically undermined for months, with both the hydroxychloroquine emergency use authorization approval, and then, of course, the plasma emergency use approval.

And so I want to ask—and what I've been asking all of the experts when I talk to them is, I keep hearing about these guardrails to prevent the pressure, the undue pressure that's been put on the agencies by the President for these other EUAs to be used in a vaccine approval. And what I hear from everybody is we have these guardrails.

Dr. OFFIT, in your testimony, you talked about several different guardrails—the Data Safety Monitoring Board, the FDA's VRBPAC, and other systems for review and approval of these vaccines—that you—and plus, of course, the wonderful FDA and NIH scientists. Do you think that these will be sufficient to prevent undue pressure from coming on the agency or even an abrogation of the process and just simple ordering of approval by the President and the administration?

Dr. OFFIT. Yes. And there's a third thing. I mean, the Advisory Committee for Immunization Practices, once a vaccine is licensed or approved, will independently review data and independently make a decision about how they would recommend giving that vaccine. I, frankly, don't—I mean, I, like you, am worried about the politicization of science, but I do think that it would be hard to politicize this.

I think hydroxychloroquine—

Ms. DEGETTE. Let me stop you, because I want to ask the other panelists. So you feel confident in the guardrails we've put in place for the vaccine.

Dr. OFFIT. I do.

Ms. DEGETTE. Is that right?

And what do you think, Dr. McClellan, do you think that these guardrails are sufficient to stop undue politicization?

Dr. MCCLELLAN. I do, and not just me, but yesterday, seven former FDA Commissioners over the last three decades, five administrations, all said the same thing. This is a very robust process that is hard for any political influence to disrupt. What we are more concerned about is the impact of political influence on confidence, as we've been talking about today.

Ms. DEGETTE. Yes. And that's why we're having this hearing today.

And I believe there was an article in The Washington Post this morning about that statement, and it's titled, Seven former FDA commissioners: The Trump administration is undermining the credibility of the FDA.

And I will ask—Mr. Guthrie, at the end of this hearing, I will ask unanimous consent to put this article in the record.

What about our other witnesses? Dr. Khan, do you think that we have sufficient guardrails in place to stop undue politicization of this process?

Dr. KHAN. Thank you, Chairman Guthrie. I think the guardrails are actually quite excellent—

Ms. DEGETTE. I'm actually Chairman DeGette.

Dr. KHAN. Chairman DeGette, I think the guardrails are quite excellent, but I think we all need to remember that those guardrails have not worked so far where we have looked at CDC guidance. For example, whether we test asymptomatic individuals, what is the guidance for children in school. So there's a number of guidelines from CDC that have not—that have not been subject to those guardrails.

Ms. DEGETTE. But what do you think we can do to ensure that those protocols are followed? Very briefly.

Dr. KHAN. So even for CDC, I think we need to ensure the same set of guidelines for public health in general. I'm not sure the public differentiates FDA from everything else they're reading about in terms of the politicization of science.

Ms. DEGETTE. Gotcha.

Dr. Jha, what's your view of this? Do you think the guardrails that were outlined by Dr. Offit are sufficient?

Dr. JHA. Well, the guardrails are strong, and I think—I completely agree with all of my fellow panel members. The problem is some of the signaling that—so for instance, Dr. Hahn has been very public in saying he doesn't have to listen to his advisory committee, which is true, but that is unhelpful. And it is also unhelpful when we know that he has succumbed under pressure. And so while his words are reassuring, what I would like is much greater clarity that the scientists will get to really drive this process, that the FDA Chief won't override the advisory committee's recommendations. If all of that happens, I will feel more comfortable that the guardrails will hold up.

Ms. DEGETTE. Well, and I think that you have bipartisan agreement with that. I think everybody agrees that we need to make strong statements that all of the scientific principles will be followed and that this will be a very rigorous review.

Congressman Guthrie, I now recognize you for 5 minutes.

Mr. GUTHRIE. Thank you very much for the recognition.

And, Dr. Offit, I want to thank you for your testimony and also what you just said just a few minutes ago, that you really have a lot of confidence in the FDA, the FDA scientists, the FDA Advisory Committee, independent data monitoring committee. They really have strong guardrails in place, and a couple of other witnesses seem to say that they are in place, but we still need to—I don't know—they could go off rails, I guess. And I'm just concerned that we're going to say things and not have people confident about vaccines.

We already had a hearing on measles about vaccine hesitancy, and it's something that, I think, Dr. Offit, you said that the scientists would scream and yell if something like that happened. And so we need to make sure that people can have confidence, when a safe and effective vaccine is approved by the FDA, it will be safe and effective. And so, hopefully, we can keep our rhetoric going that direction.

But, Dr. McClellan, in that point, because we really need to be that direction, I'd like to ask you, if the vaccine manufacturers apply for an emergency use authorization prior to submitting a biologics license application, or BLA, what kinds of extensive scientific data would the companies have to provide to the FDA about the safety and performance of the vaccines for the EUA, and how similar are those packages to be submitted under the FDA's gold standard preapproval process for that BLA? Did you get all of that?

Dr. MCCLELLAN. I think so. Representative, I had a chance to talk with Dr. Peter Marks at a public event last night where he reiterated that he expects the evidence for safety and effectiveness for the vaccine approved under an EUA to be very similar to that for a full approval. Remember, the full approval includes a lot of additional documentation, thousands and thousands of pages, dealing with a lot of issues like is the vaccine going to be stable on a shelf for the next six months. That is not the context that we're concerned about here.

And to make sure, all of this is not only reviewed fully by the FDA, as Dr. Offit said, there will be an advisory committee meeting for each vaccine—each vaccine—that comes forward with an emergency use application, for the FDA to write a written review for discussion with these expert independent advisers about whether the vaccine standards are being met. And I have full trust, not only in the FDA staff to do that right, but people like Dr. Offit who have been doing this for years and have tremendous amount of experience with vaccine safety, including for vaccines used in infants.

And after that, the FDA will write a written basis for its decision, and then, even before its used, it's going to go to another independent review by the CDC's Immunization Practices Committee.

So those are a lot of steps that people should be looking for in terms of transparency and independent, regulatory expertise, scientific expertise, all coming to bear to make sure we got the right, sufficient amount of evidence on safety and effectiveness.

Mr. GUTHRIE. My guess it will be pretty transparent if we don't follow those pathways.

Can you explain why the EUA for a COVID-19 vaccine would be different than the EUA for COVID-19 therapeutics?

Dr. MCCLELLAN. It's a very different context. And as you know from working on these issues over the years, the Emergency Use Authorization was implemented to give the FDA flexibility to respond as needed in a public health emergency. And so, as you mentioned earlier, it's about the totality of the evidence in a particular context.

So, in the context of something like convalescent plasma, where the treatment has been around for a hundred years, been used in many different infections, it's on the market now, it's being—it's been used in thousands of sick COVID patients with no significant

evidence of safety side effects—now, we don't have good evidence on benefits, and that's where I think some of the political leadership got it wrong when they were characterizing what the FDA career staff decision was here. They made it sound like it was a clear, beneficial treatment.

But what we're talking about is a treatment that's already being used for people who are hospitalized that the evidence shows is not harmful. And that kind of expanded access is something that FDA has a tradition of doing for unmet medical needs in people who are very high risk while evidence is being developed.

I hope we get a clinical trial done more comprehensively to answer this question, but it's a very, very different context than a new vaccine used in people who are not sick who are trying to keep well.

Mr. GUTHRIE. OK. Then, finally, I have just a few seconds, but can you explain why EUA—or could you—what the FDA's guidance is for COVID-19 vaccines that gives you confidence that there will be strong science behind any decision made and then any safeguards outside of the FDA to make sure you have confidence?

So I want to end with the next 15 seconds why you are confident we will have a safe and effective vaccine when it is safe.

Dr. MCCLELLAN. We've already covered that. There's a whole checklist I think that we've already talked about of public events and writings that will be coming from the FDA staff before any decision is made. Make sure that happens and lets inform the public about that.

And as you pointed out earlier, all of the vaccine manufacturers have said they are going to follow this process. And even though this FDA written guidance on EUA hasn't been released, believe me, all of the manufacturers know what's in it. And Dr. Marks and the FDA staff, again yesterday, just reiterated again publicly what all is in it.

So we've also got a lot of independent experts, other agencies. It's a very robust process that has been developed over decades because vaccine safety is so important.

Mr. GUTHRIE. Thank you, and this is important. Appreciate it.

Appreciate it, Madam Chair, and I yield back.

Ms. DEGETTE. Thank you so much.

The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Madam Chair.

If the months of the Trump administration undermining science, now we have a number of polls that show that the majority of Americans have reservations about getting a COVID-19 vaccine once it becomes available.

So let me start with Dr. Khan. What do you believe are the consequences of this repeated subversion of science and attacks on, you know, the public health agencies?

Dr. KHAN. Thank you, Chairman Pallone.

There's no doubt that over the last eight months we've undermined public health science in the United States through a combination of, I would say, three or four things.

One is misinformation and manipulation of science. The second is elevation of personal liberty above our social responsibility. The

third is equating public health science with having enough hospital beds, ventilators, and body bags. And, fourth, would be probably discounting the value of a life with 20,000 preventable—200,000-plus preventable deaths in America. And there have been numerous now documented evidence of manipulation of science.

So there's no doubt that, from a public perspective, it's easy to see why anything coming out of the administration could be mistrusted. So it's fortunate, as in the prior conversation, that there's a lot of independent review of vaccines. But this politicalization really has undermined public health science in America.

Mr. PALLONE. Well, thank you.

And, Dr. Jha, you have expressed your disappointment in the Nation's pandemic response, and you described it as among the worst in the world. That's a quote. Has the Trump administration's politicalization of science contributed to this failed response? And what do you think the impact of that has been?

I think he is—

Dr. JHA. Sorry. Sorry, Congressman, I was muted.

Mr. PALLONE. Sure.

Dr. JHA. So a couple of quick things. I mean, first of all, there's no doubt, if you just look at the data, if you just look at the numbers, as Dr. Fauci said last week, if you just look at the numbers, we are among the worst performers in the world, certainly the worst performer among high-income countries.

We have the best public health scientific agencies in the world. CDC and FDA are gold standards that everybody else in the world looks up to. Unfortunately, we have not let them function in a way that we really need them to function.

So there is no question, I think, on anybody's mind, certainly I doubt on anybody on this panel, about the integrity and the capability of the great scientists at both of these agencies. The problem has been that their voices have not always won the day and that their voices have often been overridden and subverted by a political process that is unprecedented. It has never been done before under a Republican or a Democratic administration, and that has substantially hampered our response, made it much, much harder for us to get the disease under control and, unfortunately, has led to a lot of people dying unnecessarily.

Mr. PALLONE. Well, thank you.

Now, Dr. McClellan, you have mentioned that you joined six of the former FDA commissioners in this op-ed in the Washington Post raising concerns over the Trump administration's action, not only undermining credibility of FDA but eroding public confidence.

Do you believe that if left alone to do their jobs that the career staff at FDA could be trusted to let science guide their decisions, whether for the vaccine, or new tests or treatments?

Dr. MCCLELLAN. I do believe so, Mr. Chairman. And as we said in that op-ed, despite recent political actions, we continue to have confidence in the integrity and high quality of the scientific work of the FDA staff.

And this, unlike, say, CDC just writing a guidance and having that blocked, this is a major process with a lot of regulatory oversight, all of this independent scientific engagement from advisory bodies, actions, including enrolling and conducting very large clin-

ical trials by multiple companies. This is not an easy process to this route just because somebody says something about it. It does undermine confidence, though.

Mr. PALLONE. Well, let me just ask, Dr. Jha, I mean, look, we have got to fix this, right? What can we do to restore trust in the Nation's pandemic response? I mean, you have heard some of the things that were put in this new updated Heroes Bill.

The experts, the scientists, the processes are in place. What do we need to get the President and his cronies out of the way or to fix this so that we can go back to having the FDA do its job?

Dr. JHA. Right. So, first of all, I have said this. I think all political leaders need to stop talking about things like timelines. Politicians don't know what the scientific timeline is and, unfortunately, the political appointees have not been very helpful either.

And so what I have said is if the career scientists of the FDA or the ones at the CDC get to do their job and we hear from them directly that they believe that the process has had high integrity, I think that would be enormously helpful and would go a long way to offer an assurance to the American people that this is a process with integrity.

I generally don't believe we need whole new sets of independent bodies at State or other levels. Now, we have got independent bodies. If—the one that Dr. Offit is on, if that committee comes out and says the scientific evidence is strong and clear, I think the American people will have—will feel assurance by that.

But we need to make sure that their words and voices carry the day and not those of political leaders.

Mr. PALLONE. All right. Thank you.

Thank you, Madam Chair.

Ms. DEGETTE. Thank you so much.

The Chair is now pleased to recognize the ranking member of the full committee, Representative, Mr. Walden.

Mr. WALDEN. Good morning—or good afternoon, and thank you again, Madam Chair, for this hearing, and thanks to our witness for your fine testimony.

Dr. McClellan, some State officials, as you know, are expressing skepticism about Federal reviews of potential COVID-19 vaccines, and indicate that their States plan to conduct their own independent review of the clinical trial data before distributing a vaccine, despite an approval or authorization from the FDA.

Do you believe such a review by States would be necessary? Has it been done before? Are they equipped to do this? Did they do this on anything else that the FDA approves? And do you think that this would actually slow down access to an FDA-approved vaccine that could save lives?

Dr. MCCLELLAN. Mr. Ranking Member, I just, like Dr. Jha has expressed, I do have some concerns about it. We just talked about how extensive and developed and how much resources go into the FDA's process.

That's a process that you all have supported through your implementation on a bipartisan basis, have continued efforts to strengthen and improve the Federal Food, Drug and Cosmetic Act, which is meant to provide a high level of confidence about safety and effectiveness of medical products in general and vaccines in par-

ticular for the American people. It is a huge undertaking with a lot of expertise, experience, culture.

It is hard to see what a State body of some kind could add to that. I understand where the impulse is coming from. Maybe if what the group would do is just go through this kind of checklist, you know, is the—all of the things we've talked about today, are they actually happening, are we hearing from the career staff, is the process being followed, maybe that could help improve confidence. But it's hard to see how to replicate anything like this national gold standard system that we've developed.

Mr. WALDEN. Well, and I would just say in—I have been through a lot of closed-door discussions with the HHS, with NIH, Dr. Fauci, Dr. Hahn, Dr. Redfield. They all say we are going to follow the standards, we are not going to yield in any way, it's all going to be about the science, it's all going to be about the data.

And, by the way, there's—aren't there independent scientific review boards set up outside of the FDA to look at these things, to look at the data, do the evaluation—I mean, it might be technically encompassed within FDA and CDC, but aren't they completely separate, independent and, I would think, people of great integrity and scientific capability?

Dr. MCCLELLAN. That's right. It's not just FDA, but a whole system of regulatory oversight, scientific expertise. Dr. Offit talked about how the Data Safety Monitoring boards, which NIH is generally involved in for these trials, NIH expertise, as you just mentioned, CDC expertise and CDC drawing in a whole set of independent experts through their Advisory Committee on Immunization Practices, which will also provide a review as part of this well-established process.

It is a system like no other in the world, and we are very lucky to have it in the United States to give us as much confidence as—

Mr. WALDEN. Yes. Let me ask you about that because we're hearing internationally supposedly Russia has a vaccine they're ready to push out and China. Tell me how their systems work in contrast to ours.

Dr. MCCLELLAN. Mr. Ranking Member, in China and Russia, there are people getting vaccines now that have not been through anything like the process that we've described, these large so-called phase III trials that actually have to prove, demonstrate that the vaccine reduces the number of infections, reduces severe infections, that have these very large data bases of tens of thousands of people who have been followed after they get the vaccine, that have the FDA's authority on top of that to set up additional monitoring on the people who are first to get the vaccines, our first responders, our health professionals, and others who are at such big risk today because of the ongoing pandemic. It's very different. It's a system that really is setting standards for the world.

Mr. WALDEN. Mr. Khan, do you want to weigh in on these matters? I saw your head nodding there like you wanted to add in.

Dr. KHAN. I just want to add in to Dr. McClellan's comments.

So, in Russia, the vaccine was licensed with less than a hundred people who had been vaccinated in a phase I, II trial. That is impossible in the United States.

Mr. WALDEN. And do you agree that there are these independent organizations that are comprised of people with great integrity and scientific ability that aren't going to be pushed around, if you will, by anybody?

Dr. KHAN. Oh, absolutely, there's no doubt about the integrity of the people, for example, in the ACIP. So there's no doubt about that.

So it's really an issue of confidence and how do we assure that when these vaccines are available the checklist has completely been followed.

Mr. WALDEN. All right. Thank you very much again to all of the witnesses.

And, Madam Chair, I yield back.

Ms. DEGETTE. The Chair now recognizes Congresswoman Schakowsky for 5 minutes for questioning.

Ms. SCHAKOWSKY. Thank you so much.

I first want to welcome Dr. Helene Gayle who, in addition to her role today, I know as head of the Chicago Community Trust. And so welcome today.

I am so glad that my colleagues and I have passed legislation to provide COVID-19 vaccines to most Americans at no cost, but we must extend that protection to the uninsured people as well. A vaccine can only be as effective—can only be effective if Americans and people around the world can afford to take it.

But let's be honest about it. Just because people don't have to pay when they receive the vaccine doesn't mean that a vaccine is free. U.S. taxpayers have already paid drug companies over \$10 billion for vaccines that—for vaccine research and development, costing—and that's through Operation Warp Speed.

In the years to come, public plans, like Medicare and Medicaid and the VA, et cetera, will all be harmed by the drug companies if they are allowed to use monopolized—monopolizing power to charge whatever they want.

And let's be clear, that if the Republicans and the President of the United States have their way to end the Affordable Care Act at the Supreme Court, then the ACA, so right now, prohibits cost sharing for preventive services, and that would be eliminated. And that means that all Americans will face copays for all vaccines, including COVID-19 vaccines, once the public health emergency is over.

And, finally, I just want to say that Oxfam just issued a report that, quote, wealthy nations represent just 13 percent—representing just 13 percent of the world's population, unquote, have already bought over 50 percent of future COVID-19 vaccine doses.

So I would like to ask Dr. Jha two questions. First, to ensure equitable access, do you believe the Federal Government should require pharmaceutical companies to sell a taxpayer-funded COVID-19 vaccine at a transparent, fair, and reasonable price?

Dr. JHA. Well, let me start off with that question, Congresswoman, by saying absolutely necessary for the U.S. Government since it has been a major investor in these efforts, whether it's Moderna, whether it's companies that are part of the Operation Warp Speed, that the U.S. Government needs to make sure that the vaccine set it buys does so at a fair price. And, of course, the

big question would be what is a fair price, what's a reasonable price?

One of the points I would like to make is that these vaccines are going to be needed by billions of people around the world, so you don't need a large margin on every single vaccine to still make plenty of profit. It is absolutely essential that the vaccines be affordable, be affordable to Americans, to American taxpayers, but also affordable to the rest of the world.

Ms. SCHAKOWSKY. Well, I want to thank you so much for mentioning that in your opening statement. I appreciate your mentioning cost because when we talk about access, cost is so important.

And that was really my second question. If we can, we as Americans can really be protected if other countries can't afford the COVID vaccine. I wonder if you want to elaborate on that anymore, especially given the Oxfam research that was just announced.

Dr. JHA. Yes, absolutely, Congresswoman. So if your only goal is to protect the American people—let's say, we didn't care about other people in the world, though, of course, we as Americans do.

But even if our only goal was to protect the American people, we would want to make sure that much of the world was vaccinated because, if there continues to be large outbreaks in other places, those outbreaks will see their way here. Nobody believes that any vaccine will be a hundred percent protective and that a hundred percent of Americans will take it.

So there will still be vulnerable Americans, and part of protecting America is making sure there's widespread vaccination all over the world.

Ms. SCHAKOWSKY. Thank you so much.

And I yield back.

Ms. DEGETTE. Thank you, gentlelady.

The Chair now recognizes Mr. McKinley for 5 minutes.

Mr. MCKINLEY. Thank you, Madam Chairman.

Last night's presidential debate truly was a debacle, an embarrassment to the American people. But now the Democrat leadership and the literal media are expressing similar disrespect to the integrity of our scientific community by sewing the seeds of doubt about the efficacy of a safe vaccine and interjecting politics into this.

Ever since the virus broke out, there's been a rallying cry across the globe to get a vaccine as soon as possible. And to his credit, President Trump instituted Operation Warp Speed to do just that, and Congress overwhelmingly voted to fund the program.

But now, just as we are on the cusp of having a viable vaccine and safe, Democratic leadership wants to move the goalpost once again and slow down the process; but speed is still of the essence.

So my question, what part of Operation Warp Speed don't they understand? Look, scientists don't give two hoots about who the President is or who controls the House or the Senate. Using the same protocol they have been using for decades, these scientists simply want to create a vaccine so people can confidently return to work and our schools.

The public has been clamoring for a vaccine, and now the Democratic leadership wants to perpetuate the political conspiracy theories that only confuse the American public more.

It's time. Can't we just stop this foolishness and put aside our political grandstanding? Let's trust the scientists, our career scientists, and the FDA to do their job.

Now, my question is to McClellan, if I could, Dr. McClellan. Do you think politics is motivating the Democrat leadership to question the efficacy of a drug even before it's finished clinical trials?

Dr. MCCLELLAN. Oh, Representative, there's certainly a lot of politics around this issue and the coronavirus response.

I would just say a couple of things. One is, I agree with you about the value of Operation Warp Speed for making the vaccine development process faster and leading to the potential for actually having a vaccine by the end of the year and maybe in widespread use next year can potentially have such a big impact on the pandemic and our health and our economic well-being.

I would also to—

Mr. MCKINLEY. If I could go back again. So these seeds, these seeds of mistrust and the misinformation from the Democratic leadership are alarming. Public trust—as you so pointed out here, the public trust in this COVID vaccine has dropped by nearly 30 percent in just the last couple of months.

So, therefore, is it reasonable to assume that this mistrust of a COVID vaccine could permeate into the mistrust of other vaccines that we need?

Dr. MCCLELLAN. It certainly is, and that's why this hearing and, I think, the bipartisan support that this committee has over the years steadily provided for the scientific process at FDA, NIH, CDC is so important right now.

And I hope together you all can help restore the confidence in the public in what I think is a very strong vaccine development and oversight process.

Mr. MCKINLEY. OK. So, again, let me just reinforce again what you were saying earlier. You think the guardrails are there in place—

Dr. MCCLELLAN. Yes.

Mr. MCKINLEY [continue]. To be able to provide this?

Dr. MCCLELLAN. Yes.

Mr. MCKINLEY. And this is involving politics—that's what I heard you say, yes, politics are involved. Isn't that a shame?

Dr. MCCLELLAN. Yes. I think that politics—

Mr. MCKINLEY. Because we have a chance, if the guardrails are in place and we've demonstrated that, the only reason I think this is being raised to this point is because an election process is coming up in 5 weeks. Comments?

Dr. MCCLELLAN. I would like to get the politics out of this, and I appreciate the bipartisan interest on the committee, it seems, in making that happen or helping to make that happen—

Mr. MCKINLEY. Shame on people for making this partisan. This thing we should resolve. We've had the mission to try to get this vaccine approved, and people want to play politics in delaying, and only politics, and I think all of this panel knows that. This is politics, raw unmitigated politics.

Thank you very much. And I yield back the balance of my time.  
Ms. DEGETTE. The Chair now recognizes Representative Kennedy for 5 minutes.

Mr. KENNEDY. Thank you, Madam Chair. And thanks to all of the witnesses for being here, and thank you for convening this important hearing.

Diverse enrollment of participants in vaccine clinical trials has been a concern long before COVID-19. It's due to a long-standing racism within a system that systematically targeted people of color and placed them without consent into clinical trials. So it's not surprising that there would be hesitancy in those communities to participate in now clinical trials.

Given the increasing data on the disproportionate impact of COVID-19 on communities of color, it is more important than ever that we ensure diverse participation in clinical trials and build trust in a vaccine in those communities.

I am particularly concerned by statements from some companies researching vaccines that they are struggling to recruit black participants in their clinical trials, since it is on them, to try and right the wrongs of the past and to engage communities and people who have historically been undervalued.

So, Dr. Offit, I wanted to start with you. I know you have been involved in numerous clinical trials. From what you've seen so far, will the current clinical trials provide us with enough information about the safety and efficacy of the vaccine on populations that are hardest hit by COVID-19?

Dr. OFFIT. That's certainly the goal. I mean, I know that one of the companies who have slowed up because they wanted to make sure that they had gotten adequate representation. I mean, you know, one doesn't expect that you are going to have critical differences in terms of safety or immunogenicity based on gender, race, or ethnic background. What you—you know, where as you could obviously have instances regarding age. I mean, people who are older may not respond as well to certain vaccines as others.

So I think that certainly is the goal. I think—because if we are going to go to people and we are going to say, look, you need to get this vaccine, we have to be able to say you have been represented in these trials, otherwise people won't trust that the vaccine is formed.

Same thing with older people. I am, what, 65. I am not going to get any vaccine that hasn't been adequately tested for people in my age group to be found safe and effective, and the same is true for ethnic background—ethnic or racial minorities.

Mr. KENNEDY. Thank you, Doctor.

And, Dr. Gayle, what are the consequences—Dr. Offit talked about this a little bit, but what are the consequences if we do not adequately—or if we don't have adequate representation among a diverse range of populations amongst trial participants? And what should Congress and the Federal Government be doing to help address it?

Dr. GAYLE. Yes. So thank you for that.

You know, obviously, this has been a pandemic that has disproportionately impacted people of color as you mentioned and as Dr. Offit also mentioned. It's so critical to have people of color en-

rolled in these trials so that there can be confidence that these trials actually have looked at this in populations that are reflected by this pandemic.

And so I think, while we've talked a lot about the guardrails within the Federal Government system, that's clearly important to develop the—to have the overarching trust in the development of the vaccine, but it also means that partnerships beyond the Federal Government, with trusted institutions, with communities, all of that needs to happen in order to build that kind of confidence.

And I think there's a lot that can be done to make these clinical trials much more accessible to communities of color: Where the trials are done, what doctors' offices participate, what medical institutions are part of it.

So I think there's a lot more that can be done to make sure that the trials are made in a—done in a way that are accessible to the populations that are being most hard hit by this pandemic.

Mr. KENNEDY. Dr. Gayle, thank you.

And, Dr. Jha, I saw you nodding to her comments. I wanted to get your thoughts on this, and also from somebody down the street from you in Massachusetts, thank you for your incredible work and your outspokenness on these issues.

But you speak about some of the potential vaccine confidence concerns amongst communities of color in your testimony, stating that a level of, “mistrust amongst people of color isn't surprising considering the long history of structural racism and unethical medical experimentation on this population.”

Briefly, what more do you believe needs to be done to ensure that any future vaccine will be safe, effective and trusted within those communities?

Dr. JHA. Yes, Congressman. Again, thank you for being my Representative.

So very quickly I will say that, building on what Dr. Gayle said, it is absolutely critical that we engage community leaders, we relate—we engage religious leaders.

So it is, first of all, completing what Dr. Offit said about having representation is the first step, and that's going to require a lot of work. But even after that, building up confidence in communities of color is going to require engaging with leaders in those communities, trusted voices in those communities, and working with them. And they are not going to give you a pass. They are not going to give anybody a pass, unless they are confident that their communities have been well represented and that this is beneficial to them.

So I think there's a whole strategy here that is necessary. This is not a we show up one day, knock on the door and say, Hey, we have a vaccine. How would people like to get it? We've really got to take a proactive approach here.

Mr. KENNEDY. I appreciate that.

Dr. GAYLE. I would add that there's a lot to build on, and this doesn't have to start from scratch. You know, we know a lot about who are the leaders who are trusted. We know a lot about the institutions that are trusted in communities of color. And we just need to build on some of those things and make it a priority and be intentional about it.

Mr. KENNEDY. Dr. Gayle, thank you.

Dr. Khan, I had a brilliant question for you, too. Unfortunately, my time is up. So I will get it before you.

But I will yield back the negative time I have. Thank you for your patience.

Ms. DEGETTE. I thank the gentleman.

The Chair now recognizes Mr. Griffith for 5 minutes.

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

Building on those questions, Dr. Offit, you indicated to Mr. Kennedy when he was asking questions that one company had slowed down their process in order to get a diverse demographic group mix. Can you tell us who that company was?

Dr. OFFIT. It was Pfizer.

Mr. GRIFFITH. OK. And I just thought it was interesting, and I had not heard that, so I appreciate that information.

Also I would ask you and Dr. McClellan, AstraZeneca's phase III clinical trial was recently put on hold due to an adverse event occurring in one of its enrollees. The trials have resumed in the United Kingdom, Brazil, and South Africa. But, to my knowledge, the trial is still paused in the United States.

Would you agree that this action taken by the FDA signals a commitment to safety and not rushing the clinical trial process?

Dr. OFFIT. Yes, absolutely. I think—first of all, the AstraZeneca vaccine trial in the United Kingdom was put on clinical hold twice, once in July and then a second time in September. So when you do that, there's—because there's so many investigators involved, that will always be known by the press and, ultimately, the public.

The problem then becomes that you don't really know the details because confidentiality precludes you from knowing those details. And I have talked to the head of the Data Safety Monitoring Board in the United Kingdom about this, and he can't give me the details. And it's very frustrating for all of us because we think we know what those two cases were, but we don't.

We also know that the U.K. regulators have now taken that clinical hold off because they presumably felt that this association was coincidental and not causal, but that hasn't happened here. And we don't know why the decision was made in one place or the other place, and that's part of the frustration of all of this.

I mean, people talk about transparency, but the fact of the matter is you can't really be transparent about these cases because of confidentiality issues. So it's sort of like, since Joe Kennedy is on this call, I mean, it's like driving in Boston. You know, you're bound to have an accident. And I think that that's the way this is set up.

Dr. MCCLELLAN. I appreciate that.

Mr. GRIFFITH. Yes, Dr. McClellan.

Dr. MCCLELLAN. Yes. Just to add to that, I think also as a reminder that this is a scientific process that is very much in process, and as you said, the FDA is right on top of this, watching closely.

Before anyone gets broad access to this vaccine, there will be a public opportunity through that advisory committee review to go over this and any other significant safety issues that have come up during the clinical trials and a chance for people like Paul, who I

know he wants to get that information now, but he will get his chance before there is any actual decision about this vaccine.

And this is the way it goes with vaccine development. These events happen. They need investigation. They need to be put in the context of the overall trial and all of the rules and safeguards, including blinding and confidentiality that are—

Mr. GRIFFITH. I appreciate it.

Dr. MCCLELLAN. And that will all happen before there's any decision on the vaccine.

Mr. GRIFFITH. Let me shift gears just because I see the clock ticking.

Dr. Offit, there was an op-ed in the New York Times last week in which Dr. Peter Doshi—I don't know if I'm pronouncing that correct—and Dr. Eric Topol expressed concerns about clinical trials for the COVID-19 vaccine stating, according to the protocols for their studies which they released last week, a vaccine could meet the company's benchmark for success if it lowered the risk of mild COVID-19 but was never shown to reduce moderate or severe forms of the disease or the risk of hospitalization, admissions to the intensive care unit, or death.

To say a vaccine works should mean that most people no longer run the risk of getting seriously sick. That's not what these trials will determine.

Do you agree with those concerns? And either way tell me why.

Dr. OFFIT. I don't agree. If you look at the natural history of people who are infected with SARS CoV-2, if they have moderate to severe disease the first time they are infected, typically when they get a second infection, it's much more mild or asymptomatic. That was also true with the virus I worked with, norovirus, and it was also true with the norovirus vaccine.

I think they are exactly wrong. I think it's actually much harder to prevent asymptomatic infection or mildly symptomatic infection. If you can prevent that, you are much more likely to prevent moderate to severe disease. So I think they have it backwards. That's not really in the history of vaccine development. So I think they are wrong.

Mr. GRIFFITH. All right. So since I already had it, what you're saying is if I get it again, it will be mild?

Dr. OFFIT. And that's what you want. I mean, as a developer of a vaccine, what you want to see when you develop a vaccine is you want to make sure that natural infection can protect you against challenge. Then you know that there's hope for a vaccine. And when you see that, usually you—all you care about is that you can be protected against moderate to severe disease on reinfection because that keeps you out of the hospital and out of the morgue.

It's not usually the case where you are also prevented against having mild disease or asymptomatic disease. And if you look at the animal model studies for SARS CoV-2, you can protect lower respiratory disease; i.e., pneumonia, but you don't really protect against shedding, which is to say asymptomatic infection or mild infection.

So I honestly think that op-ed piece was just wrong.

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

I yield back, Madam Chair. My time is up.

Ms. DEGETTE. Do we have Mr. Ruiz? He is next in the order.

OK. Not seeing him—

Mr. RUIZ. Yes, you do.

Ms. DEGETTE. Oh, there he is. OK. Mr. Ruiz, you are recognized for 5 minutes.

Mr. RUIZ. Thank you so much. I really appreciate this hearing. It is so vital that people have the confidence in the science of the development of the vaccine.

As this pandemic continues to ravage our communities, we have seen repeatedly that certain populations remain at high risk for contracting and dying from COVID-19. This includes high-risk essential workers, people of color, the elderly, and individuals with preexisting conditions.

I know we all wish that there would be enough vaccines for everyone as soon as one is identified, but that just will not be the case. In fact, some experts, like CDC Director Robert Redfield, say it will be mid to late 2021 at the earliest before the U.S. is widely immunized.

Once the first vaccine is approved, things are going to move fast, and that vaccine will be distributed immediately. So it is imperative that we finalize distribution plans now that prioritizes the most vulnerable or those at highest risk, and the most vulnerable or those at highest risk here means those who are most likely at highest risk to get infected and at highest risk of dying from COVID-19.

So these vaccines can't just go to the highest bidder. It has to have that public health approach to save as many lives and get through this pandemic as quickly as possible.

Dr. Gayle, you state in your testimony that, "while spread throughout the society, the pandemic damage has more significantly harmed some populations more than others, particularly causing high rates of infection, serious illness, hospitalization, death among people of color due to the long-standing impact of systemic racism and inequity."

This is what I and so many of my colleagues have been concerned about throughout this pandemic and what we have sought to address. Yet I notice that communities of color are not specified as priority population phases in the National Academies Committee discussion graphs.

Furthermore, essential workers have been mentioned, but there's a difference between high-risk essential workers, people that work in the farm fields, in grocery stores, versus low risk, younger affluent people who can work from home and have their own room to work from and be physically distanced from everybody else.

So, Dr. Gayle, recognizing that the final report will not be released until this Friday, could you shed some light as to how the committee considered and addressed these disproportional impacts of COVID-19 on Black, Latino, and indigenous people in this country?

And is there any classification of the risks of essential workers, those that are at high risk versus those who can self-isolate, work from home that are at low risk and don't have any underlying illnesses?

Dr. GAYLE. Yes. Thank you very much.

And, you know, it was for the very reason you started out with that this framework was asked for by the NIH and CDC so that, in fact, as this moves rapidly, there was an overarching guideline for these allocations.

And as you mentioned, you know, one of our principles, as I mentioned in the report, in my statement, was the mitigation of health inequities. We felt very strongly that we needed to have—

Mr. RUIZ. So how do Latino, African American, and indigenous people identify directly if they are not specifically mentioned? And how are essential workers categorized as high risk versus low risk?

Dr. GAYLE. Right. And so, in our full report, you will see a lot of discussion of this. But what we tried to do was to use the Social Vulnerability Index, as well as the categories, including high-risk critical workers, as a way of getting at the issues because it's not because you're Black or Brown that you are at risk. It's because of the social economics, the historic impact on health as a result of racism and inequity.

And so what we really tried to do in our tiers, in our phases, was to address those issues. And by using the Social Vulnerability Index, which is an index that looks at minority status, household crowding, other issues that put people at risk, by using that as a guide across all of the different phases, saying you should prioritize the geographic areas that—

Mr. RUIZ. Well, are there any recommendations to have transparency and measure if these principles are being followed?

Dr. GAYLE. Well, you know, that's our role as the National Academies is to do these studies. We did this at the request of NIH and CDC, so we expect that they will look at these recommendations and use—

Mr. RUIZ. So I would suggest that their recommendation, as any public health expert would say, and I—you know, I am one of those public health experts, graduating from the School of Public Health at Harvard, that recommendations on evaluation, transparency, metrics, in order for the community to see if these systems are being followed, is important because the current system has left out these communities and rendered them high risk of getting infected and dying to begin with.

And I yield back.

Ms. DEGETTE. The Chair now recognizes Ms. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman, and thank you all, to all of our panelists.

And I completely agree with, I believe it was Dr. McClellan, who said it is so critically important to help us restore trust and make sure there is trust in the vaccines.

And so, Dr. McClellan, I want to talk with you about the fact that we have these vaccine candidates in the phase III clinical trials. We've already heard that they recently released their vaccine protocols, that the companies have, which contain details about how the participants are being selected and monitored and the conditions under which the trials could be stopped early if there were problems and the evidence that researchers will use to determine whether people who got the vaccines were protected from COVID-19.

So I think it's unprecedented that the companies are making these disclosures at this point in the process. And how does this level of transparency help the experts and but, more importantly, the public—and I think that's what we are most concerned about, it's the public's confidence in the safety?

And what, if any, additional information should these companies be disclosing about their clinical trials or what should the companies be doing to increase Americans' trust in the COVID-19 vaccine process?

Dr. MCCLELLAN. Representative, I think the companies have done a couple of things this time around that are unusual. First, as you mentioned, more transparency than has generally been the case about exactly what their trial plans are that they are in the process of executing now.

Second, as we talked about earlier, a pretty extraordinary written letter from all of the companies that are involved in this vaccine development, stating that they are firmly going to adhere to the FDA processes. So those are really important.

I know now people care so much about what's actually happening in these trials. As we talked about before, there are just going to be some things that we won't know for sure for a little while. You know, are the events that are happening in the trials related to the vaccines? What do they really mean?

And so when you get some of this transparency, it also creates some opportunities for confusion. For example, some of the studies, as is usually the case, have some review checks along the way by that independent expert group, the Data Safety Monitoring Board that NIH is generally involved with, and so forth. And those may show that the vaccine is really working way better than people expected.

That could lead to the trial coming to an earlier conclusion, at least in terms of leading to a proposal to the FDA. And that's gotten tied up in some of this discussion around the, you know, could a vaccine happen before the election? Very, very unlikely. Technically possible if there's just an absolute home run, which I don't think we have seen evidence of yet, but the trials are still ongoing.

So it is challenging through this process to make sure people get transparency about the process but recognize that we don't have answers for a lot of these questions yet, and we really need to take the time, as we talked about, for the FDA scientific review to happen on any emergency use proposal, for it to be presented to—in writing with FDA comments and review to that independent oversight group before we reach any conclusions.

And, again, the more we can keep the politics out of this the better.

Mrs. BROOKS. Thank you.

Very quickly, Dr. Offit and/or Dr. Gayle, we are so concerned about flu season, about children not getting vaccines right now, vaccine hesitancy happening, not just with what's coming with COVID vaccine but other childhood vaccines that we are seeing a decrease in the numbers.

What are your recommendations for how we implement a better strategy in making sure that we are tracking flu and COVID and

also getting children—making sure that they continue to get vaccinated?

Dr. Gayle?

Dr. GAYLE. Yes. Well, you know, I think we really need to build on the existing programs we have. You know, we have such a strong system for childhood vaccination that needs to continue to be strengthened.

You know, I think it also, as has been mentioned in several of the other questions by other panelists, you know, we've got to restore the trust and confidence that has been eroded in vaccines.

So I think, you know, those two things to me are essential, you know, build on the systems that we know work, get the right information out, and continue to build on the messages of why it really makes a difference to have children vaccinated and build on those systems that we know work.

Mrs. BROOKS. Dr. Offit, in my 15 seconds?

Dr. OFFIT. Sure. So initially what happened was, because of the pandemic, there was a dramatic decrease in childhood immunizations for measles containing vaccine, pertussis, or whooping cough vaccine as reported by the Morbidity and Mortality Weekly Report. That started to come up. So I think now that people are more comfortable going to the doctor's office, that's come up.

But you're right, we need to certainly make sure we get a flu vaccine coming into this next winter because of this feared twindemic as they say.

Mrs. BROOKS.OK. Thank you. I got my vaccine—my flu vaccine. Thank you, I yield back.

Ms. DEGETTE. Thank you.

The Chair now recognizes Ms. Kuster for 5 minutes.

Ms. KUSTER. Thank you, Madam Chair, and thank you for this hearing.

I just want to say at the outset—and, yes, this is bipartisan—I got my flu vaccine as well. We are not trying to politicize. The problem is that the President of the United States has politicized this vaccine coming just weeks before an election.

And we owe it to the American people to explain the process and the system and the transparency in the hopes that one of these multiple vaccine candidates will be proven safe and effective.

But that will be only half the battle. Once we have an approved vaccine, we still face the formidable challenge of distributing hundreds of millions of the doses around the country. This will be an unprecedented effort, and we need to start preparations right now.

Dr. Khan, what are some of the essential lessons learned from past vaccination programs, such as H1N1 pandemic, regarding the mass distribution of the novel vaccine?

Dr. KHAN. Thank you, Congresswoman Kuster.

As I have stated in my testimony, I think it starts with appropriate messaging, so under promise, over deliver. Make sure we have excellent planning at all levels, local, national, State level, Tribal and territorial level. Make sure we have prioritization.

We know there's not going to be enough vaccine the moment it's released, and people need to understand why if there's a hundred people in the hospital only two are getting it as opposed to the other 98. So that needs to be clear up front.

And there needs to be—and part of the planning needs to deal with the logistics. This is going to be logistically extremely difficult. Unlike the H1N1 pandemic in 2009, in the end there was only a need for one dose. In this case you need two doses of the exact same vaccine 21 to 28 days apart, which will be problematic.

There's complex requirements for storing these vaccines. And then depending on how—what the size of the orders are, those may need to be split up and sent to various places in rural areas. And we talk about mass vaccination, but we need to be careful what the word “mass” means because during a pandemic, you don't want, you know, hundreds of people all gathered together because that's a good way to infect them as opposed to protect them, and we would like to keep those two pieces apart, the infection and the protection piece.

So there's going to be significant challenges throughout the system. And then I didn't even get into the data systems, which—

Ms. KUSTER. So I was just going to ask you further about one of the challenges with the vaccination program on this scale is the data systems to track the distribution and schedule the immunizations, especially if they need two separate doses.

How important is this aspect? And what should Congress be doing to ensure we have good data on a vaccination program?

Dr. KHAN. So how do we strengthen the four or five systems that are going to have to work together in terms of vaccine tracking, immunization registries within the State, the vaccine adverse event systems.

So there's three vaccine—actually, there's another VAM so—which is overarching vaccine systems. How do you make sure those are working, are robust, are interoperable. And will give you the data real-time that you will need to ensure that not just where the vaccine is being distributed but it's actually getting into people's arms and what the side effects are.

And that's going to be critical going back to Dr. Helen Gayle and others' comments about equity to make sure that as the vaccine is getting out that we are being equitable in the distribution. And that's only going to be determined by data.

Ms. KUSTER. And, Dr. Offit, is our existing health infrastructure adequate to meet the storage and transportation needs for national and equitable distribution, including rural communities, communities of color that have been disproportionately hit by the COVID-19 pandemic?

And then distributing a global vaccine will require extensive air travel via cargo flights. Do we have the workforce and capacity to achieve this logistical feat?

Dr. OFFIT. Well, I think the one thing in this that does worry me is the requirement of at least for one of the messenger RNA vaccines, the mRNA vaccines, to shift and store at minus 70 to minus 80 centigrade, which will require then at least, you know, dry ice constantly being needed to contain it.

And when they are doing studies now, which—where I'm sure that the company has been very good about making sure that the sites that are containing that virus should be maintained—or the vaccine, when it gets out into the real world, it's hard. There's no historical precedent for us maintaining vaccines on dry ice in the

United States. That's never happened. We've always shipped and stored it at most at freezer temperatures, not minus 70 or minus 80. So I do worry about that. I think it's going to be an enormous challenge.

Ms. KUSTER. Thank you very much.

My time is up and, Madam Chair, I yield back.

Ms. DEGETTE. Thank you, gentlelady.

The Chair now recognizes Mr. Mullin for 5 minutes.

Mr. MULLIN. Thank you, Madam Chair, and I do appreciate holding this hearing, although I am concerned by the fact that everybody keeps brings up not to politicize it, the administration is politicizing it. But, in some aspects, that's exactly what this hearing is, we are politicizing it.

I had a constituent tell me a couple of weeks ago that says, you know, you can tell when a natural disaster or a national disaster is serious is when Republicans and Democrats are both on the same page; but when we start politicizing it, it becomes less serious.

And that's exactly what we are doing here. We have members on this panel that is extremely bias towards the President, and within our testimonies, you are hearing that. And that alone drives down the confidence of the American people of do they really need it, is it really that serious? Well, the fact is is if you are one in the vulnerable positions, you do need to get the vaccine, and you need to get it when it's available, not worrying about if the President brought it out too fast.

Because do we really think that the pharmaceutical companies or the FDA would allow that to happen? It's their name. They are the ones that are trying to get it to the American people to save lives. But the more we question it, while underneath the disguise of trying to say we are trying to keep the American people safe, the more we could actually cost people's lives.

And we need to be very, very careful about that. Every one of us have a responsibility to the American people and to the public. Regardless if you are a witness or if you are a member here, we need to keep that in mind. You, yourself, could be driving down the confidence of the American people.

With that said, Dr. McClellan, I would like to talk to you just real quickly about the pharmaceutical companies and the vaccine. Do you think that the companies would knowingly produce a vaccine that's unsafe for the public?

Dr. MCCLELLAN. No, Representative, I don't think so. And they've affirmed the same thing in writing, and they're affirming it by following the FDA's guidance on how to conduct the development, the clinical trials, and making sure they are doing safe manufacturing as well.

Mr. MULLIN. So underneath President Trump's administration with warp speed, do you think the pharmaceutical companies or the FDA are cutting any corners in developing the COVID vaccine?

Dr. MCCLELLAN. Well, the warp speed process is happening much faster, and I know that makes people nervous about cutting corners. It's important to recognize, though, that FDA is firewalled off, even from warp speed.

So the work that the government is doing in Operation Warp Speed with the companies on additional manufacturing and on supporting these very large trials, with NIH getting them up and running at an unprecedented pace is different from the review that's going on independently by FDA.

So it's sort of like independent oversight within this very accelerated process to make sure that—and that's FDA's role, to make sure we're not cutting corners on the safety and effectiveness evidence.

Mr. MULLIN. Would any other panelist like to add to that?

OK. If not, we will go on then.

So are you confident, then, that when a vaccine is authorized, that it will be safe to the public?

Dr. McCLELLAN. Yes, I am. The other former FDA commissioners, the group of seven, all stated their confidence in the FDA process as well. We've heard that from Dr. Tony Fauci, from Dr. Francis Collins, from other public health leaders in and out of the administration.

Mr. MULLIN. Well, thank you so much. I don't have anything else.

With that, I will yield back.

Thank you sir.

Ms. DEGETTE. Thank the gentleman.

The Chair now recognizes Congresswoman Castor for 5 minutes.

Ms. CASTOR. Well, thank you, Chairman DeGette, for having this very important hearing today on how we can ensure a safe and effective COVID vaccine, COVID-19 vaccine. The experts have been direct and straightforward and simply outstanding, very helpful.

You simply can't gloss over the fact that the administration's public health response to COVID-19 has been weak and overly politicized. It's cost lives. It's caused a lot of pain. So the importance of developing a safe and effective vaccine is paramount.

Once a vaccine is approved, we will face the daunting task of distributing it across the country. For that effort to be successful, everyone must work together, our Federal agencies, States, territories, local, and Tribal communities, and our public health agencies.

At the last O & I hearing, I asked the vaccine manufacturers about the importance of our State and local public health professionals in vaccine distribution, and they all agreed that our local trusted public health agencies are critical to successful distribution.

Now, communities across America are very diverse, and COVID is like bearer of many weaknesses in our long established public health infrastructure, but it will be more critical than ever that our State and local public health professionals are empowered to implement an effective and timely vaccine distribution.

Dr. Khan, you point to this infrastructure as a key component of a successful COVID-19 vaccine distribution and uptake, stating that, quote, We can leverage our Nation's existing vaccine distribution infrastructure to ensure efficient and equitable access to COVID-19 vaccine.

What role will they play as the partners for effective distribution? And do you want to highlight any weaknesses in that infrastructure now for us to address?

Dr. KHAN. Thank you, Congresswoman Castor.

So let me start by saying that we don't need a vaccine, all right. We know from experience from China, Vietnam, Thailand, New Zealand, Taiwan that you can get pretty much zero cases based on good public health practice, and those would be the CDC guidelines that I discussed previously in guidance.

So we know—a vaccine is critical and will help do this, but we know we can do this without a vaccine with the public health tools we have today if we wanted to. And critical to make that happen is that we have strong State and local, Tribal, and territorial infrastructure to do what needs to be done in terms of trace, isolate, contact, and ensure community engagement around wearing masks, social distancing, and handwashing.

This same infrastructure will be put to the test as we try to undertake the most complex vaccine national campaign we've ever done before. And Dr. Offit and others have highlighted why it's going to be more difficult than what we had done, for example, in 2009.

So do they have the people that are necessary to do all of this? And this is not just the epidemiologists. This is the epidemiologists, health communications, the laboratory people, the emergency planners, the public health advisors.

I mean, it's a complete public health core of people that we need to make sure they have and the associated resources with those people to ensure that this vaccine is well planned, can get out, has a need to get out within our communities.

Ms. CASTOR. Dr. Gayle, what is your view? You've devoted your life's work to public health and boosting our trusted authorities in that infrastructure. What do we need to be focused on right now?

Dr. GAYLE. Yes. Well, I would just add to what Dr. Khan has already said is that what we really need to do is to make sure that we make it possible for the systems that we know have delivered for decades and decades have what they need to be successful, you know.

And so all of the things that people have already talked about around building those systems, you know, starts with building the confidence in those systems, adequately funding those systems, making sure that we have the personnel, and then making sure that we have the data systems in place that are going to be so important for continuing to track the distribution. Also I think—

Ms. KUSTER. So, Dr. Gayle, I'm afraid. I'm afraid because I have watched in my home State of Florida over the past decade where the public health agencies, they've let them wither on the vine, and we don't have the same kind of infrastructure in place. So what can we do about that?

Dr. GAYLE. Yes. Well, I think, you know, part of it starts with having the right kind of national leadership in place. You know, it's always been important for vaccine efforts that we've had a strong CDC, that the other agencies that are involved in the immunization programs are fully funded, have the support that they need.

So it starts with national leadership, national guidelines, which is what the States, territories, and tribal leaders look to to be able to then do what they do at the State, local, and territorial level.

So, you know, you have to have those systems in place with the national guideline, the infrastructure, and then make sure that those are then being partnered with the State, local, and territorial leaders, who really are the ones who can get to the people and make sure that these programs are implemented.

But it takes having that whole system. You can't have the fractionated, fragmented system. You need the whole system working in tandem.

Ms. CASTOR. Thank you very much.

Ms. DEGETTE. I thank the gentlelady.

The Chair now recognizes Mr. Duncan for 5 minutes.

Mr. Duncan?

Mr. DUNCAN. Thank you, Madam Chair.

A hearing entitled, Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust, has taken a lot of different paths today, and it's been very interesting to hear the comments from my colleagues in Congress but also the panelists.

I thought Mr. Khan's comments recently about, we don't need a vaccine, we can do all these other things, and we're spending billions of dollars on development of a vaccine. And I don't disagree with him. I believe in herd immunity. I believe in taking those necessary steps. We have a flu vaccine too. We could take a lot of those same steps and probably eliminate a lot of folks catching the flu, but yet we push a flu vaccine every year. So—and it's just kind of interesting to hear the banter back and forth.

I agree with Markwayne Mullin. Y'all talk about how this thing, you're not trying to politicize it, but you're doing exactly that by pointing out that the President said this, that, and the other. I will say one thing about the President. He's a real estate developer and a businessman who had to rely on the CDC experts, epidemiologists like Dr. Fauci, to give him the advice, and they have been all over the board. So if they're advising the President and he seems to have been all over the board, things he's said, it's because of the advice he's been given by nonpartisan members of the CDC. So—and other organizations that advise him.

I want to ask Dr. McClellan. You know, I understand that FDA Vaccines and Related Biological Products Advisory Committee, which is an independent forum of government—independent from the government, and pharmaceutical companies, they review and evaluate data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products. My question is this: Why should the American people have confidence that this committee will provide unbiased recommendations regarding a COVID-19 vaccine to the FDA Commissioner when we've seen so much partisan rhetoric from all fronts, not just my colleagues, from Members of Congress, but really the media and other groups? How can we have confidence as the American people that this committee will provide unbiased recommendations, Dr. McClellan.

Dr. MCCLELLAN. I have a lot of confidence in the committee, and it goes from my own experience. You know, I was FDA Commissioner not at a time of this level of public health emergency but through a whole series of public health emergencies, including dealing with the first coronavirus, SARS.

And, you know, the agency is used to getting pressure and different views, both political pressures and different scientists somehow—sometimes have different views and different interpretations of the evidence. As well, the evidence evolves over time, so what we thought might be the best answer, you know, in February is not what we—

Mr. DUNCAN. You know, wait a minute. Let me—let me ask you—let me stop you right there, Dr. McClellan, and then to say, you’ve just said this was—basically, I know it’s a novel coronavirus known as COVID-19, and we actually were learning things about the virus from the time it came on the scene in January until today, that things that we learn, we shift course, right? So they’re saying the President has lied to the American people, basically shifted course based on the knowledge that we learned about the virus. Would that not be fair to say?

Dr. MCCLELLAN. Well, I think to your question is, do I trust the advisory committee? I trust that they will bring all this information together, they’ll use the FDA’s expert oversight and experience to enable FDA to make an informed decision that reflects all of the science. And that’s a process that I think we should have a lot of confidence in.

Mr. DUNCAN. So let me talk to Dr. Offit. In the last vaccine hearing back in July, I questioned a witness on how they would create a vaccine that is safe and effective for the most vulnerable population. We know who the most vulnerable are, and that’s the 60-plus population, especially those with underlying health issues or comorbidities.

In an interview you did with MetScape, you stated, regarding individuals in the 65-and-up age group: I can’t see how anybody—the Data Safety Monitoring Board or the FDA vaccine advisory committee—would ever allow a vaccine to be recommended for that group without having adequate data.

My question to Dr. Offit, do you stand by that statement today?

Dr. OFFIT. Sure. I’m on the FDA’s vaccine advisory committee. I mean, if you wonder how we operate, I can tell you how we operate. We operate as scientists, clinicians, academicians. That’s what we are. Politics doesn’t enter into that at all. We are given a—

Mr. DUNCAN. Do you think Dr. Fauci has operated as a scientist?

Dr. OFFIT. Absolutely.

Mr. DUNCAN. You think the other advisers to the President within the epidemiologist field have operated as scientists?

Dr. OFFIT. I think Dr. Collins and Dr. Redfield have operated as scientists. I think that—well, that’s what I think. You want me to tell you what—I’m sure I’m going to—

Mr. DUNCAN. Absolutely. They have operated as scientists and they have advised the President about a novel coronavirus known as COVID-19, which we have learned more and more about as the virus has been evident within the population. And so, sure, as the data comes in, remedies and other things will change.

Dr. OFFIT. Well, you always learn as you go. I mean, but the point is, you have to be open-minded to the fact—to that knowledge and adjust your recommendations based on what you learn. And now we know. I mean, what do we know? We know that masks work, even though—even though you’ll have, for example, Rose

Garden meetings, or you'll have these rallies where everybody is inside not wearing a mask. You know, you know what—

Mr. DUNCAN. What about protests?

Dr. OFFIT [continue]. Didn't work, yet still it was pushed. You know that convalescent plasma had no evidence for—that it worked, but it was pushed. I mean, it's not—I don't understand why we're having this meeting, to be honest with you. We shouldn't need this meeting, because we should trust the FDA. We don't trust the FDA largely because of what has happened with the administration's pushing the FDA to do things it shouldn't have been doing. That's why people are upset about this.

Ms. DEGETTE. The gentleman's time is expired. The Chair now recognizes Mr. Sarbanes.

Mr. DUNCAN. Just like some people are now in nursing homes when they shouldn't be there.

I yield back.

Ms. DEGETTE. The Chair now recognizes Mr. Sarbanes for 5 minutes.

Mr. SARBANES. Thanks, Madam Chair. Can you hear me? Good.

Ms. DEGETTE. I can hear you, yes.

Mr. SARBANES. So I want to return to a topic that's been touched on because I'm very concerned about this decline in confidence we see in the public when it comes to the COVID vaccine that we're working on, and we've seen that confidence decline over the last few months pretty precipitously.

In a Pew survey, only 51 percent of U.S. adults now would get a vaccine if one were available, and that's down from 72 percent in May. And a Kaiser Family Foundation poll found that 62 percent of Americans worry that political pressure from the Trump administration will lead FDA to rush in its approval of the vaccine without making sure that it's safe and effective. So that's not a good situation to be in. That's very alarming as we're trying to tackle this pandemic.

Dr. Khan, in your testimony, you emphasize, "Trust of the vaccine will be as important, if not more so, than the safety and efficacy." That's a pretty powerful statement. I wonder if you could elaborate on it.

When you're thinking of factors, you always—you think efficacy and safety are right at the top of the list, but you're saying you got to put trust up there or else it will not be effective. Can you talk to that a little bit?

Dr. KHAN. Yes. Thank you, Congressman Sarbanes. I'll give you two specific examples. So the first example was with the H1N1 outbreak in 2009, when individuals failed to get vaccine, when they thought they were supposed to get it, that they—in the end, I believe only about 27 percent of Americans got vaccinated. So we did not vaccinate as many Americans as we would have wanted for H1N1 because of this mistrust in what they were being told.

The second example I will give you is for a highly efficacious Lyme vaccine that was taken off the market in three years, not because of any concern about efficacy or side effects but due to a perceived efficacy of side effects. So there was—essentially, it lost within the public cord of trust, and that vaccine was pulled from the market.

So there's two examples right there where trust were really critical to allow us to get to the vaccine coverages we would have liked to prevent those diseases.

Mr. SARBANES. You're pointing to how tenuous this trust can be with the public and how careful we have to be in the process in order to convey that sense of comfort and safety and efficacy that will allow people to take advantage of this opportunity when it presents. And that's what's really at stake here and I think is cause for real concern.

Dr. OFFIT, you said in your testimony, the administration's politicization of science in areas like masks, hygiene, and social distancing, as well as the push to approve drugs like hydroxychloroquine or biologicals such as convalescent plasma through an EUA without clear evidence of safety or efficacy, caused some to wonder whether the same low standards would be applied to a COVID vaccine.

Answer this for me. We could go a long way towards restoring trust, could we not, if the President, if the administration, the political people, in other words, not the public health experts but the political folks who operate in this space, beginning with the President, who's, you know, leading the executive branch, if they would ally themselves with the public health experts and follow them?

It doesn't mean you don't watch over the process. It doesn't mean you don't kick the tires and make sure it's being vetted properly, but you could convey broadly your view that the public health experts, the scientists, the people that are most knowledgeable in this field, are the ones that are going to call the shots. And couldn't that very quickly, if that was the posture the President and the administration took, couldn't that begin to restore trust in a meaningful way? Could you speak to that?

Dr. OFFIT. Absolutely. I mean, people look to the President for leadership. And at the very least, as Dr. Redfield and Fauci and others have said, other countries have done much better on getting on top of this pandemic, and we have—and the biggest reason is the hygienic measures. That is the most powerful thing to do. That is more powerful than vaccines.

I mean, as I'm walking down the halls a couple weeks ago when I'm at Children's Hospital of Philadelphia, a hospital that is now loaded with children who have COVID-19, I mean, if you gave me the choice of a mask or a vaccine, I would choose the mask every time. And it's such an important tool, such a powerful tool, and I think, you know, the President could do so much to promote that, and he doesn't.

Just one other thing, by the way, I grew up in Baltimore, Maryland; huge fan of your father.

Mr. SARBANES. Thank you very much.

Madam Chair, as I yield back, I would just say that if you're fighting with the public health experts, you're politicizing this, and if you're allying yourself with them, then you're depoliticizing it.

And with that, I yield back.

Ms. DEGETTE. I thank the gentleman.

Do we have Mr. Burgess on the phone? He's next on my list, but I don't see him. Going once, going twice?

Mr. Peters, I'm going to recognize you for 5 minutes.

Mr. PETERS. All right. You surprised me, Madam Chair. Sorry about that.

Ms. DEGETTE. Sorry.

Mr. PETERS. I would just—I would just offer, a lot of the questions that I had have been answered, but just to follow along with what Mr. Sarbanes was saying, I think you and Mr. Guthrie deserve credit for putting on this hearing. The idea is that it not be political, but, you know—and I think to—even to throw a bone to the administration, I like the idea of the way that Dr. Fauci has characterized this warp-speed effort.

That effort, by the way, is to accelerate manufacturing once a safe vaccine is developed. And he's emphasized over and over again that the risk that we're taking is a financial risk, and it's—and I think that's totally appropriate. So that once you have a formulation, that you would be able to hurry up in making it available. I think that makes all the sense in the world.

But I do think it's important for all of us—and you may call this political—if anything you say against President Trump is necessarily political, I suppose it's political. But it's necessary for us to say, you can't set a date for this vaccine to be safe. That's something that has to follow through the process of—that we've developed over many years and which we're not just lucky to have, but we're smart to have in our country, to develop these vaccines. And we have the confidence that our public health infrastructure, from research to industry, can come up with a vaccine. I think we all believe that that's true. We'd maybe like to see a one-dose vaccine.

But in any event, I don't think it's—I don't think it's inappropriate to call out any politician who suggests that that timeline should be modified to fit a political schedule. And I think that's absolutely appropriate. So I would just say, I appreciate the testimony of the witnesses. And I'll yield back.

Ms. DEGETTE. I thank the gentleman, and I want to agree with your comments.

Do we have Ms. Clarke on the phone?

Oh, there she is. Ms. Clarke, you're recognized for 5 minutes.

Ms. CLARKE. Thank you so much, Madam Chair.

I've been listening attentively, and so much of the concerns that we've had have been—have been responded to. But I want to raise the issue, being a New Yorker who was at the epicenter of this outbreak, around things that we can do to really drill down on how we continue to protect ourselves. I'm concerned about the mixed messaging around the public health protocols that have been working in tandem with our awaiting of a vaccine.

We know that today's hearing focuses on what much of the world is eagerly anticipating: The approval of a safe and effective vaccine for COVID-19. And we're all rooting for that, but we all must keep in mind the bigger picture.

Public health experts have been warning for months that an eventual vaccine, while critical, will not be a silver bullet that instantly kills off this pandemic. And I really want us to drill that home with the American people when I see there being some retreating from the initial protocols that has brought New York City down to record lows. And we're beginning to see small upticks. It's

because, I believe, people are beginning to relax around those public health protocols.

So, Dr. Jha, we can all agree that a vaccine will be a critical tool in this fight. Why won't this be like flipping a switch? Will a vaccine alone be enough to stamp out this virus or will we still need to rely on other public health measures to some extent?

Dr. JHA. So, Congresswoman, thank you for that critical question. And, of course, we all wish it would be like a light switch that we could flip on, life would go back to 2019, and we could move forward. There are several reasons why it won't be that way.

First of all, even under the most optimistic scenarios, I don't expect the vaccine to be 98 or 100 percent effective. If it's 70 or 80 percent effective, that would be terrific. There's so little we know about what will happen after you're vaccinated, about your ability to transmit to others. And so it may be that you're vaccinated, you may even be protected, but you may still be able to transmit to others.

It is highly unlikely that 95 percent of Americans will get vaccinated. In a good year, we get 60, 65 percent flu vaccine uptake. But given all these issues of hesitancy, even if we're effective at addressing them, a lot of people won't take it.

So if you have 70 percent of Americans, let's say, get the vaccine, which would be wonderful, and 70 percent efficacy, that doesn't get you kind of population level everything is done. But let's be clear, it will be immensely helpful. It will allow us much of our lives back, but there will be some high-risk things we're going to need to continue to manage very carefully.

We're going to have to continue probably avoiding large indoor gatherings without masks. But I think a lot of the things that we care most about—schools and work—a lot of that will be possible again. And that's why the vaccine is so incredibly important. But it is not a silver bullet. And even into 2022, 2023, we'll still be dealing with this virus, though hopefully it will be much better than where we are today.

Ms. CLARKE. Thank you.

Dr. Khan, in your testimony you state, and I quote, "we cannot wait for a vaccine to contain this outbreak," that we must use, and I quote, "the public health tools we already have available." So how does a vaccine fit into the larger public health strategy for fighting COVID-19 if it will not be a silver bullet and instantly end the pandemic?

Dr. Khan, you have to unmute.

Dr. KHAN. Thank you, Congresswoman Clarke. I think Dr. Jha has very nicely and succinctly stated why vaccine itself is insufficient. Vaccine needs to sit on top of a public health response. We know that this public health response can contain disease from experiences in not just now multiple countries but what we actually saw in New York and what we're seeing in a lot of the northeast.

So we know these public health measures by trusted guidance, by trusted CDC scientists can make a difference. We know what the control tetra is. There's four things you need to do. We've known this from back in January. The first is integrated, coordinated, local, State, national leadership, that's evidence-based, con-

sistent messaging, looking at metrics. That's number one is leadership.

Number two is drive down community transmission, with trace, isolate, and quarantine people.

Number three, increase community engagement. That's masks, hand-washing, social distancing.

And number four, which we're actually doing a very good job at, is decrease deaths amongst people who unfortunately still get infected. And our case management has markedly improved, and our options—our therapeutic options have markedly improved that we've been dropping down deaths.

But those are the four things that we need to do, and we still have not fully implemented those in the United States yet, which is why we see 750 deaths a day, and why we can't wait for the vaccine to drop these deaths down to zero or as close to zero as we can get.

Ms. CLARKE. Thank you very much.

Madam Chair, after having experienced what I did in New York City, it pains me to see the rest of the Nation going through what it's going through, that they have not learned from our experience and what we have done to keep our curve flat. I hope that this discussion today, in collaboration with the vaccine, will really provide a guide, a roadmap, to those portions of the Nation that are still struggling with the answer to keeping Americans safe.

And I yield back the balance of my time.

Ms. DEGETTE. Thank you so much.

I believe now all of the members of the subcommittee have asked their questions, and I'm now pleased that we're joined by several members of the full committee who are not subcommittee members. And I'm going to start with Congressman Carter.

Congressman, you're recognized for 5 minutes.

Mr. CARTER. Thank you very much, Madam Chair, for allowing me to participate.

Let me begin by saying that, you know, as a practicing pharmacist for over 30 years, confidence was extremely important. When I recommended a product to—an over-the-counter product to a patient, it was important for me to be confident and to exude confidence that this was going to work for that patient.

So, you know, having said that, we've spent a lot of time today talking about the politicizing, if you will, of this whole vaccine and this whole process. And I want to just say that as a healthcare professional, as a pharmacist, I find it irresponsible that Members of Congress would be doing this. This is something that we should all be together on.

I've dealt with the FDA. I have seen the process work. Over 30 years, I've seen products that were—that went all the way up to the fourth stage and then were not allowed to go any further. I've seen that happen, and that's—that has built up confidence in me in the process and knowing that the process works. So that's all I'm going to say about politicizing this whole ordeal.

I want to talk about something that's very important, and that is distribution of this, and making sure that we have the process in place, specifically, the critical aspect of allowing pharmacists to be able to administer this vaccine.

Dr. McClellan, I want to ask you, 95 percent of all Americans live within five miles of a pharmacy. Pharmacists are the most accessible healthcare professionals in America. In order to make sure that when we get this vaccine safe and effective and when it is out there, in order to make sure that it gets out, would you agree that pharmacists need to be able to administer this COVID-19 vaccine?

Dr. MCCLELLAN. Yes, Representative, I agree. We've got experience in the pandemic of pharmacists playing a critical role in access to testing and helping people respond more quickly, get greater access there, in helping with flu vaccines and other issues that also play into the pandemic as we talked about already today.

And they're also an important part, as you've said, of that trust. People still trust their health professionals, their doctors, their pharmacists, even if it's gone down for FDA unfortunately, and that's another check on making sure that we're going to really have an effective vaccine that can be brought to the public. So pharmacists have a critical role to play in this.

Mr. CARTER. Well, I appreciate that. I always tell, one of my favorite stories is the fact that I went from being a pharmacist, the second most trusted profession in America, to being a Congressman, the second least trusted profession in America. But the point I'm trying to make here is that it is important for pharmacists to be able to administer that.

Now, we've got a situation where a lot of the States have authorized it, but we need a blanket policy, if you will, so that we could have all pharmacists, whether it be independent retail or chain retail, to be able to administer this in order to get it out quickly.

Dr. McClellan, you were a former CMS Administrator, and I wanted to ask you, you're aware of the issues that deal with pharmacists getting reimbursed and being able to bill Medicare for these types of things. This has led to a lot of problems. And right now, we're trying to get a temporary pharmacist provider status so that pharmacists will be able to get reimbursed for administering these vaccines. Obviously, we've got to have insurance, we've got to have coverage, everything that we should have, in order to administer these vaccines. That is something we've been working with CMS with in trying to get that done.

Do you agree that Congress should grant temporary authorization for pharmacists provider status to be able to administer this vaccine?

Dr. MCCLELLAN. Well, Representative, if that's what it comes to. As you know, CMS has authority to expand scope of practice and coverage in a public health emergency. When I was there, we did that in circumstances like in Hurricane Katrina. So there are some precedents for handling this administratively.

But I think this goes to one of the themes from today, is that while there seems to be broad agreement that FDA's processes around approval and to make a vaccine available are in good shape—they're sound, they're science-based—we all have work to do together on the distribution and access to the vaccine, where that depends a lot on—you know, I'd love to see more activity at the State level, the local level, focusing on that, since we do have a good program in place for the safety of the vaccine itself.

Mr. CARTER. Right. Well, Madam Chair, again, this is—this is not a partisan issue with pharmacists being able to be granted provider status in order to distribute and to administer these vaccines, and I would solicit your help, as well as my colleagues on the other side of the aisle, as well as everyone on this committee, to be able to help us to get CMS to grant temporary provider status for pharmacists to be able to administer the vaccines.

And I thank you, and I yield back.

Ms. DEGETTE. I think—Mr. Carter, I think you raise an excellent point. Millions of Americans get their flu shots right now at pharmacies, so we will work together with you on that.

Mr. CARTER. Thank you.

Ms. DEGETTE. The Chair is now pleased to recognize Mrs. Dingell for 5 minutes.

Mrs. DINGELL. Thank you, Madam Chair, and thank you for allowing me, like you allowed my colleague from Georgia, to wave on. And I'd just like to tell my colleague from Georgia, when we know this vaccine is safe, I trust him to have him give it to me.

But that's one of the things that people have been talking about all day and—both members and the witnesses—about ensuring that any eventual COVID-19 vaccine is safe and effective, and making sure it's available is going to be critical when we know it's safe.

Given the magnitude of this challenge, I appreciate the committee's constructive role in helping shed light on the challenges we face as vaccine candidates progress into Phase 3 clinical trials.

Dr. Jha, I wanted—you noted in your testimony that while we sometimes accept a certain level of potential harm in any experimental treatments for those who are severely ill, vaccines are given—

[Video malfunction.]

Dr. JHA. Am I frozen?

Ms. DEGETTE. I believe we've lost—

Mrs. DINGELL [continue]. FDA's—

[Video malfunction.]

Can you hear me?

Ms. DEGETTE. Yes, we can hear you now.

Dr. JHA. So I believe I have the gist of the Congresswoman's question, so I can take a shot at it.

Mrs. DINGELL [continue]. Analysis of whether to authorize a COVID-19 vaccine, which as you point out would—

[Video malfunction.]

Ms. DEGETTE. OK.

Mrs. DINGELL. Can you hear me?

Ms. DEGETTE. You know what, Debbie, Dr. Offit thinks that he gets the gist of your question, so we'll go ahead and have him answer.

Dr. JHA. Yes. I believe—

Mrs. DINGELL. OK.

Dr. JHA. I think she was directing that to me.

So, Congresswoman, I think the question is really important, and this is an important point that I think American people need to understand, is that we do use a different bar for using emergency use authorization for therapies because these are for sick people who

otherwise might die and you have a lower threshold for what you would call effectiveness.

And when you give vaccines, you're giving it to healthy people. And we know how to protect healthy people without a vaccine. We can protect healthy people by having people wear masks, by doing social distancing, by all the things that we know about.

And so you have to have a relatively high bar for authorizing a vaccine. This is a basic principle of medicine, of first do no harm. Whenever you intervene on healthy people, you have to have very clear evidence that you're going to do much more good than you are harm to that person. And that is why one of the reasons why we've all have said that, and actually the processes at the FDA around vaccines have acknowledged this and I think have been built around this, but it's been really critical to all of us that those processes be followed in the COVID-19 vaccine development and approval.

Mrs. DINGELL. And so I am not an anti-vaxxer, let me make that clear, but I'm a swine flu, Guillain-Barre person, so I did——

[Video malfunction.]

Ms. DEGETTE. You're frozen again.

Mrs. DINGELL. I'll yield back.

Ms. DEGETTE. OK. Thank you.

And all members can submit questions for the panelists in writing, so we can have you go ahead and do that.

The Chair now recognizes Mr. Bilirakis, if he is still with us.

Mr. Bilirakis?

Ms. DEGETTE. OK. I see he's sitting down.

Mr. BILIRAKIS. What we're trying to do is get this——

Ms. DEGETTE. Mr. Bilirakis, you need to unmute.

Where did he go?

OK. We've lost Mr. Bilirakis, and so I'm going to recognize Mr. O'Halleran for 5 minutes.

Mr. O'HALLERAN. Well, thank you, Madam Chair, I appreciate that. And thank you to the panel for all their great conversations and information that they've put forward this morning and this afternoon.

Over the past six months, this committee has held multiple hearings featuring public health experts and officials, as well as witnesses from pharmaceutical companies involved in the development and manufacturing of the vaccine, while discussing the public health response to the coronavirus pandemic.

Through the CARES Act, and as we have seen, the government made significant investments, in a bipartisan way, in the private sector to manufacture and scale a vaccine to protect Americans from the coronavirus. And early reports on development of vaccines are promising. The release of an effective vaccine will mark a milestone in scientific progress and will serve as an effective weapon to finally defeating the public health crisis.

However, Americans are confused and scared. A Pew Research Center poll released just two weeks ago showed that only 51 percent of Americans, adults, would definitely, or probably, get a COVID-19 vaccine if it were available today. These numbers represent a 21 percent drop from survey numbers released in May. This has the potential to be a massive—of massive concern.

I also want to address the issue of what this means to development of future vaccines and future medicines as we go down a path of injecting politics into this process. This is about scientists and researchers and the process as it has been for many, many decades. In my mind, we need—much transparency is needed in the vaccine— from the vaccine manufacturers, our public health agencies, like CDC, FDA, and NIH, so that the public knows the vigor and the scientific discovery that are going into the development of these products.

Unfortunately, we're seeing the current process that has casted doubts on our apolitical public health agencies with new stories being released daily. Clear and straightforward information from our leaders is necessary to ensure that Americans are vaccinated when these products are brought to market.

Further communication is also needed from the pharmaceutical companies, though, and their role is critical, and their business depends on public trust that their vaccines and medications work as intended. The American people need unprecedented transparency from pharmaceutical companies to explain what the various trial stages mean, what possible side effects are, and eventually when a vaccine is approved, are the individuals who may be given the drug, are they compromised in any way. This first vaccine will not be the last vaccine and hopefully will not be the only vaccine.

Dr. Jha, I would like to ask you, you have cautioned against politicians publicly suggesting dates by which a vaccine will be available. Can you talk about how political intrusions into the vaccine development process are harming Americans' trust in our public health officials and public health agencies, and importantly, how this will be undermining the importance of Americans being able to be vaccinated when a safe and effective vaccine is approved? Thank you.

Dr. JHA. So, thank you, Congressman, for that very important question. The bottom line is that so far, the scientific integrity of the vaccine process has been superb. It's been really world-class scientists working in the private sector, working with NIH, to do what I think is an unbelievable job in bringing a vaccine forward in record time.

The problem is that when I speak to people working on the clinical trials, they can't give me a day. They don't know when a vaccine is going to be ready for—there are processes for looking at the data. There are independent boards that are going to be doing this. And what we all want is we all want a vaccine yesterday, but we want a vaccine that's safe and effective, and we've got to let the science play that process out.

And it makes me very anxious when I hear CEOs of companies who technically don't have access to the data or political leaders who are picking specific dates and saying, we're going to have a vaccine by a specific date. I know that they don't know what they're talking about. I'm hoping they're not meddling in the process, but it makes the American people deeply concerned because they don't know all of the safeguards that are in, and we all worry that those safeguards are going to be undermined.

So what I've been asking is for politicians to basically be quiet, to knock it off, to stop talking about dates, let the scientific process

move forward, and we'll have a vaccine when the scientific process, run by the FDA, and other scientists will declare, based on scientific principles, that the vaccine is ready for authorization and eventually approval, but not a day before then, unfortunately. And that's what we have to work on.

Mr. O'HALLERAN. Thank you. Madam Chair, I yield.

Ms. DEGETTE. Thank you so much.

OK. Mr. Bilirakis, you're going to have the last word. I'll recognize you for 5 minutes.

Mr. BILIRAKIS. Thank you. Thank you, Madam Chair. Appreciate it. We had technical issues. I'm sorry about that before, but thank you for giving me the time.

Dr. Gayle, I understand that you are here in your capacity with the National Academies, but given the importance of enrolling diverse populations in large-scale COVID-19 clinical trials, I wanted to ask whether your organization, the Chicago Community Trust, has undertaken any efforts to promote and encourage participation in clinical trials among racial and ethnic minorities. And if so, would you be able to share the details of those efforts?

Dr. GAYLE. Yes. Thanks so much for your question. And I would just say, you know, here in Chicago, we have an outstanding department of public health that has really wonderful relationships with the community. We continue to work with them. We have had a really close relationship with them throughout this pandemic, and we'll continue to work with our department of public health to make sure that these efforts actually serve all people.

And so we don't have specific details now but just to say that this is something that we here in Chicago feel is incredibly important, and we've always put health equity at the center of the work that we do in public health. And so, you know, we will stand by our public health department and, you know, make sure that we can be part of making sure that this vaccine, when it's available and safe, is something that is available in an equitable fashion.

And our guidelines that, you know, we're talking about in this hearing, really puts a real focus on equity and on mitigating health inequities because we know that has been so much a part of this pandemic. It's been highlighted, the long-standing health disparities that exist in this country among people of color, and so this is going to continue to be a big focus for us as an organization and clearly as something that's highlighted in our report.

Mr. BILIRAKIS. Thank you. Thank you.

My next question is for Dr. Khan. Can we reach out to communities—how can we reach out, tell us how to reach out to communities and groups that are disproportionately affected by COVID-19 but have high rates of vaccine hesitancy. And who are the most effective messengers to these communities? I think this is so vitally important. Dr. Khan, if you could respond, I'd appreciate it.

Dr. KHAN. Thank you, Congressman Bilirakis. So I would say you need to reach out with them for their current concerns about how the disease affects people of color disproportionately, their access to care, their access to testing. And so that needs to happen now based on those issues to develop the trust once it comes to the vaccine being available. And that needs to be done by local and State health department working with the local community organi-

zations, make sure that you're engaging those organizations, including faith-based organizations in that work.

So that's a good community engagement work you need to do. And as part of that work, you can help protect that community today with the tools that are available to us. So please, you know, make sure you make yourself available for contact tracing if somebody calls, please wear a mask, wash your hands, social distance. Right? So it's working with the community now to decrease transmission that will markedly increase the trust once the vaccine comes in to help all of our communities get vaccinated.

Mr. BILIRAKIS. Excellent, excellent.

All right. Dr. Offit, are you familiar with the vaccine hesitancy education programs? And if so, can these programs help increase public confidence and increase immunization rates?

Dr. OFFIT. Yes. No, I think most people who are [inaudible] This vaccine, hesitant or just skeptical, and they should be skeptical. I think you should be skeptical of anything you put into your body, including vaccines. I mean, if you asked me would I get a COVID-19 vaccine right now, I'd say, no, I want to see the data first, because I'm skeptical like—as is true of everybody who sits around the FDA Vaccine Advisory Board.

And so I think when that's true, I think that what you do is you use reason and logic and passion and compassion to try to explain those data, to frame those data in an emotional, human story, to let people know that a choice not to get a vaccine is not a risk-free choice. It's a choice that they take a different and arguably more serious risk. So you have to explain, here's what we know. I mean, we know, say, that the vaccine is safe in 20,000 people. That doesn't mean it's safe in 20 million people. But there are systems in place like the vaccine safety data link and others to find those rare adverse events when they occur.

We don't know—we know this vaccine, let's say, is 75 percent effective, but we don't know for how long it's effective. But we will know that over time. And so then the question when you launch a new vaccine is not whether you know everything, you don't know everything. The question is when do you know enough. And of those things that you don't know, how are you going to find them out in the near future. And I think with most reasonable people, what I would call vaccine skeptics, you can do that.

I think there is a group, and they're a much smaller group, although arguably disproportionately loud, who I would call anti-vaccine activists. I mean, these are largely conspiracy theorists who just believe that the pharmaceutical companies control everything, control the government, control the medical establishment. I just don't think you can reason with them. I mean, as Neil deGrasse Tyson says, if someone comes to a conclusion that—without using logic or reason, you're not going to talk them out of it using logic or reason. I think that's true here too.

So I think most of the people who I talk to, I'd say 85 percent of the people who are concerned about vaccines are reasonably concerned and can be talked, I think, talked down, as long as you provide data in a clear, compelling, and compassionate way.

Mr. BILIRAKIS. Thank you very much. I appreciate it.

I yield back, Madam Chair.

Ms. DEGETTE. I thank the gentleman.

And I want to thank all of the witnesses. I think I can speak for everybody on both sides of the aisle here that in agreeing with what Dr. Jha said, which is the integrity of the research process that we've had so far has been superb. We have the pharmaceutical companies working at breakneck speed through Operation Warp Speed, and we're hoping that we'll get a vaccine as quickly as possible, but that we really can't—I think, Dr. Jha, as you and the other panelists said, we cannot force a timeline, and all of us just have to be ready to accept a timeline. We hope it's fast, but we can't be stating dates. And politicization includes, not just meddling in the research process, but also announcing deadlines or timelines before they're—before they're really appropriate.

So I think it's just imperative that we follow the process. It's imperative that the public has confidence, and that's what this hearing was all about today.

Frequently people ask me, why do you do oversight hearings? And the reason we do oversight hearings is to shine the light. Because sunlight is the best disinfectant, and we think the more we have experts like you coming and talking about the process and what we need to do, then the more likelihood it is that we will have a process that will not be meddled with and that will produce not one, but we hope more, safe and effective vehicles.

So I want to remind Members that they have ten business days to submit additional questions for the record to be answered by the witnesses who have appeared before the subcommittee—looking at you, Representative Dingell—and I also want to ask that the witnesses respond quickly to any such questions should you receive any.

We have some documents that have been asked for the record. We have Mr. Walden's request, the second wave project report on vaccines and therapeutics from the committee's minority staff, dated July 1, 2020; the clinical trial protocols from four COVID-19 vaccine manufacturers—Moderna, Pfizer, AstraZeneca and Janssen vaccines; the letter signed by nine drug companies pledging the safety of any COVID-19 vaccine, dated September 8, 2020; the FDA guidance to industry on COVID-19 vaccines, dated June 30th 2020; a USA Today opinion from senior FDA career staff, dated September 10, 2018. We have The Washington Post opinion from seven former FDA Commissioners on the Trump administration undermining the credibility of the FDA, dated September 29, 2020, which I offered; and then we have the Oxfam report on the world's COVID-19 vaccine supply, dated September 17th, 2020.

Without objection, these articles and information will all be entered into the record.

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. And with that—thanks again to everyone—this subcommittee is adjourned.

[Whereupon, at 2:21 p.m., the subcommittee was adjourned.]



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## following the science to protect public health in pandemic

*We are committed to making decisions guided by the best evidence. Our approach has been and must remain the gold standard that all can rely upon.*

**Patrizia Cavazzoni, Peter Marks, Susan Mayne, Judy McMeekin, Jeff Shuren, Steven Solomon, Janet Woodcock and Mitch Zeller**

Opinion contributors

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A lot has been said and written recently about the Food and Drug Administration. The integrity and independence of the agency have been called into question.

We are the senior career civil servants who direct the work of the various centers at the FDA. Together we are responsible for over 17,000 employees, and among us we have over 100 years of experience at FDA. We care deeply about our agency, its mission and its people.

The current FDA was created about a decade before the 1918 pandemic. Congress established our predecessor, then in the Department of Agriculture's Bureau of Chemistry, to protect the public from unsafe foods and remedies. Since then, the scope of our work has increased to address emerging public health issues, promoting innovation while ensuring safety for the products that we regulate. The foundational and fundamental principles of the FDA, however, remain steadfast: to protect and promote the health and well-being of the American public, and to base our decisions in support of our public health mission on sound science.

### **COVID challenges for FDA**

Over the years, the FDA has encountered numerous challenges and criticisms. We understand that — it comes with the territory. It is not possible for an agency with the impact and reach of the FDA to do its job without inviting controversy and disagreement, particularly when health or even life is at risk. Nevertheless, when protecting the public health is our beacon, and sound science is our guide to navigate controversial waters, we stay true to our mission as we fulfill our duty to the public.

The current pandemic presents new challenges for our country, for the entire health care community and all levels of government, including the FDA. We continue to make decisions



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scientific information can be openly debated. The FDA is at its best when its scientific, clinical and other experts are free to do what they do best — follow the science to address the public health issues and revise policy if the understanding of the science changes.

We absolutely understand that the FDA, like other federal executive agencies, operates in a political environment. That is a reality that we must navigate adeptly while maintaining our independence to ensure the best possible outcomes for public health. When it comes to decisions to authorize or approve the products we regulate, or to take appropriate action when we uncover safety issues, we and our career staff do the best by public health when we are the decision-makers, arriving at those decisions based on our unbiased evaluation of the scientific evidence.

***An apolitical process:*** *Secretary Alex Azar on how HHS is developing a COVID-19 vaccine at 'Warp Speed'*

Maintaining the American public's trust in the FDA is vital. If the agency's credibility is lost because of real or perceived interference, people will not rely on the agency's safety warnings. Erosion of public trust will leave consumers and patients doubting our recommendations, less likely to enroll in clinical studies or to use FDA-regulated products when they should to maintain or improve their health. This is problematic under normal circumstances but especially if we are to ultimately overcome COVID-19. Protecting the FDA's independence is essential if we are to do the best possible job of protecting public health and saving lives.

## **Health of Americans is our beacon**

The FDA staff is dedicated to advancing public health. We are physicians, pharmacists, nurses, engineers, veterinarians, nutritional scientists, microbiologists, chemists, toxicologists, and many other professionals and support staff who share a common mission. All of us have dedicated our professional lives to public health. Over the years we have encountered opinions or ideas brought forward by our stakeholders that have initially seemed promising, only to be found flawed once subjected to sound scientific review. It is why we are always learning and innovating, be it in the regulation of medical products, foods, or tobacco products. It's why we have a scientific method. And it's why we have the FDA.

***Coronavirus journey:*** *Don't count on herd immunity for COVID-19 yet. A vaccine is the best way to get there.*



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the FDA's 17,000 plus career staff will continue to work to the best of our ability on their behalf, and with their health and well-being as our beacon.

*The co-authors of this column are the senior career executives at FDA who oversee all the work of the agency's centers and field operations. The views expressed here are exclusively their own and do not represent the position of the FDA, the Department of Health and Human Services or the U.S. government.*

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## Biopharma Leaders Unite to Stand with Science

September 8, 2020

– Nine CEOs sign historic pledge to continue to make the safety and well-being of vaccinated individuals the top priority in development of the first COVID-19 vaccines –

NEW YORK--(BUSINESS WIRE)--Sep. 8, 2020-- The CEOs of AstraZeneca (LSE/STO/NYSE: AZN), BioNTech (NASDAQ: BNTX), GlaxoSmithKline plc (LSE/NYSE: GSK), Johnson & Johnson (NYSE: JNJ), Merck (NYSE: MRK), known as MSD outside the United States and Canada, Moderna, Inc. (Nasdaq: MRNA), Novavax, Inc. (Nasdaq: NVAX), Pfizer Inc. (NYSE: PFE), and Sanofi (NASDAQ: SNO), today announced a historic pledge, outlining a united commitment to uphold the integrity of the scientific process as they work towards potential global regulatory filings and approvals of the first COVID-19 vaccines.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20200908005282/en/>

All nine CEOs signed the following pledge:

*We, the undersigned biopharmaceutical companies, want to make clear our on-going commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.*

*The safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, such as the United States Food and Drug Administration (FDA). FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. FDA's guidance and criteria are based on the scientific and medical principles necessary to clearly demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.*

*Following guidance from expert regulatory authorities such as FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we pledge to:*

- *Always make the safety and well-being of vaccinated individuals our top priority.*
- *Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.*
- *Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.*
- *Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.*

*We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.*

Together, these nine companies have collectively developed more than 70 novel vaccines that have helped to eradicate some of the world's most complex and deadly public health threats, underscoring their experience in clinical development and regulatory rigor, as well as their longstanding commitments to patient safety and public health.

### About AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit [astrazeneca.com](http://astrazeneca.com) and follow the Company on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

### About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit <https://biontech.de/>

### About GlaxoSmithKline

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

**About Johnson & Johnson**

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at [www.jnj.com](http://www.jnj.com). Follow us at [@JNJNews](https://twitter.com/JNJNews).

**About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://twitter.com/JanssenGlobal) or [www.twitter.com/JanssenUS](https://twitter.com/JanssenUS).

**About Merck**

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](https://twitter.com/Merck), [Facebook](https://www.facebook.com/Merck), [Instagram](https://www.instagram.com/Merck), [YouTube](https://www.youtube.com/Merck) and [LinkedIn](https://www.linkedin.com/Merck).

**About Moderna**

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) and the Coalition for Epidemic Preparedness Innovations (CEPI). Moderna has been named a top biopharmaceutical employer by Science for the past five years. To learn more, visit [www.modernatx.com](http://www.modernatx.com).

**About Novavax**

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

For more information, visit [www.novavax.com](http://www.novavax.com) and connect with us on [Twitter](https://twitter.com/Novavax) and [LinkedIn](https://www.linkedin.com/Novavax).

**About Pfizer: Breakthroughs That Change Patients' Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.Pfizer.com](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@PfizerNews](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/Pfizer), [YouTube](https://www.youtube.com/Pfizer) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**About Sanofi**

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

For further information, please visit [www.sanofi.com](http://www.sanofi.com)

#### **Forward Looking Statements of BioNTech**

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning BioNTech's efforts to combat COVID-19. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; the ability to effectively scale our production capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which is available on the SEC's website at [www.sec.gov](http://www.sec.gov). All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

#### **GSK Cautionary Statement Regarding Forward-Looking Statements**

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk Factors" in the company's Annual Report on Form 20-F for 2019 and as set out in GSK's "Principal risks and uncertainties" section of the Q2 Results and any impacts of the COVID-19 pandemic.

#### **Forward-Looking Statement of the Janssen Pharmaceutical Companies of Johnson & Johnson**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of potential preventive and treatment regimens for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

#### **Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the recent global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2019 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

#### **Forward-Looking Statement of Moderna, Inc., Cambridge, MA, USA**

This news release of Moderna, Inc. ("Moderna") contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to: statements regarding the conduct of clinical trials for Moderna's vaccine candidate against COVID-19 ("mRNA-1273"), the process for obtaining regulatory approval for mRNA-1273 in the United States and other jurisdictions, and the global supply of mRNA-1273. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. These risks, uncertainties, and other factors include, among others: no commercial product using mRNA technology has been approved, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with Moderna's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking

statements are based on Moderna's current expectations and speak only as of the date hereof.

#### Forward-Looking Statements of Novavax

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2019, and Quarterly Report on Form 10-Q for the period ended June 30, 2020, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [sec.gov](http://sec.gov), for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

#### Pfizer Disclosure Notice

The information contained in this release is as of September [8], 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19 and the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from current and future preclinical and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for any potential vaccine candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

#### Forward Looking Statement of Sanofi

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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Source: AstraZeneca and BioNTech and GlaxoSmithKline plc and Johnson & Johnson and Merck and Moderna, Inc. and Novavax, Inc. and Pfizer Inc. and Sanofi

## **7 former FDA commissioners: The Trump administration is undermining the credibility of the FDA**



The Food and Drug Administration building is seen from a bus stop on the agency's campus in Silver Spring in 2018. (Jacquelyn Martin/AP)

Opinion by **7 former FDA commissioners**

September 29, 2020 at 5:16 p.m. EDT

*Robert Califf, Scott Gottlieb, Margaret Hamburg, Jane Henney, David Kessler, Mark McClellan and Andy von Eschenbach are all former commissioners of the Food and Drug Administration. Kessler is an adviser for the Biden campaign. Gottlieb and McClellan serve on the boards of Pfizer and Johnson & Johnson, respectively, both of which are developing covid-19 vaccines.*

With our country having passed the grim milestone of 200,000 covid-19 deaths, losing the equivalent of the entire population of Salt Lake City, the Food and Drug Administration might soon face one of its most important decisions in our lifetimes: the authorization of a [coronavirus](#) vaccine. A vaccine is urgently needed to reduce the health impacts of the virus and help Americans return to normalcy.

But a safe and effective vaccine will not be enough; people will also have to choose to take it. This depends on widespread confidence that the vaccine approval was based on sound science and not politics. If the White House takes the unprecedented step of trying to tip the scales on how safety and benefits will be judged, the impact on public trust will render an effective vaccine much less so.

These are matters of medicine over which political leaders have no expertise, which is why our nation has long recognized the importance of having sound science drive public health and safety decisions. In 1906, when President Theodore Roosevelt signed a bill to create what is now the FDA, one of his first actions was to delegate the oversight of food and drug safety to the agency's scientists. In the 114 years since, FDA professionals have created a consumer safety net that has been a worldwide model for evidence-based public health policy. Indeed, for decades, when we and our predecessors spoke as FDA commissioners about issues of regulation and people's health, the public knew we were speaking on behalf of experts whose judgments were grounded in science.

*[Full coverage of the coronavirus pandemic](#)*

That is changing in deeply troubling ways. The White House [has said](#) it might try to influence the scientific standards for vaccine approval put forward by the FDA or block the agency from issuing further written guidance on its criteria for judging the safety and benefits of a potential covid-19 vaccine. This pronouncement came just after key leaders at the FDA, the Centers for Disease Control and Prevention and the National Institutes of Health all publicly supported that guidance.

The White House statements came on the heels of other concerning actions that could impact the FDA's scientific standards. On Sept. 15, Health and Human Services Secretary Alex Azar [revoked](#) the FDA's authority to establish rules for food and drug safety, instead claiming that sole authority for himself. This [came in the wake](#) of acknowledged acts of political influence on the FDA's coronavirus communications, significant misstatements by the secretary and [other political leaders](#) about the benefits of hydroxychloroquine and [convalescent plasma](#), and the overruling of FDA scientists on the regulation of covid-19 laboratory tests. At risk is the FDA's ability to make the independent, science-based decisions that are key to combating the pandemic and so much more.

These actions are eroding the public's confidence. This month, an Axios-Ipsos poll found that [42 percent](#) of Americans lacked trust in FDA decision-making. Although the FDA fared far better than pharmaceutical manufacturers, and the federal and state governments, it was a striking departure from previous levels of trust. Public [confidence in the FDA](#) was once much higher.

The implications of the recent shift are potentially dire. When the FDA warns about a risk from contaminated food, will people heed it? When a new drug for cancer or heart disease is approved, will clinicians and families trust it to work? And most urgent for today: When the FDA approves a covid-19 vaccine, will Americans accept it?

The number of Americans who would be willing to take a coronavirus vaccine has declined sharply. The Pew Research Center recently [reported](#) that 78 percent expressed concern that the approval process will be too hasty. Only 21 percent of respondents said they would *definitely* take the vaccine — half the percentage that said this only four months ago.

If the FDA makes available a safe and effective vaccine that people trust, we could expect to meaningfully reduce covid-19 risk as soon as next spring or summer. Without that trust, our health and economy could lag for years.

[\*We are interested in hearing about how the struggle to reopen amid the pandemic is affecting people's lives. Please tell us yours.\*](#)

Despite recent political actions, we continue to have confidence in the integrity and high-quality scientific work of FDA staff. Following defined practice, each vaccine clinical trial will continue until independent oversight boards and the sponsoring manufacturers stop them. The FDA has already effectively communicated its strict standard for evidence from these trials to the manufacturers, despite comments from the White House. The health professionals whom people still trust won't recommend a vaccine that hasn't met the FDA's standards. Drug makers have also pledged to use the FDA's scientific standards.

But the perception of political influence matters. With more than 750 Americans on average dying a day from covid-19, the FDA must be supported to play its unique and essential role. Scientists should make decisions based on data, unfettered by political pressure or the intrusions of ideology or vested interests. Political intrusion only prolongs the pandemic and erodes our public health institutions.



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## Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders

Published: 17th September 2020

Wealthy nations representing just 13 percent of the world's population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates, Oxfam warned today as the health and finance ministers of G20 countries meet to discuss the global pandemic.

Oxfam analyzed the deals that pharmaceutical corporations and vaccine producers have already struck with nations around the world for the five leading vaccine candidates currently in phase 3 clinical trials, based on data collected by Airfinity.

The international agency also warned that the same companies simply do not have the capacity to make enough vaccines for everyone who needs one. **Even in the extremely unlikely event that all five vaccines succeed, nearly two thirds (61 percent) of the world's population will not have a vaccine until at least 2022.** It's far more likely some of these experiments will fail, leaving the number of people without access even higher.

The calculations expose a broken system that protects the monopolies and profits of pharmaceutical corporations and favours wealthy nations, while artificially restricting production and leaving most of the world's population waiting longer than necessary for a vaccine.

One of the leading vaccine candidates, developed by Moderna, **has received \$2.48 billion in committed taxpayer's money. Despite this, the company has said it intends to make a profit from its vaccine and has sold the options for all of its supply to rich nations** —at prices that range from \$12-16 per dose in the US to around \$35 per dose for other countries— putting protection out of reach for many people living in poverty. While it may be making real efforts to scale up supply, according to reports, the company only has the capacity in place to produce enough for 475 million people, or 6 percent of the world's population.

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9/30/2020 Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders | Oxfam International

**Chema Vera, Interim Executive Director of Oxfam International, said:** "Governments will prolong this crisis in all of its human tragedy and economic damage if they allow pharmaceutical companies to protect their monopolies and profits. No single corporation will ever be able to meet the world's need for a COVID-19 vaccine. That's why we are calling on them to share their knowledge free of patents and to get behind a quantum leap in production to keep everyone safe. We need a People's Vaccine, not a profit vaccine."

Beyond the five leading vaccine candidates, reported vaccine deals also reveal stark inequalities between countries. **The UK government has managed to secure deals on several leading vaccine candidates, equivalent to five doses per head of population. By contrast, Oxfam analysis reveals that Bangladesh has so far secured only one dose for every nine people.**

There are also large differences in the willingness of pharmaceutical companies to set aside supply for poorer nations. **While Moderna has so far pledged doses of its vaccine exclusively to rich countries, AstraZeneca has pledged two-thirds (66 percent) of doses to developing countries.** Although AstraZeneca has done most to expand its production capacity by partnering with and transferring its technology to other manufacturers, it could still only supply up to 38 percent of the global population, and only half of this if its vaccine requires two doses.

**Winnie Byanyima, Executive Director of UNAIDS and Under-Secretary General, said:** "We in the AIDS movement have seen in the past how corporations use monopolies to artificially restrict supplies of life-saving medicines and inflate their prices. UNAIDS and other members of the People's Vaccine Alliance are calling for a new approach that puts public health first by sharing knowledge and maximising supply. Anything short of that will lead to more deaths and economic chaos, forcing millions into destitution."

**The estimated cost of providing a vaccine for everyone on Earth is less than 1 percent of the projected cost of COVID-19 to the global economy.** The economic case for requiring pharmaceutical companies to share their vaccine knowledge free of patents so that production can be scaled up as fast as possible could not be clearer, the agency said.

### Notes to editors

The G20 Health and Finance Ministers meeting takes place virtually on Thursday 17 September 2020.

Nine COVID-19 vaccines are currently going through phase 3 clinical trials, of which supply deals have been made public for five. These vaccines are being developed by AstraZeneca, Gamaleya/Sputnik, Moderna, Pfizer and Sinovac. Data on vaccine supply and production has been provided by [Airfinity](#), the data and science analytics company.

Oxfam calculated the combined production capacity of these five vaccine candidates at 5.94 billion doses, enough for 2.97 billion people given that all five future vaccines will or are highly likely to require two doses. Supply deals have already been agreed for 5.303 billion doses, of which 2.728 billion (51 percent) have been bought by developed countries including the UK, US, Australia, Hong Kong & Macau, Japan,

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and the Serum Institute of India to 'accelerate' the production of 100 million AstraZeneca or Novavax vaccines is already captured within those companies' respective supply deals with the Serum Institute.

The calculation for the UK is based on Airfinity's data and includes all of the UK's published vaccine deals. The calculation for Bangladesh is based on the country's share of the doses currently available under the Covax AMC, and would be the same for all 92 AMC eligible countries if the vaccine is distributed evenly.

The People's Vaccine Alliance is a coalition of organizations and activists united under a common aim of campaigning for a 'people's vaccine' for COVID-19 that is based on shared knowledge and is freely available to everyone everywhere. The alliance is calling on pharmaceutical corporations to share all vaccine knowledge with other companies and research institutions, including through the COVID-19 Technology Access Pool (C-TAP).

The IMF's latest World Economic Outlook from June 2020 projected the cumulative loss to the global economy for 2020 and 2021 at \$12 trillion. Using data provided by the Access to Covid-19 Tools (ACT) Accelerator, Oxfam has calculated that the estimated cost to research, make, procure and distribute a vaccine to everyone on the planet could cost \$70.6 billion. Therefore, the cost of providing a vaccine for everyone on Earth is equivalent to 0.59% of cost of COVID-19 to the global economy.

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Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”

September 30, 2020

**Mark McClellan, M.D., Ph.D., Founding Director**  
**Duke-Margolis Center for Health Policy, Duke University**

**The Honorable Frank Pallone, Jr. (D-NJ):**

1. Your testimony states that, “Vaccines will not provide a short-term silver bullet under any plausible circumstances. Even as we begin to use vaccines, we will still need the other proven steps that work—masks, distancing, avoiding large groups especially indoors, and personal hygiene like hand washing and sanitizing.” What should the public expect over the next few months and coming year even if a vaccine becomes widely available? To what extent will a vaccine enable a return to pre-pandemic life?

*The availability of a vaccine will not immediately or single-handedly return Americans to their pre-pandemic lives. While a crucial part of the overall strategy for overcoming the pandemic, the use of vaccines must be accompanied by continued physical distancing and public health measures like wearing masks in order to continue mitigating the spread of virus among individuals yet to be vaccinated. Anticipating a staged distribution and access plan for vaccines, it will take an all-of-the-above approach for many months to return to any semblance of normalcy.*

**The Honorable Diana DeGette (D-CO):**

1. If any member of the Administration authorizes or approves the use of a COVID-19 vaccine prior to or over the objection of the U.S. Food and Drug Administration (FDA), or against the recommendations of the Vaccine and Related Biological Products Advisory Committee, what impact do you believe this action would have on the American people’s confidence in the vaccine?

*It remains incredibly unlikely that a vaccine will be approved by the Administration against the expert judgment of career experts at FDA. The American public should have confidence in the well-established process and multiple safeguards in place for proper regulatory review and approval of vaccines – a process that FDA has publicly committed to fully maintaining.*

**The Honorable Brett Guthrie (R-KY):**

1. Data Safety and Monitoring Boards (DSMB) meet in both open and closed sessions. Following the open session, the DSMBs convene a closed session to review emerging trial

Dr. Mark McClellan

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data. How does the industry balance both clinical trial transparency and participant confidentiality and proprietary information?

*One of the most critical considerations a DSMB makes when deciding whether to convene an open or closed session is the need to avoid sharing data that may introduce bias into the study. For example, DSMBs do not usually share data on study outcomes, since this may bias researchers and affect how the study is conducted or how the analyses are planned. However, certain aspects of the study can be discussed openly without biasing the conduct of the study: for example, information about accrual and dropout rates, how many patients were deemed eligible, and how quickly data was submitted. This information may help researchers conduct the study more efficiently and help the public better understand how the study is proceeding.*

2. At a full Committee hearing in June, FDA Commissioner Hahn said, “I can assure you that we will retain our regulatory independence. We will use the science and data that come to us, and we will use our high standards to assess the safety and efficacy of a vaccine. We have world-class experts who will continue to maintain that.” Similarly, Commissioner Hahn said, “[w]hat I can promise the American people, we will work with companies. We will work with Operation Warp Speed to provide the assistance, so the right studies are done with the right information. But we will independently look at those data and we will make a decision in the best interest of the American people with respect to safety and efficacy. We will use science and data to do that.” Commissioner Hahn made a similar commitment at a September 23, 2020 hearing before the Senate Committee on Health, Education, Labor and Pensions. Should the American people believe Commissioner Hahn when he says that the FDA will retain its regulatory independence? Why or why not?

*Yes, the American public should have faith in not only the regulatory independence of the FDA but also the commitment of its career officials and scientific experts to adhering to well-established gold standards for regulatory review and approval of a vaccine. This is based in repeated public statements to this effect by leadership and staff at FDA during the course of the pandemic, as well as decades of FDA experience at the forefront of trusted medical product regulation.*

3. At a July hearing before the Oversight and Investigations Subcommittee, Dr. Julie Gerberding of Merck stated: “And, in fact, we’re quite relieved that the FDA insisted upon applying the same high standards of safety and efficacy, even under these emergency conditions, that they would apply to any of the vaccines that we’ve prosecuted in the past.” She later added: “I think the way to think about this, really, is to understand that the FDA is not loosening any standards, so business as usual. Whatever portfolios or dossiers that we bring to the FDA have to meet these rigorous standards.” At the same hearing, Dr. Macaya Douoguih of Johnson & Johnson stated: “We also agree that the standards are appropriate, and perhaps even more stringent than some of the criteria we’ve had for some of our other products.” Do you agree with these statements about the rigor of FDA’s guidance? Why or why not?

Dr. Mark McClellan

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*I agree that FDA both has rigorous standards for regulatory review and approval of vaccines, and that the agency has demonstrated its commitment to these standards through published guidance related to COVID-19 vaccines. These guidance documents demonstrate that FDA will be holding candidate vaccines to these standards within the regulatory flexibility that the agency has under statute.*

4. In a recent opinion piece in The Wall Street Journal that you co-authored with former FDA Commissioner Scott Gottlieb, you wrote, “[w]e also reject the idea that the FDA’s professional staff can be cowed by outside influences.” You also said, “[p]olitical appointees shouldn’t intrude in these endeavors, though the FDA’s thorough and transparent process doesn’t lend itself to meddling. Any deviation would be quickly apparent. That should reassure those worried about furtive influences.” Can you please elaborate on these comments and why you believe the American people can trust the FDA to do the right thing?

*There are many well-established steps in the process for regulatory review and approval of a vaccine, including for any candidate vaccines that might be considered under an Emergency Use Authorization. First, and prior to a formal application from a manufacturer, is the analysis of independent Data and Safety Monitoring Boards (DSMBs) that help manufacturers assess the evidence being generated in clinical trials and whether or not to move forward with an FDA submission. At FDA, these steps include the typical standards for expert review and analysis by FDA’s career staff, public consultation with the independent experts that form the FDA’s Vaccine and Related Biologic Products Advisory Committee (VRBPAC), and a transparent process for reporting out the FDA’s ultimate decision. It would be very hard for political influence to overcome or override any individual step, whether the independent expert consultation with DSMBs and VRBPAC or the day-to-day adjudication of the evidence by FDA career staff. It is built to be a trusted, transparent process.*

5. In a recent opinion piece in The Wall Street Journal that you co-authored with former FDA Commissioner Scott Gottlieb, you wrote, “[t]here is concern that an [Emergency Use Authorization] EUA is a lower bar than the FDA’s rigorous standard for safety and effectiveness. Or that the EUA decision could be subject to political influence similar to some clumsy, recent intrusions into reports issued by the [CDC]. We reject the claim that a vaccine EUA inherently falls short of FDA’s gold standard review, or that the process will be hijacked.” Can you please explain why you believe that?

*As noted above, the EUA guidance documents have made it clear that FDA intends to adhere to the well-established regulatory review and approval standards and will not be lowering those standards for a vaccine EUA. It would be very hard to interfere with that process.*

- a. Has your opinion changed in light of the EUA guidance that FDA released on October 6, 2020? Why or why not?

*My opinion has not changed since the publication of the most recent guidance document. If anything, public-facing statements like that guidance document help to further ensure*

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*that FDA is adhering to its long-held gold standards for regulatory review and approval,  
and is exercising appropriate judgement in meeting those standards.*

**Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Hearing on  
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”**

**September 30, 2020**

**Ali Khan, M.D., M.P.H., M.B.A., Dean  
College of Public Health, University of Nebraska Medical Center**

**The Honorable Frank Pallone, Jr. (D-NJ):**

1. You state in your testimony that “we cannot wait for a vaccine to contain this outbreak” and that we must use “the public health tools we already have available.” How does a vaccine to prevent coronavirus disease 2019 (COVID-19) fit into the larger public health strategy for fighting the pandemic if it will not be a silver bullet and instantly end the pandemic?

We have the public health tools today to contain the pandemic as demonstrated in multiple countries worldwide: the control of triad of evidence-based and data driven leadership at all levels of government; testing, isolation, and quarantine; and engaging our communities to wear a mask, social distance, and wash their hands. The current failed national strategy is causing 700 preventable deaths a day so we cannot wait at this death clip of 20,000 deaths a month for a vaccine. We must use our available tools to stop the continued health, social and economic devastation. A vaccine will be immensely helpful in this multi-layered approach to contain the outbreak. However, a COVID-19 vaccine will not be analogous to the, for example, the highly efficacious and universally administered measles vaccine. A COVID-19 vaccine likely be 50% efficacy and, according to many surveys, about ¼ to ½ of the U.S population would be reluctant to receive a vaccine (Neergaard & Fingerhut, 2020). This a COVID-19 vaccine not a silver bullet and we will need to continue to test, trace, isolate and wear masks. To sum up, to end this pandemic we need to immediately adapt the multi-layer protection strategy used successfully in other countries and plan to continue as vaccine is made available.

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2. You stated in an National Public Radio interview in September that although the Centers for Disease Control and Prevention and the States work to provide equitable access to existing vaccines all the time “this is going to be a complex process to vaccinate potentially all Americans. And it’s very appropriate to get the planning done and make sure that states are ready for receipt of vaccine.” Based on your past experience overseeing responses to H1N1 and other public health crises, why is it so critical to have plans in place to meet the needs of communities that are at higher risk of infection or may face additional hurdles to accessing care?

In the U.S, we are witnessing a wide disparity of COVID-19 burdens and other preventable diseases among people of color, socioeconomically disadvantaged, and non-English-speaking populations due to many factors impacting access to care including; under or uninsured, transportation, timing, and cultural barriers. We must understand and address these community challenges if we want to optimize the vaccination outcomes. For example, during the 2009-H1N1 influenza pandemic, there were disparities in 2009-H1N1 vaccine uptake between Blacks and Whites as the vaccines were mainly offered in Physician offices (Uscher-Pines, Maurer, & Harris, 2011). The local health authorities pivoted to adopt new outreach strategies that offered the vaccine through multiple sites such as retail clinics and school-located clinics but still for limited periods of time which did not fully address the gap in vaccine uptake between Whites and Blacks. Thus, we must understand the preferences of the community to increase the uptake rate and cover the largest proportion of the population. If we are not proactive with our planning, we will not be able to get already under-resourced communities vaccinated.

**The Honorable Diana DeGette (D-CO):**

1. If any member of the Administration authorizes or approves the use of a COVID-19 vaccine prior to or over the objection of the U.S. Food and Drug Administration, or against the recommendations of the Vaccine and Related Biological Products Advisory Committee, what impact do you believe this action would have on the American people’s confidence in the vaccine?

Approval of a COVID vaccine outside the routine FDA and CDC safeguards will destroy trust in the vaccine and markedly decrease vaccination rates. According to many surveys conducted to determine public acceptance toward receiving COVID-19 vaccine, participants highlighted safety concerns and distrust issues are the major factors for being reluctant to get the vaccine once it is available (Neergaard & Fingerhut, 2020) (Thunstrom, Ashworth, Finnoff, & Newbold, 2020). Therefore, trust of the vaccine will be as important if not more so than the safety and efficacy which are much easier to manage.

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2. Based upon your prior roles with the Centers for Disease Control and Prevention and your expertise, please describe the role of personal protective equipment (PPE) in a wide-scale vaccination program. What kind of providers will be administering vaccines around the country, and what will their PPE needs be?

States will need PPE to protect vaccinators who will be in close proximity and at high risk of getting infected because they will not know if vaccinees are potentially infectious and may vaccinate a 100 people or more a day. CDC data for February 12 to April 9, 2020 indicated that out of the 9,282 U.S. COVID-19 cases reported among health care workers, about 55% reported contact with a COVID-19 patient only in health care settings (CDC, 2020). Thus, PPE is critical to protect our frontline health workers and give them the courage to practice their critical work in these high-risk conditions.

3. What supply challenges are facing states, territories, Tribes, and localities when it comes to preparing for a future COVID-19 vaccination program? Are they able to easily obtain the supplies needed to administer a vaccine on their own?

Earlier when the pandemic started, the country faced numerous challenges in testing and tracing, ventilators, PPE, and staffing. Once the vaccine is available, we will move to a mass vaccination that will result in additional or similar challenges but mainly in the distribution and administration of vaccines (Wang, Peng, Xu, Cui, & Williams, 2020) (Szabo, 2020). Health departments need to recruit additional health professionals to administer the shots, including nursing students, medical students, dentists, dental hygienists and even veterinarians. Health departments need to pay for supplies such as protective medical masks, gowns and gloves in order to keep vaccinators safe, with enough protective gear and syringes to do their jobs. The new coronavirus may require two doses which pose additional challenges to track recipients, remind them to receive their second shot, monitor patients and report serious side effects, and ensure they get the same brand of vaccine. Finally, according to a poll from AP-NORC Center for Public Affairs Research, only 50% of the population say they would get the coronavirus vaccine (Neergaard & Fingerhut, 2020), thus we need education campaigns to cut the speed of the misinformation and increase the vaccine coverage rate.

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4. During the hearing, Mr. Duncan stated, “I thought Mr. Khan's comments recently about, we don't need a vaccine, we can do all these other things, and we're spending billions of dollars on development of a vaccine. And I don't disagree with him. I believe in herd immunity.” Is this an accurate reflection of your testimony and prior statements and if not, please respond and clarify your position on the need for a COVID-19 vaccine and herd immunity related to COVID-19

I never proposed a herd immunity approach for containing the COVID-19 pandemic, what I proposed was a robust public health response that aims to decrease cases and deaths, not increase cases and deaths! Herd immunity, independent of vaccination, is an unethical, disastrous, and racist approach that has never been used in human history to combat a deadly infectious disease. It is only appropriate in the setting of a highly efficacious and safe vaccine for a disease with no reinfections – none of these conditions is true for COVID. Even though vaccine serve as an excellent adjunct to upgrade public health strategy, there are many countries worldwide that did not wait for a vaccine nor employ a herd immunity strategy to control their outbreaks (A Alwan, et al., 2020). They used existing public health tools; leadership, drop community transmission, and community engagement. We can implement the same strategy here in the U.S and get this outbreak controlled in less than 4 incubation periods without a vaccine.

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Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”

September 30, 2020

Paul Offit, M.D., Director  
Vaccine Education Center, Children’s Hospital of Philadelphia

**The Honorable Frank Pallone, Jr. (D-NJ):**

1. As a member of the Vaccine and Related Biological Products Advisory Committee (VRBPAC), are you confident that the U.S. Food and Drug Administration (FDA) will follow VRBPAC’s recommendations regarding potential coronavirus disease 2019 (COVID-19) vaccines? Are you confident that the President and U.S. Health and Human Services Secretary Alex Azar will adhere to VRBPAC’s recommendations?

Although it’s hard to predict how the administration will act, I have become more and more confident over the past couple of months that the FDA and HHS will follow the advice of the committee regarding approval of vaccines through an EUA. But that’s just the first step. The ACIP, which is the principle recommending body in the US for vaccines, will also independently review the vaccine data and make a recommendation, as is always the case.

2. As a vaccine development expert, what would be the benefit of a COVID-19 vaccine that is only 50 percent effective? How drastically would that improve our effort to combat this virus?

It would be a good start. Historically, the first vaccine licensed for a particular disease is often not the last best, vaccine. But a vaccine with 50 percent efficacy would offer something in the fight against this disease. The influenza vaccine is also roughly 50 percent effective.

**The Honorable Diana DeGette (D-CO):**

1. If any member of the Administration authorizes or approves the use of a COVID-19 vaccine prior to or over the objection of FDA, or against the recommendations of VRBPAC, what impact do you believe this action would have on the American people’s confidence in the vaccine?

I think Americans right now have a fragile confidence in vaccines and generally don’t trust the administration to get the science right. If the administration allowed use of a vaccine over the objections of academics and researchers who decried it, I think few people would choose to get it.

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**The Honorable Brett Guthrie (R-KY):**

1. FDA has scheduled a meeting of its VRBPAC on October 22, at which the committee will discuss the general development of COVID-19 vaccines publicly. While this meeting is not intended to discuss any particular vaccine candidates, the FDA has said the agency is also prepared to rapidly schedule additional meetings of this Committee upon submission of any Biologics License Applications or requests for an Emergency Use Authorization to further ensure transparency. Should that process further boost public confidence in the legitimacy and scientific basis of the FDA's decision on COVID-19 vaccines? Why or why not?

Yes, it should boost confidence. But we have a long way to go to again build up trust from the American public in science-based federal agencies like the EPA, FDA, and CDC given recent events.

2. Some state officials are expressing skepticism about federal reviews of potential COVID-19 vaccines, indicating that their states plan to conduct their own independent review of the clinical trial data before distributing a vaccine, despite an approval or authorization from the FDA. Do you believe that such a review by the states would be necessary? What resources and expertise would a state need to have to conduct a review of clinical trial data at the same level as the FDA?
  - a. How would such second-guessing of the FDA impact the confidence that the American people have in the FDA and any future vaccines that are approved by the FDA?
  - b. If states went in such a direction, do you think this would make the problem of vaccine confidence even worse?

I think that the fact that several states have expressed an interest in forming their own vaccine advisory committees is a terrible idea and will only sow seeds of confusion. But it's a sign of how little people think of the FDA right now. I believe that the CDC and FDA can turn this around by getting good information out there once all the data on these vaccines are available.

Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”

September 30, 2020

Helene Gayle, M.D., M.P.H., President & Chief Executive Officer  
The Chicago Community Trust

**The Honorable Frank Pallone, Jr. (D-NJ):**

1. How is the work of the National Academies of Sciences, Engineering, and Medicine’s (National Academies) Committee on Equitable Allocation of Vaccine for the Novel Coronavirus different than the traditional role in vaccine allocation by the Advisory Committee on Immunization Practices (ACIP)?

a. **RESPONSE:**

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) requested this study from the National Academies of Sciences, Engineering, and Medicine in order to provide independent, expert advice to supplement analyses and inform the decisions by the federal government and state, tribal, local, and territorial (STLT) authorities as COVID-19 vaccination plans and guidelines are created. The study conducted by the National Academies is an independent, nongovernmental study. Given that the COVID-19 pandemic is such an important, complex, and unprecedented issue, it makes sense that the federal government would seek advice from a broad array of expert sources in order to decide how to best move forward. The National Academies has a proven track record of providing trusted advice in similar situations, such as public health emergencies and disasters like Ebola and Hurricane Katrina.

Meanwhile, ACIP is a well-respected and highly effective federal government advisory committee with expertise and experience in advising CDC on vaccination practice and policy. ACIP’s scope of work will also continue beyond that of the National Academies report since our study committee has completed its work. Importantly, ACIP will have the ability to adjust its priority groups and plans for allocation and distribution—drawing from the National Academies report and other resources—as more information about the availability of COVID-19 vaccine emerges.

2. How is the National Academies’s Committee on Equitable Allocation of Vaccine for the Novel Coronavirus working with ACIP to ensure there is clear guidance on vaccine allocation once a vaccine is available?

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a. **RESPONSE:**

While the National Academies conducted its study independently, we remained in contact with ACIP throughout the study process. Current ACIP chair, Dr. Jose Romero, presented to our study committee at our first public meeting in July 2020 to discuss the role of ACIP in vaccine policy. A number of committee members and National Academies staff attended the public ACIP meetings in July, August, and September 2020 as well. In coordination with CDC staff, Dr. Romero also attended the briefing we provided to CDC upon the report's release in October 2020. We stand ready to answer any questions that ACIP and CDC may have as they continue to consider COVID-19 vaccine allocation.

**The Honorable Diana DeGette (D-CO):**

1. If any member of the Administration authorizes or approves the use of a coronavirus disease 2019 (COVID-19) vaccine prior to or over the objection of the U.S. Food and Drug Administration, or against the recommendations of the Vaccine and Related Biological Products Advisory Committee, what impact do you believe this action would have on the American people's confidence in the vaccine?

a. **RESPONSE:**

Our report addresses this issue in the chapter titled *Achieving Acceptance of COVID-19 Vaccine* (Chapter 7). Among the unique challenges to COVID-19 vaccine acceptance in the United States are evolving concerns about the politicization of the vaccine development and approval process. To counter potential political interference and assuage concerns about the safety and speed of vaccine development, FDA has developed recommendations for the performance of any approved COVID-19 vaccine and committed to the use of an independent advisory committee to decide about licensure of candidate vaccines.

While the scenario posed in the question is not explicitly addressed in the report, given concerns over the FDA process and the lack of confidence in broader failures to contain COVID-19, it is my personal belief that such action would erode public confidence in COVID-19 vaccine, which is already of concern based on recent polls.

**The Honorable Brett Guthrie (R-KY):**

1. Given that the vaccine supply schedule for H1N1 projected by manufacturers was much faster than what could actually be achieved, even for the initial supply target populations, how do you think ACIP and the Centers for Disease Control and Prevention (CDC) can reduce the possibility of unrealistic projections of the COVID-19 vaccine supply schedule?

a. **RESPONSE:**

This question falls outside the scope of the study and is better suited to be answered by ACIP, CDC, Operation Warp Speed, and other federal partners. However, we acknowledge throughout the report that the number of vaccine doses to be initially made available remains a key unknown affecting vaccine allocation and could be

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lower than anticipated. As a result of this unknown as well as other unknowns, we also stress the importance of risk communication in COVID-19 vaccination planning.

2. The discussion draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine notes a major success from the H1N1 pandemic was the use of public-private partnerships to allocate and distribute the vaccine. What steps would you advise the CDC to take to ensure these types of partnerships are maximized so the COVID-19 vaccine can be distributed timely?

a. **RESPONSE:**

The federal government's Operation Warp Speed is a public-private partnership leveraging relationships with pharmaceutical companies, manufacturers, and distributors to support the development and distribution of COVID-19 vaccine (e.g., McKesson will support distribution plans). In the final report released on October 1, we also recommend the importance of leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government to support coordination and ensure equitable allocation of COVID-19 vaccine, which could include existing public-private partnership mechanisms in place across jurisdictions. Specifically, we recommend:

**RECOMMENDATION 2. Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.**

The U.S. Department of Health and Human Services should commit to leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government and provide the resources necessary to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration. Specific action steps to implement this recommendation are as follows:

- Provide resources (including resources for staff) to state, tribal, local, and territorial (STLT) authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
- To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect and integrate the necessary data (digital and other) from public health and private providers of care to facilitate the identification and monitoring of people with preexisting conditions and other high-risk characteristics.
- Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.

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- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.
3. In addition to the extensive efforts to support development of vaccines and therapeutics themselves, the Administration has made efforts to secure ancillary supplies needed to administer vaccines—such as glass vials, needles, syringes, and alcohol pads. With the concern of medical supply chain shortages throughout this pandemic, how much emphasis was placed on ancillary supplies when creating the framework for distribution?
- a. **RESPONSE:**  
Our report addresses this issue in the chapter titled *Administering and Implementing an Effective and Equitable National COVID-19 Vaccination Program* (Chapter 5). Recommendation 2 calls for HHS to provide resources to state, tribal, local, and territorial authorities and their implementation partners, including funding for indirect assets such as needles, syringes, and other ancillary supplies necessary for successful vaccine distribution and administration.

**Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Hearing on  
“Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust”**

**September 30, 2020**

**Ashish Jha, M.D., M.P.H., Dean  
School of Public Health, Brown University**

**The Honorable Frank Pallone, Jr. (D-NJ):**

1. Given your testimony that there have been a series of “failures and mishaps surrounding EUAs [Emergency Use Authorizations] for treatments,” what red flags should Congress be aware of that might indicate the U.S. Food and Drug Administration (FDA) has been improperly pressured to prematurely authorize a coronavirus disease 2019 (COVID-19) vaccine? Are there guardrails in place to prevent that and, if so, what are they?

The two places where there have been substantial failures surrounding EUAs for treatments did not utilize randomized controlled trials to demonstrate efficacy, which are typically considered the gold standard amongst the research community. Rather, the EUA for hydroxychloroquine relied on a small, non-representative observational study, and that for convalescent plasma relied on observational data that lacked randomization. These two treatments did not have sufficient data to demonstrate efficacy and therefore, did not truly meet the bar for an EUA. Given that all vaccine candidates are studied using a randomized controlled trial design, issues regarding observational data should not be a concern. Nonetheless, it is critical that we follow the guidance of FDA scientists in determining whether a vaccine reaches safety and efficacy standards. These rigorous standards have been clearly outlined by the FDA, and include a requirement that the vaccine lowers the rate of COVID-19 in study subjects by 50% or more compared with those who received the placebo, as well as a two-month safety follow-up period after study subjects receive their final dose. As long as the FDA remains devoted to these standards and continues with scientifically rigorous trial design, we can avoid repeating the mistakes we made with hydroxychloroquine and convalescent plasma.

2. Please explain how FDA’s decision to authorize a COVID-19 treatment should differ from its analysis of whether to authorize a COVID-19 vaccine, which, as you point out in your testimony, would be given to healthy people to prevent illness?

Given that treatments are given to sick people, who without treatment might otherwise die or suffer severe consequences, there is an understandably lower bar of evidence employed for

issuing these EUAs. But vaccines are given to healthy people, so ensuring that they are safe is of particular importance, especially considering that these healthy individuals can be protected through other means such as social distancing, mask-wearing, and hand washing. Further, we must clearly demonstrate efficacy before a vaccine is authorized to avoid providing the general public with a false sense of security that will lead to a breakdown of other public health measures or undermine trust in vaccines. Therefore, the FDA's decision to authorize a COVID-19 vaccine should rely on substantially higher bars for both safety and efficacy compared with those for COVID-19 treatments.

**The Honorable Diana DeGette (D-CO):**

1. If any member of the Administration authorizes or approves the use of a COVID-19 vaccine prior to or over the objection of FDA, or against the recommendations of the Vaccine and Related Biological Products Advisory Committee, what impact do you believe this action would have on the American people's confidence in the vaccine?

If political appointees overruled career scientists, it would greatly undermine the American people's confidence in the vaccine. Given the critical importance of widespread distribution and acceptance of a COVID-19 vaccine in order for it to be effective in combatting this virus, political meddling, such as this, would have disastrous consequences. Already, vaccine hesitancy is widespread and this type of political interference would only further the hesitations of the American people, leading some individuals to forego using the vaccine and consequently, undermining the benefits of the vaccine to the American population.

**The Honorable Brett Guthrie (R-KY):**

1. As large amounts of a vaccine become available, what checkpoints should the Centers for Disease Control and Prevention place on jurisdictions to ensure that they have the necessary resources before vaccine manufacturers ship vaccine doses to the states?

a. What are some of the challenges that you think jurisdictions will face in transitioning to the next phase to accommodate an increased volume of vaccine doses?

The widespread distribution of a COVID-19 vaccine will pose some unique challenges to jurisdictions across the country, the first of which is establishing an adequate cold chain, which is necessary for the distribution of the majority of vaccine candidates. RNA-based vaccines, such as the Pfizer and Moderna candidates, require deep-freeze storage and therefore, cannot be stored in typical refrigeration systems in doctors' offices. Challenges in establishing these supply chains will uniquely impact more rural areas, as urban areas are generally better equipped at managing cold chains, which may result in the inequitable distribution of a COVID-19 vaccine. The second

unique challenge is that this vaccine will likely require two doses, which will only increase the complexities of distribution and introduce additional logistical hurdles. Of the seven Operation Warp Speed candidates, up to six may require multiple doses. Two-dose vaccine regimens require additional tracking and follow-up with patients to ensure that they receive the correct second dose at the appropriate time.

b. How should the federal government be preparing for, and helping to mitigate, those challenges?

Investments in the infrastructure needed for an effective cold chain have substantially lagged behind investments made in the discovery and development of the vaccine itself. The federal government attests that it may implement a distribution approach consisting of distributed networks of federally managed cold chain sites to prevent specific jurisdictions from needing to procure additional equipment, but these plans have yet to be implemented. Given that vaccine distribution hinges upon the ability to adequately scale-up cold chains, it is imperative that the federal government invest in these systems and create a team of individuals who can oversee and ensure their implementation.

Further, the federal government is in the process of implementing a new vaccine tracking system to monitor COVID-19 vaccine administration called the Vaccine Management Administration System (VAMS). While this new system aims to alleviate some of the challenges inherent in multiple-dose vaccine regimens, it is unclear how this new system will integrate with existing Immunization Information Systems (IIS). There are many benefits to leveraging these existing tracking systems, such as familiarity amongst local providers and past experience with the administration of other vaccines. Rather than overhaul each state's current vaccine registry with a new one, the federal government should support states in modifying existing systems so that they have the capacity to successfully track and monitor the administration of a COVID-19 vaccine.

c. How can providers use their influenza vaccine administration period to begin operationalizing their plans for COVID-19 vaccine-distribution data reporting and patient communication systems?

While it is unclear when exactly VAMS will be released to local healthcare providers and how this new system will work alongside existing IIS, there are a few ways in which data reporting and patient communication systems can be improved in the meantime. Currently, there is wide variation across states' IIS, with different policies regarding data-sharing, provider participation, and patient consent. During the influenza vaccine administration period, providers should begin to identify the shortcomings of their particular IIS system and coordinate with public health officials to improve these systems. Further, data-sharing capabilities between states are lacking,

posing additional challenges to coordinating multiple-dose vaccine administration. In order to coordinate a national COVID-19 vaccine program, we need greater consistency and coordination across these systems. By identifying the shortcomings of existing systems and improving coordination between neighboring jurisdictions during the influenza administration period, we can hopefully avert these challenges when it comes time to administer a COVID-19 vaccine on the national scale.