PRELIMINARY TRANSCRIPT

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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, D.C.

The subcommittee met, pursuant to call, at 11:34 a.m., via Webex, Hon. Diana DeGette [chairman of the subcommittee] presiding.

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; Jesseca Boyer, Professional Staff Member; Jeff Carroll, Staff Director; Austin Flack, Staff Assistant;

Waverly Gordon, Deputy Chief Counsel; Perry Hamilton, Deputy Clerk; Chris Knauer, Oversight Staff Director; Joe Orlando, Staff Assistant; 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, O&I; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Clare Paoletta, Minority Policy Analyst, Health; Alan Slobodin, Minority Chief Investigative Counsel, O&I; 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 prospective 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 background 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.

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 8 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 emergency 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.

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

Mr. Guthrie?

[The prepared statement of Ms. DeGette follows:]

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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 and 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 concern 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 nonpolitical, 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:]

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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.

The Chairman. 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 Chairman Pallone follows:]

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

Mr. Walden?

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 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 trial, 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. Okay. 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:]

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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.

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, CHILDREN'S 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

TESTIMONY OF MARK MCCLELLAN, M.D., PH.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 parallel 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:]

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Ms. DeGette. That will be done. Thank you so much, Doctor.

Next, I'm pleased to recognize Dr. Khan for 5 minutes.

TESTIMONY OF ALI S. KHAN, M.D., MPH, MBA

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 4 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:]

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Ms. DeGette. We will do that, and thank you very much.

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

TESTIMONY 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 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 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:]

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Ms. DeGette. Thank you, Doctor.

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

TESTIMONY OF HELENE GAYLE, M.D., MPH

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 advisories 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 characterize 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:]

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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.

TESTIMONY OF ASHISH K. JHA, M.D., MPH

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 9 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 9 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:]

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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 6 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.

RPTR MARTIN

EDTR HUMKE

[12:33 p.m.]

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

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

The Chairman. 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 8 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.

The Chairman. 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.

The Chairman. 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.

The Chairman. 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 clinical 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.

The Chairman. 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.

The Chairman. 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, 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 particular 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. Yeah. 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. Yeah, 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. Okay. 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. -- 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. Yeah. 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 enrolled 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, quote, "mistrust amongst people of color isn't surprising considering the long history of structural racism and unethical medical experimentation on this population," end quote.

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. Okay. 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.

Okay. Not seeing him --

Mr. Ruiz. Yes, you do.

Ms. DeGette. Oh, there he is. Okay. 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, quote, "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," unquote.

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. Yeah. 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. Okay. 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?

Okay. 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. Yeah. 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 whither on the vine, and we don't have the same kind of infrastructure in place. So what can we do about that?

Dr. Gayle. Yeah. 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.

RPTR MOLNAR

EDTR ZAMORA

[1:34 p.m.]

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. -- 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, quote, "Trust of the vaccine will be as important, if not more so, than the safety and efficacy," end quote. 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 3 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, consistent 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 5 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. -- 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. -- analysis of whether to authorize a COVID-19 vaccine, which as you point out would --

[Video malfunction.]

Ms. DeGette. Okay.

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. Yeah. I believe --

Mrs. Dingell. Okay.

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. Okay. 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. Okay. I see he's sitting down.

Mr. Bilirakis. What we're trying to do is get this --

Ms. DeGette. Oops. Mr. Bilirakis, you need to unmute.

Where did he go?

Okay. 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 6 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 2 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 vac- -- 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 vigor -- 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.

Okay. 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. Yeah. 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 organizations, 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. Yeah. 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 10 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 follows:]

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

Ms. DeGette. And with that -- thanks again to everyone -- this subcommittee is adjourned.

[Whereupon, at 2:21 p.m., the subcommittee was adjourned.]