Preliminary Transcript

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PATHWAY TO PROTECTION: EXPANDING

AVAILABILITY OF COVID-19 VACCINES

TUESDAY, FEBRUARY 23, 2021

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m., via Webex, Hon. Diana DeGette [chairman of the subcommittee] presiding.

Present: Representatives DeGette, Kuster, Rice, Schakowsky, Tonko, Ruiz, Schrier, Trahan, O'Halleran, Pallone (ex officio), Griffith, Burgess, McKinley, Long, Dunn, Joyce, Palmer, and Rodgers (ex officio).

Also Present: Representatives McNerney, Eshoo, Bucshon, Walberg, Carter, and Pence.

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

Waverly Gordon, General Counsel; Tiffany Guarascio, Deputy Staff Director; Rebekah Jones, Counsel; Chris Knauer, Oversight Staff Director; Mackenzie Kuhl, Press Assistant; Kevin McAloon, Professional Staff Member; Kaitlyn Peel, Digital Director; Peter Rechter, Counsel; Tim Robinson, Chief Counsel; Chloe Rodriguez, Deputy Chief Clerk; Benjamin Tabor, Junior Professional Staff Member; C.J. Young, Deputy Communications Director; Sarah Burke, Minority Deputy Staff Director; Theresa Gambo, Minority Financial and Office Administrator; Brittany Havens, Minority Professional Staff Member, O&I; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Bijan Koohmaraie, Minority Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Alan Slobodin, Minority Chief Investigative Counsel, O&I; Michael Taggart, Minority Policy Director; 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 Protection: Expanding Availability of COVID-19 Vaccines."

The purpose of today's hearing is to examine manufacturers' ongoing efforts to develop and scale up production of COVID-19 vaccines in the United States.

Due to the COVID-19 public health emergency, today's hearing is being held remotely. All members, witnesses, 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, I'll remind you now -- I have a feeling we'll need to do it again during the hearing -- to unmute your microphone each time you wish to speak.

And, if any time during the hearing I'm unable to chair the hearing, the chairman of the full committee, Frank Pallone, will serve as chair until I'm able to return.

Documents for the record can be sent to Austin Flack at the email address we've provided to staff. All documents will be reviewed and entered into the record as appropriate at the conclusion of the hearing.

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

Today, the subcommittee continues its oversight of the ongoing COVID-19 pandemic. Over the last year, we've held hearings examining various aspects of this crisis, including the Federal Government's response to COVID-19, the ramping up of testing, and the development of vaccines.

Last July, we heard testimony from several of the companies represented at today's hearing about the status of their clinical trials and their production plans as they

worked diligently to develop a safe and effective vaccine. And I want to thank all of you for coming in July and all of the work that you've done.

And we're back today in a much better position to fight COVID-19, with two vaccines authorized and possibly more on the way. We're now in the midst of one of the most important public health campaigns in American history.

So it's often said: Vaccines don't save lives; vaccinations do. And, as of course we just passed the grim milestone of half a million American deaths from COVID-19, we don't have a lot of reason to celebrate. But, with the vaccination program underway, there is hope that we can begin to turn the tide against the virus.

Frankly, it's nothing short of a scientific marvel that multiple COVID-19 vaccines have been demonstrated to be safe and effective in such a short amount of time, but all of us know we're not out of the woods. The most pressing challenge that we have right now is the lack of supply of vaccine doses.

We saw the frustration late last year when the initial vaccine allocations to States were less than what was needed to vaccinate high-risk priority populations. And, while we continue to commend manufacturers' efforts to develop the vaccines, some of the companies here today are still short of the number of doses they promised to initially deliver when they testified before this subcommittee in July.

Many of the companies received significant Federal investment to build their manufacturing capacity last year, even while the clinical trials were ongoing, so that we would be able to deliver millions of vaccines just as soon as they were authorized.

Two vaccines have been authorized, and production is ramping up. But we still have way insufficient supply to meet current demand. Things are improving lately with the companies' increasing production and the Biden administration increasing weekly allocations to States as well as providing greater transparency around future allocations,

which we heard a couple of weeks ago from State health officials. And, with additional companies seeking authorizations, we have hope that the supply will increase substantially in the coming months.

But, frankly, we still face a lack of vaccine supply to meet current demand. Americans around the country are lining up, sometimes for hours, to secure their shots. Many high- risk individuals have not been vaccinated, and millions more are waiting for their turn.

Last week, President Biden said that every American who wants a vaccine should be able to get one by the end of July. That is a welcomed goal and one that the companies joining us today will be -- will play a central role in hopefully achieving. That's why it's critical for us to hear from our witnesses today a straightforward assessment about where the manufacturing capacity stands, how much vaccine they expect to be able to produce, and when they will be able to meet those milestones.

And, indeed, emerging virus variants may require us to develop even new vaccines or booster shots. So, if that's so, these shots will only put more pressure on manufacturing capacity.

This hearing is an opportunity to examine ideas to speed up the vaccination effort, whether it's something that companies could be doing differently or something more that the Federal Government can be doing to help. We're all in this together, so we look forward to exploring solutions today.

Finally, while these vaccines are undoubtedly good news, we must remember they're only part of the solution to ending this pandemic. Although the authorized vaccines are highly effective at preventing people from getting seriously ill from COVID-19, they might not prevent people from unknowingly spreading the virus to others.

Therefore, it can't be said enough, so I'm going to say it right here: It's essential that Americans continue mitigation efforts, like wearing masks and practicing social distancing, even if you've been vaccinated. These vaccines will be an enormous aid in fighting the virus, but we all need to do our part if we are to defeat it.

Once again, I want to thank these witnesses for being here today. The ongoing work of each of your companies is critically important to the country and the world, and this committee remains ready to assist in those efforts.

And now, at this time, the chair will recognize the ranking member of the subcommittee, Mr. Griffith, for 5 minutes for purposes of an opening statement.

Mr. Griffith?

[The prepared statement of Ms. DeGette follows:]

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Mr. Griffith. Thank you very much, Chair DeGette, and I appreciate you having this important hearing on the availability of COVID-19 vaccines.

I also want to thank the witnesses for taking the time to join us today.

Two of the companies before us, Pfizer and Moderna, have COVID-19 vaccines that have been granted emergency use authorizations, EUAs, by the FDA. One company, Johnson & Johnson, has filed an EUA application. And two companies, AstraZeneca and Novavax, have ongoing phase 3 clinical trials.

Thanks to the last administration's great partnership with private industry, Pfizer and Moderna started shipping vaccines across the United States within 24 hours of receiving their EUAs. They have committed to supply 600 million doses to the United States Government by the end of July. That will mean we will have enough supply to vaccinate 300 million people. In addition, more COVID-19 vaccine doses will be available should more companies receive authorization or approval from the FDA.

This timeline is unprecedented, especially since the path from clinical trial production to commercial scale manufacturing is highly complex. For example, according to a U.S. Government Accountability Office report, the traditional vaccine timeline from the exploratory stage all the way to the large-scale manufacturing and FDA review and licensure takes approximately 10 years, and sometimes longer. But, in just 11 months since our first reported case of COVID-19, two companies received the EUAs from the FDA for their vaccines. As of February 18, over 73.3 million doses of COVID-19 vaccine have been delivered across the United States.

This is a remarkable achievement. We should applaud these efforts that have been undertaken by manufacturers to help crush the virus. However, as we've heard in a subcommittee hearing a few weeks ago with representatives from a handful of States,

vaccine supplies remain the number one hurdle to vaccinating Americans at a faster pace.

The challenge is that the vaccine manufacturing process takes time. The immediate availability of vaccine doses was made possible because of the efforts of the private sector, as well as their partnerships with the Federal Government.

Because manufacturing was being done at risk and in parallel with the clinical trial process, we were able to move fast. In addition to at-risk manufacturing, the vaccine manufacturers have looked for ways to increase and expand their manufacturing capacity.

Some efforts undertaken by manufacturers include rearranging existing capacity, acquiring additional facilities, partnering with other companies to increase their production capacity, or hiring and training additional personnel to work in the manufacturing facilities. Some companies have even looked to increase the number of doses included in their vials, which conserves resources and supplies. Other companies have been able to increase efficiencies in their processes by incorporating lessons learned.

All of these efforts not only allow vaccines to reach Americans faster, but it also highlights private-sector innovation. But, to be clear, expanding capacity takes time. This is a complex process that includes the availability of every piece of equipment and material needed, making sure that the equipment is approved and assuring all of the processes and people in the facility are validated.

There have also been disruptions to manufacturing supply chains and processes throughout the pandemic. With the demand for medical supplies at an all-time high across the world and disruptions in the workforce, we have faced challenges in securing materials for vaccine production.

The Federal Government, including Operation Warp Speed and the use of the

Defense Production Act, DPA, have helped to boost and secure essential supplies that are needed to manufacture COVID-19 vaccines. While the DPA has been a useful tool thus far, we must be judicious in how we utilize it, as it can lead to major disruptions in our healthcare supply chain.

Finally, COVID-19 continues to mutate, causing new variants to emerge that seem to spread more quickly and easily. Thankfully, vaccine manufacturers are already looking for ways to stay ahead of these variants.

I look forward to our discussion today to learn more about your manufacturing processes, actions you have taken to expand your manufacturing capacity, and whether you feel more capacity or resources are needed to meet the demands for COVID-19 vaccines.

I also look forward to hearing about any challenges manufacturers are facing and how we might address them. We are all in this fight together, as you heard Chair DeGette say, and I want to thank you all for the important work you've already done.

Thank you, Madam Chair, and I yield back.

[The prepared statement of Mr. Griffith follows:]

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Ms. DeGette. I thank the gentleman.

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

The Chairman. Thank you, Chairwoman DeGette. I know that this was a hearing that you've been wanting to do for a while, so I'm glad that it worked out today and we're able to get the manufacturers here.

Obviously, we're continuing our oversight of this effort to develop and produce COVID-19 vaccines to the American people, and one of my top priorities this year is to ensure we have the tools and resources needed to crush the virus.

I do believe it's a new day, because, unlike under Trump, under Biden now, we have a national plan and effort to coordinate and get vaccine and testing and contact tracing and supplies out to States. But we need to have the tools and resources for that national plan, and we're going to do that with the Reconciliation Act, which I think will be on the House floor this Thursday or Friday.

But among the most powerful tools in this arsenal to crush the virus is obviously a safe and effective vaccine. That's why this committee is working tirelessly to find solutions for rapidly expanding the availability of COVID-19 vaccines across the country.

The pain and devastation inflicted by this pandemic cannot be overstated as we mark the tragedy of half a million lives lost to COVID in the U.S. Nearly 10 million jobs have been lost, and long-term unemployment is on the rise. Life expectancy in the United States fell for an entire year in the first half of 2020, a decline not seen since World War II, with communities of color suffering the largest declines.

In order to achieve herd immunity, which is essential to ultimately defeating the virus, we must vaccinate the majority of the population, and that starts with securing

widespread access to vaccines and ensuring reliable production lines are in place.

Unfortunately, the initial vaccine rollout under the Trump administration was marred in confusion, poor planning, and limited supply. Thankfully, the Biden administration has taken decisive action to get the vaccine effort back on track.

So, just last week, President Biden announced that States will receive their largest weekly dose allocations, a 57 percent overall increase from when he took office. The administration also announced it was doubling the number of doses being sent directly to pharmacies and will begin sending vaccines directly to community health centers, actions that will facilitate broader access across the country.

And, thanks to these efforts, we're already seeing encouraging results. Before the disruptions caused by last week's winter storm, an average of 1.7 million vaccine doses were being administered per day, marking a nearly twofold increase over the past month. And this trend is promising, and many experts believe we need to be administering close to 3 million doses per day to stay ahead of the virus.

So I recognize the goal is challenging, but the stakes of our nationwide vaccination campaign could not be higher. A protracted rollout would only result in more Americans becoming infected and would also increase the likelihood that more variants will become dominant in the United States.

And I noted in the subcommittee's last hearing, we're currently in a race to keep vaccines ahead of the new virus variants. And, in order to win this race, we have to increase our vaccine supply as swiftly as possible.

So, today, we're going to hear from five leading manufactures of COVID-19. We must acknowledge there have been setbacks on vaccine production and supply. Congress needs to hear what steps each company is taking to rapidly expand vaccine production, what hurdles might stand in the way, and what additional help is needed to

increase supply. Simply put, all options must be on the table.

While increasing vaccine supply is essential, much more is needed to actually vaccinate hundreds of millions of Americans quickly and equitably. To that end, Democrats in Congress are moving swiftly to pass the American Rescue Plan, and this is the Biden proposal that commits the resources and support necessary to crush the virus.

This legislation, which we dealt with last week and should be on the floor at the end of the week, would invest more than $20 billion to expand the Federal Government's ongoing work to aggressively ramp up vaccine distribution administration, including by establishing mobile vaccination units in underserved communities, expanding community vaccination centers, and facilitating clear communication with the public.

And I also am pleased that this committee passed its portions of this legislation without delay, and the full House, as I said, will vote later this week, and so we really look forward to getting the bill on the President's desk as soon as possible.

And I just want to thank our witnesses for taking the time to be with us today. Your work is really vital, and this committee recognizes your extraordinary efforts. If we all work together, I'm confident that this historic vaccination campaign will succeed, and we will crush COVID-19.

So thank you again, Madam Chair, for putting this together today. I couldn't think of a more important reason to have a hearing with your subcommittee.

Thank you. Thank you, Diana.

[The prepared statement of The Chairman follows:]

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Ms. DeGette. Thank you so much, Mr. Chairman.

The chair now recognizes the ranking member of the full committee, Mrs. Rodgers, for 5 minutes for purposes of an opening statement.

Mrs. Rodgers. Thank you, Chair DeGette, and Republican Leader Griffith for this hearing on COVID-19 vaccines made possible by the Trump administration and the incredible success of Operation Warp Speed.

Vaccines normally take more than 10 years to develop. Thanks to Operation Warp Speed, we have two safe and effective vaccines in less than one year, and one more on the way, and others on the way. Operation Warp Speed is one of the greatest health achievements in history, and it will help us win the future. It puts us on a path to crush this virus, to restore our way of life, and also provide a new model of innovation for future lifesaving breakthroughs.

President Biden entered the White House and inherited a vaccine program with a million Americans being vaccinated a day. President Trump set ambitious and bold goals. President Biden should, too. And that's why the Energy and Commerce Republicans will continue to push for a plan to vaccinate 2 million people a day in the first hundred days of this administration.

To be certain, mass vaccinations like our ongoing effort are complex and difficult. Thanks to American ingenuity and grit, we continue to lead the world. Last week, the CDC said that 72.4 million doses have been delivered, and more than 56.2 million of those had been administered.

Pfizer projects it will supply 120 million doses to the U.S. by the end of March, 20 million more than initially promised. Moderna expects 100 million doses 2 months earlier than expected. Based on current projections, by the end of July, we'll have

enough vaccines for 300 million people, well more than the estimated 250 million currently eligible, and we have more vaccines on the horizon.

Johnson & Johnson submitted their emergency use authorization for their one-dose vaccine, which is scheduled to be reviewed Friday. Authorizing this vaccine would significantly boost our supply.

Our current efforts and projected supply are promising. We want to make vaccines available so that everyone who wants one can get one. So we have more work to do.

New COVID variants have emerged, posing new threats. Thankfully, recent lab studies show that Pfizer and Moderna's vaccines are effective against the South African variant, and all manufacturers report that their vaccine candidates are effective against hospitalizations and death.

We seem poised to tackle these new challenges, and we must remain focused to ensure we do. Distribution issues need to be fixed.

Earlier this month, we heard from five States who made clear supply limitations are the number one barrier to getting more shots in people's arms. Hopefully, our projections for increased supply and new vaccines will resolve this. To crush the virus, States also need to resolve self-inflicted problems. My home State is no exception.

The Seattle Times revealed that the Washington's Department of Health ignored basic logistics in their rollout plan. It was called a, quote, "bureaucratic nightmare." Had Washington planned better, the most vulnerable could have been vaccinated much faster.

I also recently learned of Governor Inslee's unacceptable, unfair, and irresponsible intervention in Whitman County. After vaccinating all phase 1B, tier 1, eligible people who wanted the vaccine, Whitman County was ready to vaccinate the next group:

teachers. But Governor Inslee interfered. He threatened to withhold vaccines if they proceeded. One school superintendent called the Governor's decision demoralizing.

I agree we should be doing everything we can to get our kids back to school. That means supporting counties that are delivering the vaccine with efficiency and speed.

I know that this has been a very long year, full of fear of the unknown, the uncertainty, and more isolation. This week marks 500,000 lives lost. Social distancing, school closures, long hours and nights for people on the front lines, the rise of suicides and overdoses, it all adds up, and it's taking a toll. People are tired. Many are in despair. I'm especially worried about the mental health of our children.

So my message today is this: There is hope. Our vaccine supply is expected to increase. Distribution is becoming more efficient. We will get through this pandemic. It's American innovation and ingenuity that's going to end this crisis and give people hope, the ability to heal, and the courage to dream again. We will emerge stronger than ever before. That's our mission today.

Thank you, Madam Chair. I yield back.

[The prepared statement of Mrs. Rodgers follows:]

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Mr. Griffith. Madam Chair, you're muted. You're muted, Madam Chair.

Ms. DeGette. Sure, I have to tell everybody else to unmute, and you had to tell me.

Once again, I ask unanimous consent that members' written opening statements be made part of the record, and, without objection, so ordered.

I now want to introduce the witnesses for today's hearing, John Young, who is the group president and chief business officer for Pfizer; Dr. Stephen Hoge, who is the president of Moderna; Dr. Richard Nettles, who is the vice president of medical affairs at Janssen Pharmaceutical Company's Johnson & Johnson; Dr. Ruud Dobber, who is the executive vice president and president of Biopharmaceuticals Business Unit at AstraZeneca; and John Trizzino, who is the executive vice president, chief commercial officer, and chief business officer at Novavax.

I want to thank everyone once again for appearing today. I know you're very busy, and your testimony is very important.

I know all of you are aware that this committee holds an investigative hearing, and, when we do so, we take all of our practice of taking testimony under oath.

Do any of you have any objection to testifying under oath today?

Mr. Young. No.

Dr. Hoge. No.

Dr. Nettles. No.

Dr. Dobber. No.

Mr. Trizzino. No.

Ms. DeGette. Let the record reflect the witnesses have responded no.

The chair then advises you, under the rules of the House and under the rules of

the committee, you're entitled to be accompanied by counsel. Do any of you wish to be accompanied by counsel during your testimony today?

Mr. Young. No.

Dr. Hoge. No.

Dr. Nettles. No.

Dr. Dobber. No.

Mr. Trizzino. No.

Ms. DeGette. Let the record reflect the witnesses have responded no.

And so, if you would, would you please raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms. DeGette. Let the record reflect the witnesses have responded affirmatively, and you are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the U.S. Code.

The chair now will be pleased to recognize our witnesses for 5-minute summaries of their written statements.

You can see right in the second level of the screen, there is a timer that will count down, and it turns red when your 5 minutes have come to an end.

So, first, I'd like to recognize you, Mr. Young, for 5 minutes for your opening statement.

TESTIMONY OF JOHN YOUNG, GROUP PRESIDENT, CHIEF BUSINESS OFFICER, PFIZER; STEPHEN HOGE, PRESIDENT, MODERNA; RICHARD NETTLES, VICE PRESIDENT OF MEDICAL AFFAIRS, JANSSEN PHARMACEUTICAL COMPANIES, JOHNSON & JOHNSON; RUUD DOBBER, EXECUTIVE VICE PRESIDENT AND PRESIDENT, BIOPHARMACEUTICALS BUSINESS UNIT, ASTRAZENECA; AND JOHN TRIZZINO, EXECUTIVE VICE PRESIDENT, CHIEF COMMERCIAL OFFICER, AND CHIEF BUSINESS OFFICER, NOVAVAX, INC.

TESTIMONY OF JOHN YOUNG

Mr. Young. Thank you.

Chairwoman DeGette, Ranking Member Griffith, and members of the subcommittee, thank you for inviting me to testify today. I am John Young, chief business officer at Pfizer, and I'm honored to be a part of this panel.

When I appeared before this committee last July, we were in the middle of our journey to develop a COVID-19 vaccine. Since then, our vaccine became the first to be granted emergency use authorization by the FDA.

This EUA was based on data from our phase 3 study, which demonstrates that our vaccine met the FDA's stringent safety requirements and indicated efficacy of 95 percent, consistent across age, gender, and racial demographics, and participants reflecting the diversity of the United States' population.

As of February the 17th, we have shipped approximately 40 million doses to points of use as directed by the U.S. Government. To date, no serious safety concerns have been identified that have changed the favorable risk-benefit profile of the vaccine.

To get our vaccine to points of use, we provide the government a rolling weekly

forecast of doses available for shipment, enabling the government to provide States with a 3-week forecast. The U.S. Government then allocates doses weekly to the States. Providers submit orders through the CDC's VTrckS system, which are submitted to us, and weekday orders are shipped the day after.

We recognize the need to vaccinate more people more quickly and have worked hard to significantly increase production. Since July, we've increased projected 2021 global production from 1.3 billion doses to at least 2 billion doses.

Pfizer has made significant investments in our U.S. manufacturing sites, including St. Louis, Missouri; Andover, Massachusetts; Kalamazoo, Michigan; and Pleasant Prairie, Wisconsin. We added new lines at our site in McPherson, Kansas; started lipid production at our site in Groton, Connecticut; added two contract manufacturers.

Further improvements have come from the FDA's approval of a six-dose label for each vial, doubling batch sizes, increased yields per batch, reduced cycle times, and deployment of faster laboratory tests to reduce release times. As a result of these improvements, we expect to increase the number of doses available from approximately 4- to 5 million doses per week at the beginning of February to more than 13 million doses per week by the middle of March.

We are on track to make 120 million doses available for shipment by the end of March and an additional 80 million doses by the end of May. We anticipate all 300 million contracted doses will be made available for shipment to the points of use as directed by the U.S. Government by the end of July, enabling the vaccination of up to 150 million Americans.

We continue to gather evidence on safety and efficacy to support the use of our vaccine by important subpopulations of patients not indicated under the current EUA. We're conducting studies in patients between 12 to 15 years of age and hope to soon

begin studies in children under the age of 11. Last week, we initiated a study in pregnant women.

We are laser focused on the potential impact emerging variants of the SARS-CoV-2 virus could have on the ability of vaccine to protect against COVID-19. Our mRNA vaccine affords the opportunity to provide boosting doses if needed and the ability to rapidly alter the mRNA sequence in the vaccine to address potential changes in the virus if evidence suggests that they might reduce protection from the current vaccine.

With 95 percent protection against the original strain, we've now performed in vitro studies on immune responses elicited by the vaccine against new variants, such as those from the U.K. and South Africa. Based on these data, we believe the vaccine should provide protection from these variants. Real-world evidence from the U.K. and Israel appears to confirm this for the U.K. strain. And, to date, we've seen no real-world evidence that suggests a significant reduction in protection provided by our current vaccine.

However, we are preparing to respond quickly and hope to initiate a study to investigate the effectiveness of a third booster of our vaccine in trial participants who have already received two doses. We are discussing clinical trial designs with the FDA to investigate safety and immunogenicity of an updated vaccine that involves a change to the mRNA construct to target an emerging variant. We will fight every step of the way until this devastating pandemic is under control.

In closing, I would like to express Pfizer's sincere thanks to the more than 46,000 trial participants, the hundreds of investigators, and thousands of Pfizer and BioNTech scientists, clinicians, and manufacturing professionals who have worked day and night knowing every moment matters.

Thank you for the opportunity to be with you today.

[The prepared statement of Mr. Young follows:]

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Ms. DeGette. Thank you so much, Mr. Young.

Dr. Hoge, I'm now pleased to recognize you for 5 minutes are for an opening statement.

TESTIMONY OF STEPHEN HOGE

Dr. Hoge. Chairwoman DeGette, Ranking Member Griffith, Chairman Pallone, and Ranking Member Rodgers, and distinguished members of the subcommittee, thank you for the opportunity to appear before you today.

My name is Stephen Hoge, and I serve as the president of Moderna. Since we last spoke in July, the collaborative effort to end this pandemic has made remarkable progress. We've also confronted new challenges. We've seen continued suffering and hardship. We know that much work remains and that this is not over until all of us are safe.

The work could not be more pressing. Half a million people have died in the United States alone, and many more have been made ill. The pandemic has cost jobs, shuttered businesses, closed schools, burdened families, and disrupted countless traditions. We also know that communities of color and essential workers have been disproportionately impacted by the burdens of COVID-19. We must bring this pandemic to an end.

Now, when I testified before this subcommittee last July, Moderna was days away from starting the phase 3 clinical trial for our COVID-19 vaccine candidate, and we were cautiously optimistic that it could play an important role in ending the pandemic. With the support of the U.S. Government, we had also begun to modify our facilities, procure

supplies, hire and train staff, and establish partnerships with leading pharmaceutical manufacturing companies to give us a head start on producing a vaccine.

We've made significant progress since then. The phase 3 trial showed our vaccine was 94 percent effective at preventing COVID-19, leading to an emergency use authorization from the FDA in December of 2020. Less than 2 weeks later, we had delivered the first 17.8 million doses to the Federal Government.

Now, given the importance of vaccine availability to ending this pandemic, I'd like to take this opportunity to provide you with an update on our ongoing efforts to manufacture and deliver our vaccine to the United States.

Two weeks ago, we had delivered over 45 million doses of our vaccine to the Federal Government. Last week, we delivered another 9 million doses, bringing the total number of doses delivered to over 54 million. We currently are on track to deliver the first 100 million doses of the vaccine by the end of March. To do this, we have doubled our monthly deliveries since the end of 2020, and we are aiming to double them again by April to more than 40 million doses a month.

Our success in scaling up production recently allowed us to move up our timetable for deliveries. We are now targeting delivery of the second 100 million doses of our vaccine by the end of May, and a third 100 million doses by the end of July, a full 2 months ahead of schedule.

I want to provide you with a brief overview of our manufacturing process.

First, Moderna and its manufacturing partner, Lonza, create the vaccine at facilities in Massachusetts and New Hampshire. Our fill-finish partner, Catalent, then fills the vaccine into vials at their facility in Indiana. Catalent then follows a rigorous process for inspecting, testing, and packaging the vials for delivery. At every step, we and our partners are committed to maintaining the highest standards of quality.

Now, on any given day, millions of doses of vaccine will be at the different stages of the manufacturing process. And, over time, the buildup of this work-in-process inventory allows the entire system to operate more efficiently. The pace of production also increases as the highly skilled personnel working at each step gain experience and greater familiarity with the process.

We work continuously with the U.S. Government to identify additional opportunities to accelerate production or address bottlenecks. For example, Moderna recently approached the government about the possibility of adding more doses of the vaccine to each vial. Doing so would improve output by allowing us to complete manufacturing runs more quickly and reduce the need for some high-demand materials. The FDA has given us positive feedback on the proposal, and we are now working to enable up to 15 doses per vial in the near term.

At Moderna, we are grateful for the opportunities we've had to collaborate with the government in our efforts to deliver a safe, effective COVID-19 vaccine. We're also grateful for the many companies around the world, including my colleagues testifying today, that are working to deliver COVID-19 vaccines and treatments.

I'd like to thank this subcommittee for its commitment to this cause, as well as the diligent work of your staff. We are grateful for the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic, and we remain committed to collaborating with the U.S. Government in this fight.

Thank you, and I look forward to answering your questions.

[The prepared statement of Dr. Hoge follows:]

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

Dr. Nettles, you're now recognized for 5 minutes for your opening statement.

TESTIMONY OF RICHARD NETTLES

Dr. Nettles. Chairman DeGette, Ranking Member Griffith, and members of this subcommittee, I'm pleased to have the opportunity to update you on the remarkable progress that Johnson & Johnson has achieved by our vaccine over the past several months, allowing us to request emergency use authorization with the FDA less than 3 weeks ago. Although we are cautious not to prejudge the outcome of the ongoing FDA review process, we believe that our single-dose vaccine will be a critical tool for fighting this global pandemic.

In January 2020, Johnson & Johnson launched a major research and development effort for a vaccine. Our pace since then has been extraordinary. We selected a single-dose candidate in June, began human trials in July, launched a large-scale pivotal trial in September, released top-line results last month, and sought an emergency use authorization from the FDA on February 4.

The clinical trial showed that our single-dose vaccine addresses the most important healthcare need in the pandemic, the prevention of COVID-19-related hospitalization and death. Twenty-eight days after vaccination, the vaccine provided complete protection against COVID-19-related hospitalization and death. The vaccine was 85 percent effective overall in preventing severe disease, including across countries with newly emerging variants. The vaccine was 72 percent effective in the United States at preventing moderate to severe disease.

Based on these data earlier this month, we sought emergency use authorization from the FDA. The FDA's advisory committee will meet later this week.

Assuming necessary regulatory approvals, we are ready to begin shipping immediately and deliver enough single doses by the end of March to enable the vaccination of more than 20 million Americans. Furthermore, we will meet our target to deliver 100 million single-dose vaccines to the United States during the first half of 2021.

For many months, we have been working to expand our manufacturing capacity and contract with third-party manufacturers for additional production. We assessed nearly 100 different production sites, and we selected the sites that were able to support an accelerated timeline. We are working around the clock to scale our manufacturing capabilities to supply the United States with vaccine.

Our plans call for production in the United States, in Europe, in Africa, and Asia. Importantly, our vaccine can be distributed using the existing supply chain and routine refrigeration that we use to transport other medicines today.

The vaccine is based on Johnson & Johnson's AdVac technology. We have significant clinical experience with vaccines based on this technology, including vaccines administered for more than a decade. Johnson & Johnson is committed to ensuring that clinical trials include a wide variety of populations, including historically underrepresented communities.

The ENSEMBLE study for our COVID vaccine included approximately 45,000 participants across diverse population. Forty-five percent were Hispanic or Latinx. Nineteen percent were Black or African American. Nine percent were Native American, and 3 percent were Asian. More than one-third of the participants were over the age of 60. We are truly grateful for all the participants who volunteered for our trials.

As you know, Johnson & Johnson is making our COVID-19 vaccine available on a

not-for-profit basis for emergency pandemic use.

Finally, I want to note that the U.S. Government's support has been an important contributor to our ability to develop our vaccine on an accelerated pace. We appreciate our partnership with the government, the financial support provided by the Congress, and this committee's extraordinary leadership on this critically important effort.

Thank you for the opportunity to provide this update regarding our vaccine against COVID-19. I would be happy to answer any questions that you may have.

[The prepared statement of Dr. Nettles follows:]

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

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

And I'm now pleased to recognize Dr. Dobber for 5 minutes.

Dr. Dobber?

TESTIMONY OF RUUD DOBBER

Dr. Dobber. Thank you so much.

Chairwoman DeGette, Ranking Member Griffith, and members of the subcommittee, I'm Ruud Dobber, the executive vice- president of AstraZeneca.

I'm here today to convey AstraZeneca's continued commitment to developing and manufacturing our vaccine candidate for the prevention of COVID-19. We greatly appreciate the opportunity to engage with you today on this important topic, and I hope to emphasize our dedication to delivering safe and effective solutions for fighting the pandemic in United States and across the world.

AstraZeneca is a global science-led biopharmaceutical company which focuses on the discovery, development, manufacturing, and commercialization of innovate medicines. We are proud to have our North American headquarters in Delaware, and one of our three global R&D centers in Maryland.

Today, I will focus on four key elements of AstraZeneca's vaccine program. First, we are proud of our collaboration across all areas of the vaccine program. Our strategic approach has focused on partnering with scientists; governments; organizations like CEPI, GAVI, and the WHO; and manufacturers for the development, supply, and distribution of our vaccine in an equitable manner across the world.

AstraZeneca was the first global pharmaceutical company to join COVAX in

June 2020. Together with our partner, the Serum Institute of India, we plan to supply over 300 million doses to 145 countries through COVAX in the first half of 2021 as part of our global and equitable access pledge. The majority of this supply will go to low- and middle-income countries.

Our agreement with U.S. Government covered the development and supply of 300 million doses of our vaccine should it receive authorization. The course of the doses and the dose agreements will provide no profit for AstraZeneca.

I would like to take this opportunity to thank the U.S. Government for its commitment to advancing these efforts.

Second, to date, we have received conditional marketing or emergency authorization in more than 50 countries, and, recently, the WHO listed our vaccine for emergency use against COVID-19.

Studies conducted to date indicate our vaccine is well tolerated and effective. And, just this week, we were encouraged to see the first real-world evidence from over 5.4 million subjects in Scotland demonstrating risk reduction of COVID-19-related hospitalizations by 94 percent after the first dose of our vaccine. Comparable vaccine effects were seen across all age groups, including in those over 80 years of age.

In addition, we've completed enrollment in our U.S. phase 3 trial, comprising over 30,000 participants, to support FDA authorization. It is important to note that the dosing interval used in the U.S. trial is 4 weeks, which may not maximize efficacy. We anticipate the data will be available in the coming weeks, and we will submit it to the FDA thereafter.

In the U.K., a vaccination strategy based on a 3-month dosing interval is underway, and additional real-world evidence should become available in the next few weeks.

Third, our supply of the vaccine for the U.S. Government is being produced in the

United States, and our manufacturing operations are at or near full capacity. We are not currently experiencing significant material or equipment constraints. Despite the speed in scaling up, safety and quality standards have been and remain of paramount importance.

We are working closely with the U.S. Government to ensure transparency around our progress. In addition, we are continually identifying and implementing new ways of working to accelerate production and reduce the time to reach communities while maintaining the highest standards of quality. Based on current projections, assuming EUA, we expect to deliver up to 50 million dose by the end of April.

Fourth, AstraZeneca has initiated studies to address emerging threats posed by new COVID-19 variants. Initial analysis, while still ongoing, suggests our vaccine shows promise against U.K. variants of the virus. Additionally, as we speak, we are actively studying our vaccine in multiple variants, including the South African variants.

Before I close, I would like to recognize my AstraZeneca colleagues and our partners for their heroic efforts and unwavering commitment to bring our vaccine to millions of people around the world. Together, with the other companies with us today, we are forging ahead in our collective goal of beating COVID-19.

Chairwoman DeGette, Ranking Member Griffith, and members of the subcommittee, on behalf of AstraZeneca, thank you for the opportunity to participate in today's hearing.

[The prepared statement of Dr. Dobber follows:]

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Ms. DeGette. Thank you so much.

And now, last but not least, Mr. Trizzino, you're recognized for 5 minutes.

TESTIMONY OF JOHN TRIZZINO

Mr. Trizzino. Thank you.

Good morning, Chairwoman DeGette, Ranking Member Griffith, and members of the subcommittee. Thank you for the opportunity to appear before you today. I am John Trizzino, and I'm the executive vice president, chief commercial officer, and chief business officer at Novavax.

Novavax is a biotechnology company focused on the development of next-generation vaccines for serious infectious diseases. We are headquartered in Gaithersburg, Maryland, and we are proud to be at the forefront of the fight against COVID-19.

Shortly after the threat was identified, we initiated clinical research, and, so far, we've seen very strong data from our clinical trials. I am pleased to be here so that the American people can become familiar with our company and the vaccine platform we've been building and refining for decades.

As you'll hear, our technology was built for this moment. Our scientists continually scan the landscape for emerging threats, and we started development of our COVID-19 vaccine candidate in January 2020.

My written testimony for the subcommittee provides extensive information about our company, our clinical development program, our manufacturing capacity, and more. I look forward to answering your questions on those topics.

But, first, I want to take this opportunity to speak about how our vaccine technology works and how we are applying it to address the COVID-19 pandemic.

We've shared a slide with the subcommittee, and I'd like to request that be pulled up at this time.

You are now looking at a representation of the coronavirus on the left and a representation of our vaccine on the right. Novavax has a very unique way of making vaccines. We use nanoparticles, shown here on the right in blue.

Our nanoparticles carry a modified version of the coronavirus spike protein, shown here in red. This creates a signal for your body. This signal enables your immune system to learn to fight the real virus. To ensure your immune system hears that signal loud and clear, we boost it with our Matrix-M adjuvant. This adjuvant increases your body's ability to launch a powerful response and to help protect you.

One of the most important characteristics of our technology is that it enables us to rapidly adapt our vaccine as the COVID-19 pandemic evolves. This is extremely relevant as new variants, like those observed in South Africa and the U.K., are surfacing and spreading.

Thank you for sharing the slide. Can you please now take it down?

Vaccines like ours can be efficiently produced at massive scale to help meet global demand. Novavax vaccines are manufactured, transported, and stored at standard refrigeration temperatures, 2 to 8 degrees Celsius. This helps to simplify production, distribution, and use.

Yesterday, we announced that our PREVENT-19 phase 3 trial in the U.S. and Mexico completed enrollment of 30,000 volunteers. Last month, we reported interim results from our phase 3 study in the United Kingdom with efficacy of over 95 percent against the original COVID-19 strain and over 85 percent against the U.K. variant strain.

We are optimistic about our ability to help address urgent global health needs, and we have already initiated development of new constructs against the emerging strains. Novavax is working closely with U.S. Government partners, as well as nongovernmental organizations and industry partners, to advance development of our vaccine candidate. These exceptional partnerships have enabled us to make extraordinary progress.

Thank you so much for inviting me to participate in this hearing. It is an honor to appear before you today. I request that my longer written testimony be included in the record, and I look forward to your questions about Novavax and our COVID-19 vaccine candidate.

Thank you.

[The prepared statement of Mr. Trizzino follows:]

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

Ms. DeGette. Thank you so much, Mr. Trizzino. Your testimony will be made part of the record.

I'll note we haven't enjoyed a good meaty slide like that since the last time Dr. Fauci was over, so thank you for bringing that slide.

It's now time for the members to have an opportunity to ask you questions, and the chair will recognize herself first for 5 minutes.

As I said in my opening statement, the vaccines you've developed are really a marvel of science, and they hold the promise of turning the tide on this pandemic. Everybody on this subcommittee and the full committee, we are really amazed at the extraordinary work and the timely fashion that you've done it in.

And, as you know, a lot of the vaccines were developed as part of Operation Warp Speed, which involved the Federal Government contributing enormous amount of money to scale up vaccine manufacturing at the same time the research and approval process was going on.

I guess we shouldn't be surprised that we had some glitches, and the glitches that we had was that the -- even though several of the vaccines had emergency use approval late last year, still the amount of supply has fallen short of expectations. And, for our constituents, that has been very frustrating.

So I just want to ask some questions going forward about where we expect to be for vaccine production and distribution.

Mr. Young, I'll start with you.

Last October, Pfizer's CEO said he expected Pfizer to deliver 30- to 40 million doses to the U.S. by the end of 2020, but Pfizer only hit the 40 million mark last week. And I was just wondering: You have said that you're going to provide the Federal Government

300 million doses by the end of July. Given current production levels, are you going to be able to meet that deadline?

Mr. Young. Thank you for your question.

It's correct to say that, you know, we did initially experience some problems with the initial ramp up of our vaccine, and I think, in common with other panelists here, we've been in the process of developing a manufacturing process for a vaccine product that we've never made before. We particularly saw some great limiting steps with raw materials, but we anticipate that we will be on track to deliver those 300 million doses before the end of July.

Ms. DeGette. Thank you.

Dr. Hoge, last July, you testified before this subcommittee, quote, "We're very confident we're going to be able to deliver several hundred million doses next year."

Now, that was over 6 months ago. To date, we've had 45 million doses. Moderna has agreed to provide the Federal Government 300 million doses by the end of July, and will you be able to meet that deadline?

Dr. Hoge. Chairwoman, thank you for the question.

The short answer is we do believe we're on track to meet those deadlines. We have -- as I noted in my oral remarks, we had, as of 2 weeks ago, delivered 45 million doses.

Ms. DeGette. Right.

Dr. Hoge. And then, last week, we are pleased that we finally got to delivering 9 million doses, which puts us on a track record, if you look at the number of weeks ahead, that we should be able to continue to deliver approximately 40- to 50 million doses a month through the balance of our commitment.

If we're able to do that --

Ms. DeGette. Does that -- yeah. Does that get you to 300 by the end of July?

Dr. Hoge. Yes, ma'am, it does.

Ms. DeGette. Super.

Dr. Nettles, Johnson & Johnson's Federal contract is for 100 million doses by the end of June. Last month, a J&J board member said the goal was to have 100 million doses even earlier, maybe by April.

Now, we're hoping that the EUA for Johnson & Johnson's COVID-19 vaccine could come any day, and, if it does, will you able to deliver the 100 million doses by the end of June, if not sooner?

Dr. Nettles. Yes. We are on track to deliver the 100 million doses by the end of June, yes.

Ms. DeGette. Super. Thank you so much.

Now, Dr. Dobber, AstraZeneca's Federal contract is for 300 million doses. Last year, you testified, quote: We are scaling up to manufacture up to 300 million doses of the vaccine so that they will be able -- available immediately upon approval or emergency use authorization.

And so this seems to appear to me that 300 million doses would be ready if you got authorization, and is that the case? And, if not, then how many would be available?

Dr. Dobber. Well, thank you so much for the question. And, once again, what I said in my oral statement, the moment we have EUA -- and we are expecting that in the beginning of April -- we will release instantly 30 million doses. At the end of the month, up to 50 million, and thereafter, we will have a production roughly of 15- to 25 million doses a month.

So, in short, we are on track in order to deliver the commitment of 300 million doses.

Ms. DeGette. But not immediately upon EUA; it's going to take some time?

Dr. Dobber. It will take some time. And, as we're working on scaling our production, that will take some time, but we feel very comfortable that we will deliver the 300 million soon after.

Ms. DeGette. Okay. Keep us updated.

Mr. Trizzino, last but not least, Novavax's contract with the Federal Government is for 100 million doses, and your CEO recently said he expects to manufacture up to 150 million doses monthly by May or June. Do you think you're going to be able to immediately deliver the 100 million doses if your vaccine is authorized?

Mr. Trizzino. We are dependent upon EUA, obviously, but we would be prepared by the end of June to produce that 100 million doses per the existing agreement with OWS.

Ms. DeGette. Okay. Well, I will just say to all of you: Thank you for your efforts, and we all stand ready on both sides of the aisle to help you do what you need to do to make sure we have the production.

Mr. Chairman, I think our next hearing, I hope, will be on how we can expedite disbursal of all of these doses of vaccine so everybody gets it in their arm.

And, with that, I'm proud to recognize our ranking member, Mr. Griffith, for 5 minutes for asking questions.

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

I am sitting here amused because many of your questions were similar to the ones that I had written out, and, as so often happens, while people back home think that Republicans and Democrats can't get along or that everything is a fight, this is not one where there is a fight, and those doses are important.

And, in fact, the Director of NIH, Francis Collins, you know, remarked how amazing

it was that, with precontracting and making sure that we had, you know, contracts in place as those emergency use authorizations came in play is why we were able to get vaccines out there and why we have so many doses that you went through each one of the companies on.

One of the things that, you know, I'm really excited about in many ways -- and it does depend on the EUA coming through for some of these other vaccines besides Pfizer and Moderna, but it appears, based on the numbers that you went through, Madam Chair, it appears that, by midsummer, we may actually have a surplus of vaccine. Because it doesn't last forever, you can't just leave it on the shelf. And, while we will probably need additional doses for the following year, because most scientists believe that we'll need a second -- that it's going to be like the flu; you have to take the vaccine fairly regularly -- we may actually have enough vaccine, again, assuming that we have the EUA, the emergency use authorizations, from the FDA and that they feel the other vaccines are safe, but, by July, we may have enough that we have a surplus in the United States because there are only about 260 million people who are vaccine eligible. And I was just wondering if our witnesses could tell us: Is it a plausible scenario that we'll have a surplus and that we'll be able to share that with other countries who aren't as fortunate as the United States?

And if each of you could answer that, I'd appreciate it. Do you think that's plausible? Do you think that scenario is plausible?

Mr. Young. Thank you for the question.

I do think that there will come a point, you know, in the second quarter this year where I think the companies that you've heard from today are likely to be in a position to be able to supply significant doses of vaccine to the United States. And we certainly hope that we're going to be in a position where every eligible adult will be able to receive

vaccinations. That scenario is entirely plausible.

Thank you.

Mr. Griffith. Thank you.

Who wants to go next?

Dr. Hoge. I would just add to that that I agree that's the hope, is that we definitely have a surplus of vaccines. And then, obviously, we want to find a place to make that available to other countries who don't have access to it.

We are, on our side, just focused on making sure we deliver the 300 million doses we're under obligation to. We're going to work 24/7 to deliver on that commitment.

Mr. Griffith. And we appreciate that.

Next? Just --

Dr. Nettles. I would say much the same.

Mr. Griffith. Yeah.

Dr. Nettles. On behalf of J&J, yes, we are extremely focused on delivering that 100 million doses by the end of June. And, if the emergency use authorization is received this week, we hope to contribute to ending this pandemic as soon as possible, yes.

Mr. Griffith. I appreciate that.

Dr. Dobber. Thank you so much.

Like the other witnesses, I truly hope and believe that there will be a surplus if everyone is able to deliver and, equally, also hope that we can make those doses available to other parts of the world, including the COVAX facility.

There is a huge need in order to vaccinate people also in low- and middle-income countries. So it's a clear pledge to the U.S. Government as well as to the other companies here today in order to also to make sure that those people are getting

vaccinated sooner than later.

Mr. Trizzino. At Novavax, we've got a global supply infrastructure that is important to us and to equitable access. We're intending to make sure that our U.S. supply and manufacturing facilities are maximizing capacity out of those facilitates, and it certainly is very plausible that there will be excess capacity that we would expect and hope would be distributed around the globe where it's needed.

Mr. Griffith. I want to make sure that Americans are taken care of in this process first, but we also want to share with other countries because that helps to keep the virus from coming back or to having more mutations.

That being said, we do have children under 16 years of age that are not currently eligible to get the vaccines. If you all could briefly just tell me if you're working on research. I know Pfizer told me they were in an earlier conversation. And I'm running out of time, so if you could just say, yeah, we're working on something for children under 16, and maybe even under 12.

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[11:29 a.m.]

Dr. Hoge. Yes, we are.

Mr. Trizzino. A trial in less than 16 in the spring.

Dr. Nettles. At Johnson & Johnson, we have a track record of using our adenovirus-based platform in children and infants, and we'll look to leverage it for the coronavirus vaccine. We're in discussions with the FDA on how to move forward.

Dr. Dobber. From AstraZeneca's perspective, we have already started the pediatric trial in the U.K., and we will also start a trial in the United States. So the answer is yes.

Mr. Griffith. And let me say, Madam Chair, before I close out, if you will bear with me just a second. The reason I think that's so important is that plagues in the past, and pandemics in the past, have indicated that while they may not affect children the first time around, sometimes there's a mutation that comes back around that then affects children in ways that we hadn't originally expected. So I am glad that we're preparing for that so we are not caught unaware.

Thank you very much. I yield back.

Ms. DeGette. Good point. Thank you.

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

The Chairman. Thank you, Chairwoman DeGette.

Because of the inaction by the Trump administration, availability of the vaccine is not where the country needs to be. And as I said in my opening statement, all options

for expanding capacity and increasing supply must be on the table.

I have some questions, I'm going to try to get some short answers from you so I can get through them. Let me start with J&J. Dr. Nettles, Johnson & Johnson has promised to deliver 100 million doses to the U.S. by the end of June. You mentioned that. Your contract calls for at least 12 million of those doses to be delivered by the end of February, which is almost here. But, unfortunately, reports indicate that J&J has struggled to ramp up production and will be able to deliver only about 2 million doses in the next weeks or so.

So, what caused you to fall behind your delivery schedule? And why is it taking so long to ramp up production? And are you planning to partner with other manufacturers to boost production?

Dr. Nettles. Thank you for the question. This has really been an unprecedented effort on behalf of J&J to scale up manufacturing on for a vaccine against a disease that didn't even exist more than a year ago. We're in a position, where, as I mentioned, we will have 20 million doses of the vaccine to be made available by the end of March. And we're prepared to ship immediately, upon emergency use authorization, nearly 4 million doses of our vaccine.

The Chairman. Are you planning to partner with other manufacturers to boost production? If you would answer that.

Dr. Nettles. We have, and we will. There was an announcement just yesterday of a collaboration with Sanofi to increase manufacturing globally as well.

The Chairman. Thank you.

Dr. Hoge from Moderna, as virus variants emerge, and we work to develop new vaccines for them, I'm concerned about the potential for additional demands on our strained manufacturing capacity. So if Moderna is already taxing its manufacturing

capacity at its current level, how will you be able to rapidly produce new vaccines, or booster shots, if necessary? And are you considering partnering again with other manufacturers to expand your production?

Mr. Hoge. Yes, sir. So, on both counts, we have worked already to partner with two of the largest manufacturers of pharmaceuticals in the world, a company called Lonza, and establish production, both domestically and internationally, at their facility in Switzerland.

And then we've been partnering with Catalent to make sure that we can do the last step of that filling at high throughput. Now, if there a need for more supply, we're absolutely open to additional partnerships, and will engage in that. At this point, we think we can satisfy our obligations to the United States Government as well as develop variant vaccines.

The Chairman. So, you think that you can rapidly produce new vaccines, or booster shots, if necessary, because of variants? Did you answer that part?

Dr. Hoge. Yes, sir, we do. It's important to note that we are trying to deliver the first 300 million by July, but for the back half of the year, we'll have additional capacity. And there is work to do to develop those variant vaccines. And so a few months of clinical work before we'd even need to be scaling up that manufacturing.

The Chairman. Thank you.

Let me go back to Dr. Nettles with J&J.

I wanted to ask you about vaccine efficacy. J&J's vaccine candidate was found to have 66 percent efficacy, but it was shown to be 85 percent effective in preventing severe disease. And there were zero hospitalizations, or deaths, among the thousands of trial participants. So please explain why should the public have confidence that J&J's vaccine, if it is authorized, will protect them from the most serious risks?

Dr. Nettles. Thank you for the question. We are very enthusiastic about the findings that you just mentioned from out phase 3 ensemble study. This vaccine was tested at the height of pandemic globally, and included a significant number of participants from South Africa, from South America, and Central America, where we know these variants have emerged. And despite that pressure, the vaccine showed that 28 days after receiving a single dose of the vaccine, there were no instances of hospitalization or death, and that includes in the countries where these variants have emerged, as well as 85 percent protection against severe disease in those countries as well.

So, to us, that single-dose approach with those results make us a potential, really important addition to dealing with this pandemic.

The Chairman. I just want to thank you.

Lastly, Mr. Young, what is Pfizer's current assessment of whether your vaccine may reduce transmissions? And when would we have a more definitive answer to that about its ability to reduce transmissions? Because that's what a lot of people ask, you have got about half a minute.

Mr. Young. Okay. Thank you for your question, which is a really important question and one that we are really focused on. We don't definitively know the answer to that question today for any of the vaccines, as to whether it would reduce asymptomatic transmission. However, we believe the real-world data which we're certainly seeing from the U.K. and Israel, and some other countries, will certainly help to inform whether you see, in vaccinated populations, a significant reduction in transmission, which would allow you to infer whether you see a reduction in asymptomatic transmission as well. So it is a very important question, and one that we'll continue to monitor very closely.

The Chairman. Thank you so much. Thank you, Madam Chair.

Ms. DeGette. Thank you so much.

The chair recognizes Mrs. Rodgers for 5 minutes.

Mrs. Rodgers. Thank you, Madam Chair.

I just want to join in recognizing the success of Operation Warp Speed. And I don't think we can emphasize that enough. It is really impressive that we have two safe and effective vaccine in less than a year and, with more on the way. And that normally takes up to 10 years. So it's a very successful public-private partnership, and it is really one of our greatest health achievements. I applaud the Trump administration for the bold goals in setting up this public-private partnership that has led to helping us crush this virus.

Mr. Hoge, I wanted to ask what lessons has your company learned from Operation Warp Speed related to R&D and manufacturing that can help us speed the process from the lab to shots in the arm for future vaccines?

Dr. Hoge. Well, we have a lot to learn over this whole COVID response, and we are still learning it. And, so, I would say that we're still in the process of learning how to scale up the manufacturing and address the challenges of making sure the vaccine becomes available, and as you said, Congressman, get shots in arms.

One of the things that I think we all have already recognized, and I've heard even Dr. Fauci and other testify on, is that the aggressive approaches to making sure that we take financial risks when there is a pandemic, and accelerate the development of vaccines, and their manufacturing has been critical to accelerating our response. And I hope that Americans are proud of the all-of-government response that has happened over the last, now it's been a year, that we've been fighting this.

I think some of the unsung heroes in that are the career folks at HHS, whether it is

at NIH, or BARDA, or even the FDA, as well as DOD, the Department of Defense that have been essential in ensuring success of, at least Moderna, and I suspect all of the manufacturers.

Mrs. Rodgers. Thank you for that.

And I know it has been referred to as all-of-government, but I also really think it has been all of society, really. It's been everyone that's been a part of this response. And I certainly appreciate your commitment.

Mr. Young, would you just speak to the lessons that you believe your company has learned through the development of the vaccine and accelerating future breakthroughs?

Mr. Young. Again, thank you for the question. I think one of the things that enabled us to be able to move very quickly is that we deployed significant amounts of Pfizer's financial and human capital, at risk before we knew whether we were going to be successful. That enabled us to do really, in parallel, a whole number of things that normally, in drug development, you would do sequentially. And it was only by, you know, having a completing different paradigm to how we develop our vaccine that we were able to move so quickly.

And the second thing that I would say is that we really applaud the nature of the interaction that we were able to have with the FDA and the CDC, and other government agencies. Much more real-time sharing of information data, much quicker responses and guidance from the FDA as to how to conduct our clinical Studies. All those things together are what helped us all to be able move as quickly as we did to achieve a safe and effective vaccine approved by the FDA at the end of last year.

Mrs. Rodgers. Thank you for that.

Mr. Nettles, I think we're all learning how development and manufacturing of vaccines is incredibly complex. And I just wanted you to speak to any steps that your

company has taken to enhance domestic manufacturing capability, and how you addressed any supply chain issues that might have slowed down production?

Dr. Nettles. Absolutely. So, really, over this past year, without high level of focus, in parallel with the development of our clinical program, we've been looking at ways to accelerate the production of this vaccine. We have assessed nearly 100 sites where this vaccine can be either produced, or filled, or finished, and selected those that have the capabilities to do it on an accelerated timeline.

So what we have learned is taking this broad approach, and then partnering to bring on the necessary partners to deliver this vaccine on time.

Mrs. Rodgers. Well, I just want to say thanks to all of you. It's really extraordinary, and let's just keep the focus on getting these vaccines in people's arms as quickly as possible.

And I will yield back the balance of my time. Thank you.

Ms. DeGette. I thank the gentlelady.

The chair now recognizes Ms. Kuster for 5 minutes. We can't hear you, Annie. Looks like your headphones are on.

Ms. Kuster. Can you hear me now?

Ms. DeGette. Yes. We can hear you now.

Ms. Kuster. I'm sorry. My apologies.

I want to address my remarks to the new variants of the COVID-19 virus that are already circulating in the United States, including right here in New Hampshire, where we have identified a highly contagious variant first identified in the U.K. The CDC projects that the U.K. variant may be the dominant strain here by March, and the South African variant has been found in at least 10 States. And according to Dr. Fauci, the data on these variants are, quote, "a wake-up call."

To Mr. Trizzino, we understand your company, Novavax, has already developed vaccines against the emerging strains, and, according to your written testimony, plans to begin clinical testing of the new candidates from the first half of the year. Could you explain what that means for Novavax's production plans? And how quickly could the vaccine against the new strains be moved into production?

Mr. Trizzino. Thank you for the question. Yes, indeed, we have observed some interesting phenomenon in our clinical trials in the South Africa and U.K. trials about the significant circulation of the new variant, where 94 percent of the cases in that study were of the new variant. That caused us to pay attention to what that new strain development needs to be. And as you said, we've already begun our development work to identify that new strain, put it into discovery manufacturing so that we can develop either a pathway that would lead us to a booster vaccination of the new strain, or, potentially, a bivalent vaccine, which would be both strains in a single vaccination.

Scale-up has not begun yet in large scale, but we do have a global capacity, both with our -- an existing Novavax facility, facilities in the U.S., our partners in India and Serum Institute. And we believe that we could scale up that new strain very quickly and add it to our vaccine.

We are at a low dose because of our matrix adjuvant. And so, therefore, adding a new strain to our vaccine is something that we have experience with and are capable of doing very quickly. Thank you.

Ms. DeGette. Thank you.

Dr. Hoge from Moderna, I understand that alternating an mRNA vaccine may be easier than it is for vaccines using other platforms. You've described the process as "copy and paste." What does that process entail? And what is the approximate timeline to get from identifying a problematic variant, altering the vaccine and getting it

into production?

Dr. Hoge. Thank you for the question. Yes, I have described it as copy and paste, because messenger RNA really is just an information molecule. It sends instructions to your body and your cells, and, in this case, with any instructions to make a spike protein. And it would be a relatively quick and small change to modify that and put in the information for the new variants of the spike protein that are seen on these variants. We've done that -- actually, we announced several weeks ago that we had already started that, that transition and manufacturing and process. The actual copy and pasting part goes real fast. But we are in the process of scaling up manufacturing for clinical trial right now to test whether or not a variant vaccine booster is useful.

And, in that sense, we're already in discussions with the FDA. We are going to be following their recent guidance about the best way to test, and evaluate that, and moving forward. So hopefully, quite quickly.

Ms. Kuster. Great. Thank you very much.

And Dr. Nettles of Johnson & Johnson, I just have 30 seconds left, but depending upon how the virus mutates, people may be getting vaccines every year for the next several years. If this is the case, how do we avoid going back to square one in terms of building up production?

Dr. Nettles. Thank you for the question. So at J&J, we have undergone, over the last 6 months, really, a rapid and a broad scale-up of our ability to produce these vaccines. We really started from scratch against the disease we didn't even know existed more than a year ago. So, I think we're definitely not going to be in a position where we're starting from square one in the future.

Ms. Kuster. Great.

I have another minute. I'm sorry. Thank you very much for that.

So Mr. Young from Pfizer, how is Pfizer approaching production of boosters? And will that production have any effect on your current schedule of 300 million doses by July 31st?

Mr. Young. No. Thank you for the question. So first of all, no, we believe that we are still on track to be able to deliver 300 million doses to the United States Government before the end of July. And that's something we're focused on, and believe we will be able to deliver to you.

As I mentioned in my testimony, we are going to be -- or hope to initiate a study looking at the benefit of a booster in patients that have already received two doses of the vaccine, because we believe that there is some emerging evidence where having higher antibodies may well be protected even against newer variant strains. As I also mentioned in my testimony, we are also in discussions with the FDA to potentially developing an upgraded vaccine against a new variant of the concern, should it arise. So thank you for the question.

Ms. Kuster. Great. Thank you very much. And I will yield back just asking my colleagues to take a look at my bill, Coronavirus Vaccine and Therapeutic Development Act, to support both the development and then manufacturing of vaccines and to keep up with these emerging variants.

Thank you, Madam Chair.

Ms. DeGette. Thank you so much. I am now pleased to recognize Mr. Burgess for 5 minutes.

Mr. Burgess. Thank you. And I want to also congratulate our witnesses on the outstanding work that they've done over this past year. And, I think, one of the truly remarkable things is you've developed vaccines that are different technologies, some based on the mRNA, some based on an actual breaking off a piece of the antigen and

making the vaccine from that technology. But it is truly remarkable that with the different technologies available, we are now sitting here with five companies that may all have a component of the answer to the coronavirus.

Let me start with our two that have received emergency-use authorization, and currently are in the process of vaccinations of American citizens.

So, Dr. Hoge and Mr. Young, there has been a lot of discussion over the past week, and, certainly, the last weekend, about the use of real-world evidence, and how that may impact things going forward. So, my understanding at the current time, the FDA cannot rely on real-world evidence, but do you have any thoughts, again, this is for Dr. Hoge and Mr. Young, who have vaccines in production in the United States, is real-world evidence of value for you?

Mr. Young. Maybe I can start. John Young from Pfizer. Yes, we believe that the FDA's approach to, you know, answer the first basic question around the safety and effectiveness, and randomized clinical-controlled trials is, you know, very appropriate. But we do believe there is an enormous value for regulators, but, also, public health officials to really understand the safety, and, also, the effectiveness, you know, of a vaccine in real-world clinical practice in much larger populations than can be possible in a randomized clinical-control trial.

We have 46,000 patients in our clinical study, but we already have data from millions of patients from around the world who have been vaccinated. And that data, we believe, can be enormously helpful and informative to public health officials.

Dr. Hoge. Sir, I would completely agree with Mr. Young's comments. And I would add to it that as a part our ongoing commitment, even in the development of the drug, the vaccine, we are actually conducting very large real-world evidence studies, and we will be sharing that data with the FDA, and, obviously, with the public as well, hoping

to confirm what we are already really seeing emerge in terms of the deployment of the vaccine, which is that the large, well-powered phase 3 trials were predictive of the type of response that we are seeing. But that's an important part of developing data and driving confidence in the vaccines out.

Mr. Burgess. Well, of course, the whole issue of being able to interrupt asymptomatic spread, I think, Mr. Young, you addressed that earlier, but that is incredibly important and something that people are anxious for answers on.

Let me -- Dr. Hoge, I'll stick with you, and Mr. Trizzino, on the -- on the issue of patent -- there has been some discussion of, can patents be relaxed to allow for other companies around the world to produce your product? And I believe the Biden administration is revisiting this position with the World Trade Organization to waive patents and other intellectual property. How is that going to impact how you respond going forward? Mr. Trizzino, we'll start with you.

Mr. Trizzino. Yes. Thank you for the question. You know, there's a significant amount of know-how and expertise that takes in order to make these vaccines, in particular, the Novavax vaccine. So we are very, you know, open to tech transferring to partners where we would be sharing that know-how. We've done that already with CRM Institute, for example, for the manufacturing of significant quantities up to a billion doses on an annual basis for low- and middle-income countries. And we've done with partners, contract manufacturing organization partners, around the globe. But we feel it's critically important for us to make sure that we manage that process. The process used to manufacture it is very complicated. And, I think, it's important for us to maintain control over the quality of the product.

Dr. Hoge. I would echo many of the same ideas, and just add that we have also partnered with one of the largest manufacturers of drugs in the world, Lonza, and we

have tech transferred to them to scale up that manufacturing.

As I said in my opening remarks, I think the biggest gain we've seen as we've now moved to almost 9, 10 million doses a week, has been, really, the incredible advances of the highly skilled personnel who are operating each step of that process, both ourselves and externally at our manufacturing partners. And as they develop familiarity with that process, they've gotten better and better at it. And I think we're focused, really, intentionally, on making sure that they are successful, because if that group of people are successful in delivering more of the vaccine, then we're going to be able to satisfy the need.

Mr. Burgess. Can I just say, of course, Moderna and the Pfizer vaccine are the ones that are generally available. Texas Motor Speedway, in Denton County, has done a great job of getting shots in arms, as people say. The one thing that would help them is if they could have visibility as to the number of vaccines that are going to be available, next week and the following week, for planning purposes, to be able to begin to get the people in the parking lot so that they can receive their vaccines. If there's any way we can increase the visibility to the end user, that would be most helpful.

Thank you, Madam Chair.

Ms. DeGette. I think the gentleman.

The chair now recognizes Congresswoman Rice for 5 minutes.

Miss Rice. Thank you, Madam Chairwoman.

In New York and nationally, we are -- obviously, still have a lot of work to do to improve vaccine confidence. But I think that an important step towards achieving that goal should be to help the public understand just how effective these vaccines are.

So Mr. Trizzino, although the results from Novavax's U.S. trials are still pending, you talked about results from a U.K. trial indicating your vaccine candidates' efficacy at 89

percent, and how encouraging it was to see that none of the trial participants who received your vaccine candidate experienced severe illness or death. When we -- so, Mr. Trizzino, when we talk about vaccine efficacy, would you agree it is important for people to understand not just a vaccine's top-line efficacy results, but, also, how well it prevents severe illness and death?

Mr. Trizzino. Yes. Thank you for the question. And it's very important. And first and foremost, anybody, any manufacturer that is involved in the vaccine industry, first, is concerned with safety, and then efficacy. Right? That's kind of a hallmark of a vaccine. You want to do no harm if they are to prevent a disease and not create any additional problem.

So, safety is a critical element of everything that we do. And at this point, we have over 50,000 subjects involved in all of our clinical trials from phase 1, 2, to 2b in South Africa, the 15,000 subjects in the U.K., and another 30,000 in the U.S. And that provides a very robust database of safety information that we will report, and that will provide significant confidence to everybody that we have a safe and effective vaccine.

Miss Rice. Thank you.

Dr. Hoge, earlier this year, Moderna's CEO stated that its vaccine will offer protection. I believe he said, quote, "potentially for a couple of years." Is Moderna still confident in this assessment? And when will we know for certain how long your vaccine, and, I guess, to anyone else, how long the vaccine will offer protection?

Dr. Hoge. That's a great question, and one that we ask ourselves regularly. At this point, I think we're still optimistic, given the high efficacy that we saw in the initial phase 3, in our case, 94 percent, that there is going to be long durability, because we saw, really, high levels of antibodies in the earlier studies and really good efficacy in that base to be studied. But, unfortunately, the only real way we will know about the duration of

that protection is over time. And that's why we're trying to stay very vigilant, and looking both at whether additional boosters of the existing vaccine will be useful, or boosters with new variants and blends.

Miss Rice. Dr. Dobber, if I can just go back to, I think, my colleague, the chairman of the full committee, Mr. Pallone, asked about how to prevent symptomatic infections. I mean, your testimony highlighted a primary analysis of your vaccine candidate, which suggested that it might reduce transmission of the virus, in addition to preventing symptomatic infections. Should we be optimistic that your vaccine candidate, and other vaccines using similar platforms, will reduce transmission? You know, I just keep thinking about people, I think it is really important that we engage in educational vaccine education for the general public to give them a level of confidence to take it. But then you worry about, well, overconfidence in not wearing masks and socially distancing, until we have much more better data to suggest that there is more permanent protection.

Dr. Dobber. Yes. So once again, it is an excellent question, and, in one of our studies in the U.K., we did a short study, so that means that after vaccination, you take a swab every 2 weeks in order to detect whether there is still virus in the nose. And although the data is preliminary data, initial data, it was very promising to see there was a reduction of 67 percent in that specific study. But I completely agree with you. I think all companies, including AstraZeneca, need to do even more in managing that [inaudible] because it is one of the crucial questions they need to address but after vaccination, if it protects us but also not able anymore in order to transmit the disease.

Miss Rice. Exactly, sir. For instance, in New York now, we have 136 cases, a combination of the U.K. and the South African variant. But Mr. Young, if I could just go to you, this is not -- I mean, there's vaccine development, but then there is how do we effectively distribute it? And Mr. Young, you and I had a conversation the other day just

talking about how do you know -- where do you distribute it to and your communications with the individual States who come up with the distribution plan. But I think it is really important for us to remember that it is great to have all this vaccine development, but if we're not distributing it and getting shots in arms effectively, we're not doing our best.

So, Mr. Young, if you could just talk about, you have about 30 seconds to just talk about your conversations with New York and how you work with them?

Mr. Young. Thank you for the question. So we couldn't agree more with your premise that what's most important is that vaccines get to patients who can be protected. What we do is to provide, each week, a forward-looking, 8-week forecast of the vaccine doses that will be available. The Federal Government then liaises with States, States then order or tell the Federal Government what doses they want, and we then fulfill those orders. So that's the process.

But we also work very collaboratively with States in order to ensure that they have accurate information as well.

Miss Rice. Thank you, Mr. Young. Thank you to all the witnesses.

And I yield back, Madam Chair. Thank you.

Ms. DeGette. The chair now recognizes Mr. McKinley for 5 minutes. We can't hear you. We can't hear you. You need to unmute.

Mr. McKinley. I unmuted and it muted me again.

Anyway, let me start again with this. Thank you, Madam Chairwoman. And let me just kind of remind people about this. The Trump administration was listening during last spring, resisting was unfolding. So despite all this unrelenting criticism that's unfounded, the Trump administration actually ordered a billion vaccines from the five companies that are represented here today. A billion. That's enough to vaccinate every American and then some across America.

Chairman DeGette brought up a good point, but she said very clearly in her opening remarks, but the rollout has been slow. So my question -- we've heard from Dr. Nettles. I'm curious from Dr. Hoge, can you explain, or maybe give me some insight from your perspective, does the international supply chain impact the base and manufacturing of the vaccine from your perspective, Dr. Hoge?

Dr. Hoge. No, sir, it doesn't. We have a completely separate supply chain that we established in the United States in partnership with the Federal Government, and they are completely separate. And all of the units supplied is delivering for the U.S. Government.

Mr. McKinley. Okay. Thank you.

Let me switch gears here substantially. Last year, during 2020, we had about 400,000 people die from COVID across the country. But, at the same time, we had over 80,000 people die from substance abuse. Now, that's a horrible number to think about, 480,000 people dying unnecessarily. And the ratio is 5-1 between deaths of drug overdose and COVID. But the American Government has made an absolute commitment, and I'm proud of it, but they are spending 750 times the amount of money to deal with COVID as they are on substance abuse, even though the ratio is only 5-1, or is 5-1. It is 750. And we also know, according to Johns Hopkins, it just came out with their study that said, the 7-day rolling average for daily deaths has actually been decreasing in America during this period of time. But at the same time, drug overdoses have not been. They are continuing to rise. Vivitrol has been a proven treatment. We know about that. Numbers of you know that's a competing product, but the supply and demand has made it difficult to get.

So, thank you for stepping up, when we needed you for COVID in developing a vaccine. But I want to know whether any of you are equally committed to solving this

substance abuse problem, getting us a treatment, the equivalent of a Vivitrol, that we might be able to deal with it? Because as I said, COVID is going to go away, but not the drug abuse. So any of you want to chip in and say your companies are doing something on that?

Mr. Young. John Young from Pfizer. Let me thank you for the question. One of the things I would say is that we manufacture Naloxone injectable, Naloxone, which is an antidote to certain opioids that can cause death and other serious effects. We've worked closely with the Federal Government to make sure that we continue to supply that to States in emergency --

Mr. McKinley. Okay. I'm aware of that. If I could reclaim my time. I am aware that several of you are doing something. But I'm trying to stop it from the beginning, not treat it afterward, after the effect.

So let me flip back to the COVID issue. You all, at the beginning, when Chairman Pallone just opened up the testimony by trashing President Trump, former President Trump. And the Biden administration has been calling for unity, but the rhetoric has not been matched to words. The President has actually said, there has been no distribution plan. And the Vice President said that the cupboard was bare when they took over, they were starting from scratch.

Well, quite frankly, the cupboards should be bare. It is not meant to be on shelves in Washington, but in people's arms. So if there is no distribution plan that they are alleging, how did over 60 million doses get out to the public? And for us in West Virginia, we're now at a rate -- we're nearly 20 percent of the population in West Virginia has gotten at least one shot, and 10 percent has been fully vaccinated. So I don't know how this happens without a plan.

So Dr. Nettles, I'm going it to put you on the spot here, do you agree with

President Biden that there was no plan, and with the Vice President that the cupboards were bare?

Dr. Nettles. What I can say is that J&J very much appreciates the collaboration we've had and we continue to have with the Federal Government. It has certainly been an important contributor to allow us to move forward at the pace we have to potentially bring forward a vaccine that's under consideration for emergency use this week.

Ms. DeGette. I thank the gentleman.

Mr. McKinley. I yield back my time.

Ms. DeGette. The chair now recognizes Ms. Schakowsky for 5 minutes.

Ms. Schakowsky. It has been said today that we are all in this together. And when we say "all," it reflects an understanding that this is a worldwide pandemic, and that crushing the virus, therefore, requires the access to vaccines, and that must extend to countries across the globe.

So I want to ask you each, in a yes-or-no answer, that's it: Do you agree that the presence of the virus anywhere is a threat to humanity everywhere, including in the United States? So let me ask you, Mr. Young, yes or no?

Mr. Young. We believe the presence of the virus is certainly a threat anywhere around the world.

Ms. Schakowsky. Thank you.

And Dr. Hoge, yes or no?

Dr. Hoge. Yes, the presence of the virus is a threat.

Ms. Schakowsky. And Dr. Nettles?

Dr. Nettles. Yes, I agree, the presence of the virus anywhere in the world is a threat to us.

Ms. Schakowsky. And Dr. Dobber?

Dr. Dobber. A firm yes, correct.

Ms. Schakowsky. Thank you.

As you, I'm sure, know, that over 100 countries, and it was mentioned by Dr. Burgess, led by India and South Africa, have appealed to the World Health Organization to put a -- to put a halt on the -- on TRIPS, the Trade-Related Intellectual Property Standard. In other words, to have a waiver that would allow countries around the world, poor and middle-income countries, to be able to manufacture their own vaccines. And it seems to me that this is something that we should do so that we have plenty for us and plenty for the rest of the world.

You know, taxpayers have invested, in this issue, billions of dollars right now to be able to open our country, and to doing that, we have said that intellectual -- that we want to make sure that the airlines are supported, that all the industries that rely on travel should be supported. But if we spend all that money, and, yet, we don't have other nations that are protected against the virus, it is all in vain. Those billions of dollars are in vain.

And, so, I am very anxious because there is a meeting Monday -- Monday and Tuesday, on the question of whether or not this waiver to the TRIPS program is going to be allowed. And I want to ask again, each of you, if you can support doing that.

Mr. Young?

Mr. Young. Sorry. We don't support that waiver. We believe it incorrectly portrays intellectual property as being the barrier to update. That we have [inaudible] with other companies here, we consider all viable options and mechanisms to ensure that any potential treatment or vaccine is available to address the --

Ms. Schakowsky. Dr. Hoge?

Mr. Young. -- acceptable to those who need it.

Ms. Schakowsky. Dr. Hoge, yes or no?

Dr. Hoge. We'd agree that we want to find a way to get vaccines to everybody who needs it everywhere. I'm actually not familiar with the issue personally. I don't think we have a perspective as a company.

Ms. Schakowsky. Dr. Nettles?

Dr. Nettles. We don't believe that intellectual property is the limitation to a global supply. We have scaled up our global supply chain, and made significant contributions and commitments to WHO.

Ms. Schakowsky. Dr. Dobber?

Dr. Dobber. We are willing to give sublicenses to other parties as we have done already multiple times in order to safeguard the quality of our vaccine. I think that's much more important than what you are suggesting.

Ms. Schakowsky. And Mr. Trizzino?

Mr. Trizzino. Trizzino. Yes. Thank you, Congresswoman. We do not support, but we have tech transferred and licensed our technology to other countries.

Ms. Schakowsky. Well, let me just say this in ending, I understand that it was recorded that in South Africa, that the cost of the AstraZeneca was more than twice the amount for the Europeans. So, I'm concerned that without the waiver, that what we're going to see is that the rich countries in the world, who are the only ones really who are opposing this waiver, are going to monopolize the vaccine. I have no problem making sure that we have enough here. But the fact that we would keep these middle and low-income countries, particularly the poor countries, from having those drugs, I think, is immoral, quite frankly, and not the productive way to go forward.

And I yield back.

Ms. DeGette. The gentlelady yields back.

The chair now recognizes Mr. Long for 5 minutes.

Mr. Long. Thank you, Madam Chair. And thank you all for being here today.

The week before last, I went on a 3-day tour through my district. I toured six hospitals, two clinics, and one vaccination center. And I would highly recommended that to all of my colleagues, if they want to do something similar in their district, if they haven't already. But I called the hospitals and clinics and said, I want to sit down with your frontline workers, your nurses, your doctors. And they not only poured out their hearts, some poured out their life stories to me, and everything they have been doing throughout the last year is just incredible, whether they are doing rounds at night when they are asleep, or giving shots while they are asleep at home, or having to steal off time from their family to go in another room to call another family member and explain to them that their other family member that they were caring for for months haven't seen their family has deceased.

So, it was quite a moving 3 days, and I'm glad I invested the time in that.

Mr. Young, while I visited the hospitals in my district to hear from them about their efforts to get people vaccinated, one of the problems they mentioned after they distributed the Pfizer vaccine was that they didn't have low dead space syringes. And this impacted the number of vaccine shots per vial they were able to administer, as I'm sure you're aware. The vaccine made by Pfizer is shipped in the vials initially indicated the whole five doses. Six doses can be drawn with low dead syringes, which minimizes the amount of vaccine wasted in the syringe after it's used.

These specialized syringes are in limited supply. In fact, they were out of them when I visited. The United States Government has been giving all -- or giving healthcare providers new syringe kits to extract six shots of each vial.

Can you walk me to the change from five to six doses per vial? Is Pfizer confident

that the supply of low dead space syringes need to fulfill the obligations of its agreement with the United States Government?

Mr. Young. Thank you for the question. In order to make sure that we could, recognizing the vaccine doses were short, we did everything that we could make sure that we could maximize the supply of vaccine doses. And one of the things that we did was validate more than 30 individual low dead volume syringe-and-needle combinations to enable a sixth dose to be reliably extracted from each vial. We provided that information to the FDA, and also supplied that information to the Federal Government.

So the Federal Government supplies the kits by McKesson, which includes needles, syringes, and wipes to the States and all vaccination centers. And we work very closely in collaboration with the Federal Government in order to make sure that they were able to reliably procure those low dead vial syringes from the manufacturers concerned.

Mr. Long. Okay, thank you.

And I'll stick with Mr. Young here for a minute. Many of you-all's companies, in fact, I'll try to get to everybody, but I may run out of time. But many of your-all's companies have undertaken efforts to expand manufacturing capacity for COVID-19 vaccines. Pfizer, notably, expanded its manufacturing in my home State of Missouri. Can you share what your company has done to expand the manufacturing capacity of last year?

Mr. Young. Thank you for your question. I think probably in common with all the other manufacturers on this panel, we have made significant investments in new lines in St. Louis, Missouri, it plays an incredibly important role in manufacturing the mRNA -- I'm sorry, the DNA templates that are used to, in turn, manufacture the mRNA. That takes place in St. Louis. We've invested in significant engineering work to build

complex machines that actually enable formulation of lipid nanoparticles, and have scaled up supply of, you know, really specialized raw materials, including lipids. So we made significant investments into our U.S. supply chain.

Mr. Long. And how long does it take for additional manufacturing capacity to be built out, whether it's new line or an entirely new facility?

Mr. Young. That work that we really started in the middle of last year. We didn't wait for approval to begin that work, and began investing substantial capital, with financial and human capital at risk, even before we knew we had a vaccine. And that work has continued, and is one of the things that has helped to feed an increase in our projected 2021 production to more than 2 billion doses this year.

Mr. Long. And I am going to, again, thank you all for being here today. I'm going to submit that question to the other folks that I don't have time to be fair to today. And I'm going to yield back 14 seconds.

Ms. DeGette. I thank the gentleman for yielding back.

And the chair now recognizes Mr. Tonko for 5 minutes.

Mr. Tonko. Thank you, Madam Chair, for arranging this hearing. I think it is very important and very timely. And we thank our witnesses for joining us today.

Throughout my home district in New York's capital region, both vaccine supply and access are still major issues. I've spoken with local families whose loved ones are in their 90s, and they can't get a vaccine. Just how can this be?

So last week I sent a letter to the leaders of Pfizer and Moderna, specifically, Dr. Bourla and Mr. Bancel, asking how Congress can help remove limitations on production and distribution, so we can vastly increase access to vaccines.

Madam Chair, I can that these two letters be entered for the record.

Ms. DeGette. We will review the letters and determine at the end of the

hearing.

Mr. Tonko. Thank you, thank you.

We understand better than ever that vaccine production is incredibly complex, with bottlenecks possible up and down the line, from raw materials and supplies, to storage and distribution, even just having enough highly trained people working in lockstep coordination across the entire process. While complex systems can be difficult to manage, they also present opportunities for efficiency and ingenuity.

I'd like to hear from you on how we can do better. What solutions -- what limitations, rather, are you running into? What solutions are you looking into for increasing production and expanding your manufacturing capacity?

So Mr. Young, millions of Americans are anxiously awaiting their vaccine, and Pfizer is working around the clock to meet its obligations to provide doses to the United States. Is Pfizer currently producing at full capacity? And what would it take to produce even more quickly?

Mr. Young. Thank you for the question. I just want to underscore what I mentioned in my testimony that we are very clear that the United States and every other country needs more doses more quickly, and we are working to achieve that end. So as I mentioned in my testimony, by the end of March, we should be pretty much at maximum capacity in our U.S. supply chain and able to deliver 13 million doses a week, which is a significant increase from the around about 5 million doses a week, even at the beginning of this month.

So we are in the process right now of seeing the benefits of the various stages of process improvement that I mentioned in my testimony, and seeing that flow through to delivery to providers all around this country.

Mr. Tonko. Thank you.

And Dr. Hoge, Moderna is seeking approval from FDA to increase the number of doses per vial from 10 to up to 15 while that's encouraging news, you estimated it could take 2 to 3 months to make these adjustments. What would be the impact of increasing the number of doses in each vial?

Dr. Hoge. Thank you for the question, sir. Our -- if we can increase dosing, we can actually decrease the amount of time it takes to create a batch, and actually decrease the demand for some of these critical, high-demand raw materials, and particularly vials. We think that would accelerate delivery substantially, probably not 15 to 10 as a ratio, but we need to demonstrate an improvement in delivery or time.

Where we are right now is last month -- or actually, just last week, as I said in my oral remarks, we delivered over 9 million doses to the United States Government.

And, so, we think we're in a very good spot at about 9- to 10 million doses a week. We now need to demonstrate reliability in that production. But, obviously, any gains, for instance, like, filling more doses in a vial we will take, because I agree with Mr. Young's comment, we need to get more doses more quickly into people's arms.

Mr. Tonko. So more doses per vial, what can be done to -- is there anything that could be done do speed it up?

Dr. Hoge. At this point, the obligation is on us to develop the data that the FDA would support for us to go forward with that approach. We're in the process of doing that right now. And we are working 24/7, I assure you. We hope to pull in those timelines as best we can. But we want to make sure that we're a reliable partner to the United Sates Government so we don't want to over-commit.

Mr. Tonko. And Dr. Hoge, sticking with you for just a minute. In January, Moderna's CEO stated that if there is, and I quote, "one raw material missing, we cannot start making products, and that capacity will be lost forever because we cannot make it

up." Is this an area where Congress or the Federal Government could be providing more support?

Dr. Hoge. Well, I would say, sir, that the Federal Government is already providing tremendous support exactly on this point. And so, we have been partnered with the folks at the Department of Defense and HHS on all aspects of our supply chain, really, for almost a year now. And that means that they have visibility down to the single raw material level and those deliveries, and have been working with us to make sure that they are delivered. So I hope you take confidence in the fact that that actually is a daily exchange between us and the government.

Mr. Tonko. Is there anything else related to raw materials or otherwise that we could be doing right now to help you boost your vaccine output?

Dr. Hoge. If there are, we haven't identified it yet, sir. But we are working every day to identify new opportunities.

Mr. Tonko. Thank you so much.

Madam Chair, I yield back.

Ms. DeGette. The gentleman yields back. Mr. Dunn, do we have you?

Mr. Dunn. Yes. Can you hear me?

Ms. DeGette. I see you. You're recognized for 5 minutes.

Mr. Dunn. Thank you very much, Chairwoman DeGette.

I had the opportunity to read the testimonies of each of the witnesses. And I feel compelled to say that all of these companies represented here today have accomplished amazing things in the last year. And I want to commend you all and your staffs for the work that you did in rising to the challenge of expediting your research and development of COVID-19 vaccines to serve the entire world, and doing so in a miraculously short amount of time.

I would like to be able to tell you today to lay down your burdens and take a victory lap. But, unfortunately, we still face production and distribution hurdles. And, of course, we are dealing with a virus that, by its very nature, tends to mutate rapidly. It is entirely conceivable that some of these mutations could enable the virus to begin to invade even your brilliantly engineered vaccines. So as the vaccine supply ramps up to allow for mass vaccination, we, as Congress and industry leaders, still need to plan and prepare distribution challenges, such as the extreme weather we saw just last week in the southern States.

Not only should supply of distribution chains be resilient and redundant, but they must also accommodate the surge of more vaccines coming online over the next few months. So, from the manufacturing lines to vaccination sites, there must be adequate personnel and infrastructure to support the vaccination activities.

I also want to be sure that we're considering and planning how to come back potentially resistant variants of SARS-CoV-2 and, for that matter, the next totally new pandemic disease, whatever that may be. We already know that some of the more contagious variants have been identified in the United States.

Fortunately, according to the CDC, early data suggests that for now the existing vaccines are effective against these variants, but we will be doing ongoing collection of data and sequencing.

I'd like to hear from our witnesses on this topic. And let me address, if I may, this question to Mr. Young and Dr. Hoge. If changes are made from the original vaccine formula in order to address resistant variant strains, the FDA released, just yesterday, some guidelines for applying for a modified EUA. I wonder if you've had a chance to review these guidelines and digest them? I read them and I was concerned that another major clinical phase 3 study may be required. Do you have any insight on that, and what

kind of delay that might entail?

Mr. Young. Thank you for the question. I think we, like you, only recently received the FDA guidelines. We are still in the process of reviewing them. But in terms of the approach, you know, I think all of the companies that received an EUA, which is the authorization by the FDA, have been able to demonstrate that our vaccines are safe and effective in large, randomized, clinical-controlled trials.

Certainly, we believe that a more of a seasonal flu-like process, where a new variant might be able to demonstrate safety and immunogenicity in a smaller number of patients might be a much quicker way to expedite a new variant vaccine to patients in this country.

Mr. Dunn. Dr. Hoge?

Dr. Hoge. Yes. We also received that just recently, as we all did yesterday. We have been in productive conversations with the FDA. Ultimately, they have responsibility to set the bar and make the recommendation whether a vaccine is effective and safe against those new variants. But we are hopeful that we will be able to do it without large, randomized phase 3 trials. And, in fact, that process can proceed over the course of months rather than a long year, as it has in the past.

Mr. Dunn. So I join you in that hope. I think that would be imperative.

Another question I know I'm not going to be able to have time to get everybody to answer, but I am going to submit this. I would like to have all of you consider it. And this is the question: In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics, that is to say, antivirals that could potentially have a broader spectrum of activity across the coronavirus variants?

I already had an opportunity to talk to Pfizer about their ongoing efforts, very

encouraging. I'd like to hear from the other companies. And I see we only have 29 seconds left. I don't believe that we can get a meaningful answer in that period of time. So I'm going to ask you to take that question and respond to my office about that. We are keenly interested in therapeutics, the entire Doc Caucus is interested in therapeutics, treatments in antivirals.

With that, Madam Chair, I yield back.

Ms. DeGette. Thank you so much, Mr. Dunn. And we will ask all the witnesses to respond to that question as we do all written questions.

Mr. Ruiz, you are recognized next for 5 minutes.

Mr. Ruiz. Thank you, Madam Chair.

The disproportionate impact of COVID-19 on communities of color is undisputed. We've seen the horrible statistics of Black and Hispanic Americans being at high risk of getting infected. They are more likely to be hospitalized and die from COVID than White Americans. And yet, at this point, they are less likely to have been vaccinated against the disease.

In my county, here in Riverside County, Hispanics make up 47 percent of the population. They comprise of 65 percent of infections, but only 19 percent have received the vaccines.

We have talked a lot over the past several months about the importance of the equitable distribution of vaccines. I have used that platform many times to implore stakeholders, including your companies, earlier this summer, to make sure that these underserved communities and communities of color have access to the vaccine.

And I have continued to advocate for more vaccines to be sent to the underserved and hardest-hit areas in my own district and across the Nation. However, prioritizing vaccinations for high-risk groups hardest hit by COVID-19 is not effective if these

communities are not able to access the vaccine, or don't have the information they need to navigate the system.

Unfortunately, we are learning that many people don't have the information that they should, or worse, have wrong and inaccurate information. I have seen this firsthand when I have teamed up with other providers and nonprofits to literally go into the field and provide public health, vaccine education campaigns to farm workers, and also packing -- produce packing workers.

And working within these communities and with providers and community leaders is critical to the public health education component of our vaccines. As manufacturers of the vaccine that will help end this pandemic, it is critical to make sure the public and providers have accurate information about the vaccine through community public education.

Dr. Hoge, before the committee last July, you shared that in an effort to enroll diverse participants in this clinical trial Moderna partnered with different groups to, quote, "leverage those trusted advisers within these communities." Now that Moderna's vaccine has been available for 2 months, I'm curious if these partnerships continue? Who were they with? And if you are using them or taking additional access to provide communities of color the information they need to have confidence in getting vaccines?

So, can you tell us specifically what Moderna is doing and what resources are being directed towards those efforts? And can you tell us, specifically, how much money Moderna is spending on those efforts?

Dr. Hoge. So first, I think I would echo your comments about the devastating impact in communities of color and how they have disproportionately borne the burden of this disease. It is absolutely something we need to address, because none of us are

safe until all of us are safe. That's something we have taken very serious as a company.

On the question of distribution first, we -- our contract with the United Sates Government has --

Mr. Ruiz. My focus right now is not necessarily distribution. My question is very specific to your public health educational outreach. And do you have partnerships and what are you doing to combat the misinformation and build public confidence within the hardest-hit, highest-risk communities of color?

Dr. Hoge. So we are active in on many fronts there. I will say we are also a relatively small company, about 1,300 people, and somewhat of a newcomer. And in that sense, we are still building the capabilities to reach out to all the public health communities you are describing. However, one area that we focus --

RPTR GIORDANO

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[12:28 p.m.]

Mr. Ruiz. Do you have a program and partnerships or grants available to the community?

Dr. Hoge. We've been very active in doing that, in particular during our clinical trial. So, as has been widely reported during our phase 3 clinical trial, as you --

Mr. Ruiz. I'd like to talk to you further to get more of the specifics on what you're actually doing to increase the public health educational outreach.

I'd like to give Mr. Young the opportunity to answer that question. What is Pfizer doing? What exactly, in partnerships or funding, you are using or creating in order to combat misinformation and improve public trust and confidence within the hardest hit minority communities?

Mr. Young. Thank you for the question.

We also couldn't agree more with the question that you're asking given how impacted minority communities in the United States are.

First of all, we are doing a lot to work with minority organizations that represent minority healthcare professionals with Hispanic and Black nurses and doctors associations. We're working very closely with grassroots community organizations all around the country to be able to supply information in other languages --

Mr. Ruiz. What amount of money are you spending on those efforts? Do you know?

Mr. Young. I know we're spending a significant amount of money to support education, but I couldn't tell you an exact figure. I would be happy to follow up with

your office if that would be helpful.

Mr. Ruiz. I would like both Moderna and Pfizer to follow up with my office on these questions.

Thank you very much.

Ms. DeGette. Thank you so much.

The chair now recognizes Mr. Joyce for 5 minutes.

Mr. Joyce. Good afternoon.

First of all, thank you, Chairwoman DeGette and Ranking Member Griffith, for holding this hearing. Thanks to all the witnesses for participating today.

We all know it remains critical that we continue to build on the two existing vaccines that have already been approved for use and continued success of Operation Warp Speed. We recognize the need for more vaccine supply across the United States, and especially in Pennsylvania, where I hail from.

I remain hopeful that we will see more vaccines and receive their EUA in short order to help with this problem. The advent of additional strains could raise the amount of vaccine that is needed to achieve the necessary herd immunity, but we must remain ahead of this virus.

Americans everywhere are desperately seeking to return to their normal lives. They look to reopen their businesses and, most important, get their kids back into school. Safe, effective, and readily available vaccines are necessary to achieve this goal.

Ramping up production on this scale and in this unprecedented timeframe has presented some challenges. So I'd like to ask each of the witnesses to respond. Do you expect shortages in raw materials or component supplies, such as filters or specialized bags, that are needed to manufacture your COVID-19 vaccine, especially if you're looking to produce more vaccines and if other companies receive EUAs in the

coming months?

And I'll start with Dr. Dobber.

Dr. Dobber. Well, first of all, thank you so much for the question. I think it's an incredibly important question. At this moment, I can confirm that we are not foreseeing any shortage of raw materials as you have mentioned.

Mr. Joyce. Dr. Nettles, your response, please?

Dr. Nettles. I agree with the previous response. At this time, shortages as you describe are not a limitation to us providing the vaccine.

Mr. Joyce. And Dr. Hoge?

Dr. Hoge. As I've said, at this point, we think we have the supplies and consumables we need to do it.

Mr. Joyce. Mr. Trizzino?

And, first of all, I certainly enjoyed the graphics. It took me back to immunology in medical school to see you discuss nanoparticles, but let's -- let me allow you to address raw materials and component supplies. Do you feel that Novavax will face any shortages?

Mr. Trizzino. We've been working very closely with the U.S. Government to ensure a sufficient supply for our manufacturing facility with FUJI Diosynth, so we don't expect any shortages in the U.S.

Mr. Joyce. And Mr. Young from Pfizer?

Mr. Young. No. Thank you for the question. In common with my other panelists, we don't anticipate currently any shortages of raw materials or supplies that would prevent us being able to deliver 300 million doses by the end of July.

Mr. Joyce. Thank you.

And I'd like to continue in the fashion that we've outlined. So, specifically,

have -- each of you, have you seen issues in obtaining vaccine supplies from foreign manufacturing companies? And, if so, what type of products have you found those challenges to lie within, and during what time of production did these challenges occur?

And, again, I'd like to start with Dr. Dobber.

Dr. Dobber. So, in the United States, we have a very specific supply chain for the U.S., and, once again, I reiterate we haven't seen any shortages of essential materials in order to produce our vaccine. And we are on track to deliver 50 million doses in the month of April.

Mr. Joyce. And thank you.

Dr. Nettles?

Ms. DeGette. Doctor, you need to unmute. You're muted.

Dr. Nettles. Sorry. No, we have not encountered any shortages or issues with foreign supply of equipment that would prohibit us from delivering on the 100 million doses that we've committed to by the end of June.

Mr. Joyce. Thank you.

Dr. Hoge?

Dr. Hoge. No, we haven't identified any such issues.

Mr. Joyce. Mr. Trizzino?

Mr. Trizzino. All of our raw materials are sourced within the U.S., so we don't have any shortages for our U.S. manufacturing.

Mr. Joyce. And Mr. Young with Pfizer?

Mr. Young. We don't currently see any shortages that would constrain our ability to meet our commitments.

Mr. Joyce. And, while I have you -- and, specifically, this is regarding Pfizer -- can you please tell us if you feel that you're able to provide us any updates regarding

transportation and storage temperatures for the vaccine that would make this process easier that would allow more shots to be put into patients' arms?

Mr. Young. No. Thank you for the question.

Last week, we actually supplied an update to the FDA, which was based on data -- stability data for our vaccine that found that we would be able to reliably store it for up to 2 months in conditions that are equivalent to a normal freezer. So we were certainly very happy with that update, and we hope that would enable the vaccine to be able to supply to more communities around this country.

Mr. Joyce. Thank you. I see I'm over time, and I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes Ms. Schrier for 5 minutes.

Ms. Schrier. Thank you so much, Madam Chair, and thank you to our witnesses.

Let me first just express my gratitude to you, your scientists, your investigators, who continue to work around the clock. We are so grateful.

As a pediatrician, it may not surprise you that I'm going to ask about vaccinations in children. Now, as typical, studies in children and pregnant women always happen after studies in the general public, for very good reasons. And children themselves generally, at least with these variants, have very mild or no symptoms, so the risk-benefit calculations are also different.

And every day in practice I encounter vaccine-hesitant parents, and I expect the same thing will happen here. And the one thing that I think would change the parents' risk- benefit calculation is whether the vaccines prevent transmission. In other words, giving Johnnie the vaccine means Johnnie can visit grandma and won't bring the virus home from school to his parents.

And some of my colleagues have touched on this issue of transmissibility.

Chairman Pallone asked about studies at Pfizer. Representative Rice asked about studies at AstraZeneca. And so I was just wondering could our other witnesses comment on this, maybe starting with Dr. Hoge?

Dr. Hoge. I'm sorry. Still on mute.

So we are actively studying the vaccine in 12 to 18 population and rolling out studies very quickly, and moving into younger populations in the near term.

Ms. Schrier. I'm sorry. Any studies of whether the vaccine -- whether Moderna prevents transmissibility?

Dr. Hoge. Oh, yes. We have seen some early data that we presented to the FDA showing a decrease in patient nomadic infections between the first and second dose. The data that will hopefully support that evidence more broadly is evolving and will be a part of our subsequent filings. We don't have any data yet, but we are studying it actively.

Ms. Schrier. Thank you.

And, Dr. Nettles, did you have anything to add to that issue of studying transmissibility and what your early findings are?

Dr. Nettles. We are deep diving into our phase 3 clinical trial results in ENSEMBLE, as was just mentioned, to understand what is the impact on asymptomatic disease from our vaccine. We hope to bring forward that after discussions with the FDA.

Ms. Schrier. Great. Thank you.

And, Dr. Trizzino, did you want to add anything about transmissibility and what you're finding?

Mr. Trizzino. Just that -- thank you for the question -- we are expecting to start pediatric studies in the spring. We believe, as you do, that it's important for us to get data -- safety data, and particularly about that population.

We are looking at our clinical trials now for transmissibility and looking at future studies in that regard, but don't have any data to share today.

Ms. Schrier. Thank you.

I have another question. This is about pediatric studies, because, Dr. Trizzino, you just mentioned looking at safety in children. I was wondering, Mr. Young, can I ask you about how studies in children are different? Like the studies in adults look for endpoints of severe disease and death, but that's not a reasonable endpoint to look at in children because that doesn't happen for the most part.

Can you talk about what you're using as endpoints, whether that's antigen testing, you name it? How are you designing those studies?

Mr. Young. No. Thank you for the question.

So, as I mentioned in my comments, we have an ongoing study in children between the ages of 12 to 15 years, and we hope to do another study in children under the age of 11 later on this year. The endpoints in those studies are primarily safety. As my colleagues have mentioned, we know that that is of primary importance.

And then we're also going to look to demonstrate immunogenicity. And, in the course of those studies, obviously we'll look at reactogenicity, which is what I call the normal effects that you would see when your body begins to produce an immune response. We will be able to collect all of these data and hope to submit those to the FDA later on this year.

Ms. Schrier. That's great. So that would imply effectiveness if you have evidence of immunity.

I have just a little bit of time left, and I thought I would ask about pregnant women because, you know, of course the studies are later, because you want to test it in the general population first. And, yet, now this is really being left up to pregnant women

and their OB/GYNs to decide whether to recommend it.

My discussions with ACOG suggests that most obstetricians are recommending it because, although pregnant women are not at high risk for contracting it, they are, I believe, 70 percent more likely to die of COVID. And I was wondering if you would talk about your studies in pregnant women and what you're finding.

Sorry. I should go to Mr. Young.

Mr. Young. No. Thank you.

We actually initiated a study in pregnant women just last week, so that study is obviously in the early stages by recruiting patients. And, again, we want to make sure that that study from an endpoint perspective can demonstrate safety for the mom, safety for the baby, as well as obviously the immunogenicity data that would enable that vaccine potentially to be approved for use in pregnant women.

So that study is ongoing, and we'll move as quickly as we possibly can.

Ms. Schrier. And anything real life out of Israel?

Mr. Young. That's a really good question, but we potentially are going to be in a position where we may have real-world data for women who became pregnant after being vaccinated, and so that is an additional set of real-world data that could potentially complement that formal randomized, clinical-controlled trial.

Ms. Schrier. Thank you very much.

I'm over time. I yield back.

Ms. DeGette. Thank you so much.

The chair now recognizes Mr. Palmer for 5 minutes.

Mr. Palmer. Thank you, Madam Chairman.

Mr. Young, when was the emergency use authorization granted for the Pfizer vaccine?

Mr. Young. The EUA was granted at the end of last year in December.

Mr. Palmer. December.

Mr. Young. 11th of December, I believe.

Mr. Palmer. How many doses have been administered to date by Pfizer?

Mr. Young. Well, obviously Pfizer doesn't administer the doses. That's something which is done by the States. But I think, as I mentioned in my testimony, we're -- to date, we've supplied approximately 40 million doses, I believe, at this point in the United States since that EUA was received last year.

Mr. Palmer. Dr. Hoge, when was the emergency use authorization granted to Moderna?

Dr. Hoge. December 17th, sir.

Mr. Palmer. Since we've been doing the vaccinations, over 64 million have been administered. We'll probably go over 65 million by the end of today. So do you all -- you guys have an idea of when vaccinations -- when we started giving the vaccinations? Was it December 15th, the end of December, when they were widely available to the public?

Mr. Young. We started shipping our vaccine the day after the EUA was received so that vaccine sites were able to begin vaccinations on the Monday. So we received that EUA over the -- later in one week, and, by the Monday, vaccination sites had vaccine doses to be able to begin vaccination programs.

Mr. Palmer. Well, given the comments from my Democratic colleagues that there was no infrastructure, how do you account for the fact that we've given 65 million vaccinations in such a short amount of time? That's roughly a million a day. There was 1.6 million on Inauguration Day.

How were we able to accomplish that?

Mr. Young. We, and I'm sure in common with the other companies on this panel, have worked very closely with the Federal Government. We've worked very closely with States in order to make sure that we were clear and transparent about the number of vaccine doses that were available so that they could be allocated to the States and so that those vaccine doses could get to patients who need them as quickly and reliably as possible.

Mr. Palmer. In terms of infrastructure issues, Mr. Young, with the Pfizer drug and it needs to be maintained in a cool environment, do you feel confident that we have the infrastructure in place to make sure that that virus -- is not only available to the public, but it's available in its proper form?

Mr. Young. Thank you. Yeah. We have worked extremely hard to develop a robust and reliable supply chain. Recognizing that our vaccine currently needs to be stored at ultralow temperatures, we designed specific thermal shippers to be able to effectively and safely get those doses to site to be used.

Today, I think globally, we've supplied more than 46,000 of our shippers that contain our vaccine vials, and we have a 99.9 percent accuracy and reliability in delivering those vaccines safely to the points of use and administration. That's something we'll continue to be focused on.

Mr. Palmer. Okay. And this is kind of off infrastructure track, but do you have any confidence that these vaccines might be effective against the mutations that we're seeing now, or do you see this as something similar to the flu vaccine that people will have to get administered year after year?

And make your answers as concise as possible. I've got a couple other questions I want to ask.

Mr. Young. Thank you.

We are very focused on emerging mutations, variants of concern. To date, we believe our vaccine appears to show effectiveness, and that's something we'll continue to monitor. We're certainly prepared to develop an upgraded vaccine should that be suggested to be necessary by the real-world data that we are seeing.

Dr. Hoge. And we also have confidence that the current vaccine is active against the emerging variants, but we need to remain vigilant, which is why we've started the development of a booster against those variants.

Mr. Palmer. Very quickly, back in some respects to the infrastructure issue, given that we've really haven't had a flu epidemic and we've been pretty effective in getting flu vaccinations out to a broad population through drugstores and big-box pharmacies and things like that, I see that as an opportunity to get this out.

We also -- to Dr. Ruiz' issue, all of us need to be involved in doing what we can to educate minority populations about the vaccination. And I was going to ask you, each one of you -- you've gotten the vaccination. But, because you're under oath, I was going to ask you if it hurts.

So I will not ask that question, Madam Chairman. I yield back.

Ms. DeGette. I thank the gentleman.

The chair now is pleased to recognize Mrs. Trahan for 5 minutes.

Mrs. Trahan. Thank you, Madam Chair, and thank you to the witnesses here today. We all appreciate the efforts of the companies and the employees you work here representing to develop lifesaving vaccines as quickly and safely as possible.

This week, the U.S. sadly surpassed 500,000 COVID-19 deaths. And, with the rising death toll and millions of Americans anxious to get vaccinated, we must explore any and all options to increase supply and get more doses into our communities.

Last Congress, I introduced the Pandemic Production Act, which will incentivize

American manufacturers to maintain domestic production capacity for medical equipment necessary to respond to an infectious disease outbreak and safeguard our supply chain. And I do invite all my colleagues here today to support the PPA when I re-introduce it this Congress.

But one such tool that we can utilize now is the Defense Production Act, which allows the President to prioritize certain supplies for the vaccination effort. President Biden recently announced that he would expend -- expand -- excuse me -- the use of the DPA, which is critical to our public health and our national security. And it's important for us to hear from you all your perspectives on the DPA.

Surely it's helped expand manufacturing capacity, but how we can further expand the use of the DPA in our pandemic response and future pandemic prevention.

Dr. Hoge, earlier in the hearing, you mentioned that, in May 2020, Moderna and Lonza announced a collaboration to scale up production in manufacturing up to 1 billion doses per year of the mRNA vaccine you produce. What barriers prevent Moderna from expanding manufacturing capacity with Lonza or other contract manufacturing organizations? And, if barriers exist, could a contract or a series of contracts authorized by the DPA help expand production with Lonza or other manufacturers?

Dr. Hoge. Thank you for that question.

As I tried to describe in the opening statement, it's a pretty complicated system, as you pointed out. We don't only just need raw materials there. We need supplies. You need installed infrastructure like we've done at Lonza and Catalent. And then you need highly skilled laborers, people who actually work every step of that process, and they get better over time. In fact, that's one of the great gains in terms of production you get, is, as people get familiar with the process and experience, they get more productive.

So our challenge is that, anytime we want to bring more capacity online, we have to line all of those things in that system up, and it takes 4, 6, sometimes 9 months to establish that capacity. And what we really need to know in doing that is: Is there interest in any of our partners, including the United States Government, in supply on those timelines?

Now, the good news is we've been working hard at it for the last 6 months, which is why we think we're going to be able to get to our deliveries 2 months ahead of schedule. But, looking forward, that's really a question for the U.S. Government to answer.

Mrs. Trahan. Great. Thank you. And I think the workforce is an important issue for us to tackle.

Mr. Young, in your testimony, you say that Pfizer has been able to ramp up their manufacturing capacity because of the significant investments the company has made in U.S. manufacturing sites, including in Andover, Massachusetts, located in the heart of my district.

Because of the dire need to vaccinate more people, Pfizer has increased projected 2021 global production from 1.3 billion doses to at least 2 billion doses. And the Federal Government has reportedly invoked the DPA to help Pfizer get priority access to components you need to make your vaccine.

Has the DPA been helpful in your efforts to expand manufacturing capacity, and are there any additional ways it could aid in scaling up that production?

Mr. Young. No. Thank you for the question.

We certainly were in close collaboration with the Federal Government, and some of the rated orders that were used alongside the DPA were certainly helpful in ensuring that certain raw materials that initially were constrained, particularly some of the

specialized lipids we use in the production of our vaccine, were prioritized by our third- party suppliers.

As I mentioned in my testimony, we've actually made decisions to bring in-house the manufacturing of some of those materials, so currently we don't believe they are constrained.

I think the DPA generally is certainly very useful, but I think it's a very targeted -- a targeted piece of legislation and something that should be used to address very specific problems rather than used generally.

But we've certainly found that to be very helpful, and I'm very grateful for the government's continued support.

Mrs. Trahan. Great. That's helpful.

And, Madam Chair, with only 15 seconds left to go, I will submit my last question for the record. Thank you.

Ms. DeGette. I thank the gentlelady. You can bank those 15 seconds for later.

I'm now very pleased to recognize Mr. O'Halleran for 5 minutes.

Mr. O'Halleran. Thank you, Madam Chair, Ranking Member. I appreciate this whole process that's come today. I've learned a lot. We have a lot to learn, though.

And I guess my -- the panel has been just great. I really have respected the content of what's been said today.

The emergency use authorization has obviously helped out. The vaccines have come along pretty well. I wish you could have them earlier, but we had them as fast as history has shown that can be done.

They're safe and effective, it appears. I think we need to get more of that information out to the public. And important challenges remain.

In recent weeks, the variant COVID-19 strains have emerged around the globe,

including the United States. Two of the variants, one from -- first identified in United Kingdom and another in South Africa, appear to be more contagious, which poses a continuing and ongoing threat to our efforts to contain the pandemic.

Now, I took a look at the questions I was going to have, and they're -- kind of been represented throughout this process.

Representative Trahan mentioned something that I think I wanted to talk about a little bit more, though, and that is after-action reports, getting ready for after-action reports, getting ready to identify what we did wrong throughout this process, and what can be done better in the future.

And how are you -- how have you -- you, the different groups been identifying clearly through your process that you've kept appropriate data so that we know and can observe what we need into the future and how the working relationships have worked throughout this process and how they can be improved?

And I ask that question to each and every one of the panelists.

Dr. Nettles. Well, I can start.

At J&J, this has been a really -- an unprecedented experience for us, scaling up the process of this vaccine. So we've learned many steps along the way about how to quickly scale up manufacturing in parallel with running our clinical trials.

I would say one thing that we've learned is really the unprecedented, unselfishness of the American population, so people coming forward to volunteer for participation in our trials has been really outstanding and beyond what we could have wished for, and we want to thank all the volunteers that did that.

Mr. O'Halleran. Before we go to the next panelist, I appreciate what was just said. I want to get into specifically what you need to do or we need to do to work with you into the future, the next 10, 20, 30 years, so that this doesn't happen again, so that

we're out in front on research and identifying clearly the path ahead of us to prevent this in the future.

Dr. Nettles. Yeah. I can follow on --

Mr. O'Halleran. Next, please.

Dr. Nettles. One of the things that has helped us move forward as quickly as possible is the development and investment in the platform that we're using to bring forward this vaccine, that we've been using to develop other vaccines for Ebola, HIV, and RSV. So that's one lesson that we've learned, is that's tremendously helpful so that, in the event that you experience a pandemic, you can leverage platforms like that and transition to whatever infectious disease you're facing during a pandemic.

Mr. O'Halleran. Thank you.

I know time is fast here in 5 minutes. I still want to hear from you what -- not specifically the recent panelists, but from anybody: What are you doing now so that we can learn from this, not what we've done; what we are going to do in the future to work together so that this doesn't happen again to the American public and the people of the world?

Mr. Young. Thank you for the question.

I mean, it's a great question. We believe there are many lessons learned. I think probably all of our companies have experienced extremely productive and timely interactions with regulators. And I think that's something that we should carry forward, you know, to any future pandemic, but I think we should carry forward for other important medicines and treatments that our companies are developing.

Specifically as it relates to the pandemic, I also think that this has shown around the world that we don't have adequate capability to really conduct viral surveillance and genomic screening to make sure that we can identify variants of concern. And that's

something that I think would certainly be a real enhancement to the benefit of public health in the United States.

Mr. O'Halleran. And time is running out.

Dr. Hoge. I think --

Mr. O'Halleran. And I just want to thank -- let's go quickly. Go ahead.

Dr. Hoge. I'm so sorry, sir. The only thing I would add to that -- I agree with everything that has been said there. I think the other thing that was important in all of our cases was the investments in science. Somebody has already mentioned platforms. That was important in the private sector. But, actually, in science, in the NIH and NIAID, to identify prefusion-stabilized spike proteins on coronavirus as a key way to make vaccine, that's something we all have in common. And so those sorts of investments against new potential emerging pathogens are absolutely essential.

Mr. O'Halleran. And I'll apologize to the chair for the overtime, but this is an area that I think, in the future, we strongly need to look into on a continuing basis, and I thank you.

Ms. DeGette. And I agree. I thank the gentleman, and I thank all of the regular members of the oversight subcommittee.

As I mentioned at the outset, we now have several members of the full committee who are here to waive on, and we welcome and appreciate all of you.

And, with that, I will start with Mr. Bucshon for 5 minutes.

Mr. Bucshon. Thank you, Madam Chairwoman. I appreciate you allowing me to sit on in this important subcommittee hearing. I'm a physician before coming to Congress, so this is really critical.

Mr. Young, can you walk us through the timeline in regard to the progression of efficacy for Pfizer's vaccine? For example, per your trials, how many days after the first

dose did participants start displaying efficacy or an antibody response? And at what mark did they reach 50 percent? And then how many days after receiving their second dose did participants reach the full or near full 95 percent efficacy?

Mr. Young. Thank you very much for your question.

In our clinical trial, we certainly did begin to see some evidence of effectiveness, efficacy, in our study, you know, somewhere between 10 and 14 days compared to the placebo group, which is very encouraging.

I would say that actually recent real-world data from Israel also supports the potential benefit that patients begin to see even after one dose. However, our phase 3 study very clearly used two doses, you know, so first dose, and then, 21 days, a second dose.

And so we certainly -- our study demonstrated maximal effectiveness 7 days after that second dose, and that's really what our data set supports.

Mr. Bucshon. Well, thank you very much because I do think it's important to walk people through this timeline, because -- I mean, it is remarkable how quickly vaccines do cause an effect, but it's not instantaneous, and which doesn't make it any less effective and should cause no hesitancy for people to get the vaccine. Vaccines, as you just outlined, it's not to get the vaccine and you're immune; it takes some time for your body to respond.

Mr. Hoge, what is the key purpose of Moderna's vaccine, the main outcome of every company is striving to achieve with any COVID-19 vaccine at this point based on the data we have? What's the primary goal here?

Dr. Hoge. So our primary objective in the study and, therefore, the primary objective in deploying it under UA is prevention of COVID-19. It's a symptomatic disease. We think, if we can stop the disease, we'll actually be able to get out of this

pandemic.

We do look at secondary endpoints, like severe disease and hospitalization. And we also looked at things like transmission and infection. And the good news is all the emerging data there is very supportive of the vaccine. But the primary focus is stopping the disease of COVID-19.

Mr. Bucshon. Yeah. I mean, I think it's important to understand, I guess, at this point -- and anyone can comment. We don't know specifically whether or not this vaccine, like some other vaccines, will be completely preventive of the disease or will do some of that in some people, and then, some people, just prevent severe cases and hospitalizations, which is also, honestly, not as good, but a pretty solid endpoint. I mean, vaccines may -- this may or may not totally prevent disease.

Does anyone have any discussion on -- want to discuss that a little bit about what we know so far about whether or not our goal of preventing disease versus preventing severe cases and hospitalizations will ultimately be where we end up with COVID-19?

Dr. Hoge. I mean, I would just offer that what we do know from our clinical trials and the emerging real-world evidence, but -- from our focus on the clinical trials, is that we were very effective in the mRNA vaccines at preventing disease, so 94, 95 percent effective at disease.

And, actually, in our case, we were -- and I think in the Pfizer case parts as well -- they're even more effective at severe disease, so we did not have any cases of severe disease in our -- in our clinical trial at the interim analysis.

So, as a result of that, we're quite optimistic that we're not only preventing most terrible outcomes at severe disease, but ultimately preventing the more moderate disease.

I think part of your question, sir, is to, you know, what do we know about

prevention of infection, or prevention of transmission? And, as I think we've said, I think we have a lot of work ahead to develop that data and ultimately have that answer.

Dr. Nettles. I would jump in, too. I very much agree with your premise, and one of the features we're very enthusiastic about -- with J&J's single-dose vaccine is that, even in countries like South America and South Africa and in countries in South America where we have seen the emergence of these variants, 28 days after that single dose, we have not seen patients need hospitalization against -- hospitalization for COVID-related issues or death.

And so we agree with you. That is critical and very promising information.

Mr. Bucshon. Yeah, I think what I'm -- as you pointed out, Mr. Hoge, that -- what I'm getting at is, you know, we're still trying to determine, you know, if people are fully vaccinated, can they spread the disease? Should they still -- you know, at what point do we back away from our other public health things, which I totally agree we need to do now -- mask wearing, social distancing -- and, if we can really solidly show that this actually prevents disease at a solid level, then I think the governmental officials in all countries and also the people will feel more confident when we start to back away from our other public health initiatives that are critically important still at this point.

So that's basically, I think, the question that ultimately we'll need to specifically answer, is: Can people who have been vaccinated still infect other people but they're just not showing the symptoms?

So, with that, Madam Chairwoman, I'll yield back. Thank you.

Ms. DeGette. Thank you. Thank you.

And now thank you for waiving on, and I'll recognize you, Mr. McNerney for 5 minutes.

Mr. McNerney. Well, I thank the chairwoman, and I thank the witnesses.

First, I want to be clear. I'm very impressed and pleased by your companies' historic efforts to develop safe and effective vaccines on such a rapid timeline. That being said, it's important to understand how the taxpayer dollars were spent to increase manufacturing capacity and vaccine supply so that we can better prepare for the next pandemic.

In that spirit, last summer, Operation Warp Speed leaders told us that large quantities of vaccines would be produced at the same time, simultaneously, with clinical trials. That way, as soon as FDA authorization of a COVID-19 vaccine was available, the manufacturers would make a significant supply of doses available for immediate distribution.

In other words, American taxpayers were assuming financial risk in exchange for quick access to vaccines if and when they were authorized for use. But, as we see, vaccine supply remains limited, and manufacturing capacity is still a major concern. So, today, I'd like to better understand exactly how Operation Warp Speed helped ramp up your manufacturing capacity.

Dr. Hoge, you told this committee last July that Moderna was using $483 million in Federal grant money to help scale your manufacturing capacity. Although Moderna initially projected delivering 20 million doses in the United States by the end of 2020, it fell short of this goal and has encountered production delays.

How exactly did Operation Warp Speed help increase your manufacturing capacity? Could more have been done earlier to build a larger vaccine stockpile prior to your authorization?

Dr. Hoge. Thank you for the question, sir.

We -- as you note, we delivered by December 31st 17.8 million doses. And, in the middle of last year, we were hoping that that could be up to 20 million doses by

year-end. We ultimately had never, when we were trying to make those estimates, manufactured doses at this scale, and so we had a lot to learn along the way. And many of the challenges that we run into were the normal sort of training experiences as you train people to operate a complicated process.

And so, as we look back, could we have maybe started earlier in that process in lining up all of the critical raw materials sooner, would we have been able to get there a little bit faster instead of first week of January, last week of December? It's possible. Certainly hindsight -- and that is 20/20 for us. But we do feel very pleased with how we've moved forward with those learnings and where we are right now delivering 9 million doses this past week.

Mr. McNerney. Well, okay.

Dr. Dobber, Operation Warp Speed awarded AstraZeneca $1.2 billion last May to accelerate development in manufacturing of your vaccine.

In July, AstraZeneca's executive vice president told the committee that your company was, quote, "scaling up to manufacture up to 300 million doses of the vaccine so that they will be available immediately upon approval or emergency use authorization."

Does this mean that AstraZeneca currently has 300 million doses ready for immediate release in United States if an EUA is issued? If not, what happened? What did the American taxpayers invest in?

Dr. Dobber? Are you muted?

I'm not hearing Dr. Dobber. I'm going to move on.

Dr. Nettles, last August, Operation Warp Speed operated -- awarded Johnson & Johnson 1 billion to ramp up its manufacturing capacity. Unfortunately, J&J has already encountered manufacturing delays and supply challenges. Could these delays and supply challenges have been avoided with even greater taxpayer support, or do you -- do

your challenges go beyond the fundraising issues -- the funding issues?

Dr. Nettles. At J&J, we very much appreciated the investment. We have used that investment in the last 6 months to significantly scale up our ability to produce this vaccine, bringing on live sites in Indiana, Maryland, Pennsylvania, and Michigan. And I'm happy to say that we have, as I mentioned, continued to commit to the 100 million by the end of June, being able to vaccinate 20 million individuals in March, as well as having 4 million doses available to ship immediately if we're granted an emergency use authorization.

Mr. McNerney. Thank you.

In the interest of time, I'm just going to wrap it up by saying a significant amount of American taxpayer dollars were invested to be able to produce the vaccine immediately upon approval. We need to learn from those lessons so that, next time that we have a need like this, that the capacity is ready to meet the demand on a comparable timeline.

Thank you, and I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes Mr. Walberg for 5 minutes.

Mr. Walberg. Thank you, Madam Chair. I appreciate this hearing and appreciate the witnesses being here and, like my other colleagues have said, the good work that you've done -- historic work that you've done in a very difficult period of time, but in an amazingly short period of time as well.

I want to especially welcome Mr. Young here. As you know, Pfizer's largest manufacturing facility is located in Kalamazoo, Michigan, just 40 miles down I-94 from my district, and so we appreciate the fact of seeing what work has been done there, and I think Michiganders are summarily proud of what they see when they see the Pfizer trucks

and the lifesaving pharmaceuticals going down the road to assist us and fill the needs not only of Michigan but those of the rest of the Nation.

When President Biden visited the Kalamazoo facility last week, he called it a miracle of manufacturing. I guess that's a point that I can quickly jump in and say I agree with the President on.

Many of my colleagues have already acknowledged this, but it bears reiterating: Operation Warp Speed was an unprecedented success. In fact, NIH Director, Dr. Francis Collins, recently called the success of OWS breathtaking. In what typically takes about 10 years or longer to go from an exploratory stage to a large-scale manufacturing and FDA review and licensure, the Trump administration achieved in less than 11 months. Sadly, however, all these efforts will be for naught if we cannot get the vaccine into the arms of people who need it and want it.

In Michigan, our State government has had serious problems. Last week, Beaumont, one of the State's largest health systems, announced the cancellation of nearly 2,000 second [inaudible] unexpected reduction in the Pfizer vaccine allocation from the State. I note that was allocation from the State.

Our Governor has said that the problem is demand, which exceeds supply. And, while demand is certainly high, we're seeing certain areas of the State receive larger vaccine supplies per capita than others. As a result, the city of Detroit is now vaccinating food service, restaurant, grocery workers, regardless of age. And they certainly need it. But the residents in other parts of the State, including my district, are left wondering when it will be their turn.

Orrin in Saline, Michigan, up near the University of Michigan, whose mother is 90 years old and in need of a hip replacement, has been delaying treatment until she receives the vaccine.

Carol in Temperance, Michigan, wrote me to say that she and her husband are 81 years. They have been on a wait list for weeks and were notified that their local grocery store pharmacy is now out of doses. She and many of my constituents have instead been left to go through Ohio and Indiana health systems.

Steven from Chelsea, Michigan, receives daily chemo treatments for leukemia but said he has been unable to get on a waiting list for the vaccine.

And Mark, who is 70, said he can't get the vaccine, yet his 35-year-old son in Texas just got his second dose.

And so, Mr. Young, my constituents and I are trying to better understand the process from when the doses leave your facilities to when they are received by local health departments. In a rough estimate, how many vaccine doses is Pfizer capable of shipping out on any given day, and how specifically are those doses distributed?

Mr. Young. So thank you for the question.

I couldn't agree more that what is incredibly important is that, you know, vaccine doses are made available to everyone who needs them. And so, as I mentioned in my testimony, we're very focused on making more doses more quickly.

What we are able to currently supply is, on average, at the beginning of February, around about 5 million doses per week. We anticipate that that will get up to 13 million doses a week by the end of March.

What we do is to supply an 8-week forward-looking forecast of that weekly production to the Federal Government. The Federal Government, in turn, then tells States what is available. States then order it.

We supply our -- the vaccine doses to the points of use as directed by the U.S. Government. So we work closely with the Federal Government, but we also look to work closely with the States to ensure that they also have accurate information and

support.

Mr. Walberg. But then, if the State is responsible for ordering it from the supply that you've been instructed by Federal Government, they order it. How does it get to the places where they need to be? Do they tell you where it's to be sent?

Mr. Young. Yes, exactly. The Federal Government literally tells us which center we should deliver how many vaccine doses to. And that's something that we have -- thus far have been able to perform very accurately, 99.9 percent reliability of delivery of the number of doses to the center as directed by the U.S. Government.

Mr. Walberg. That gives needed information. Thank you. I yield back.

Ms. DeGette. I thank the gentleman.

And now I'm very pleased that the chair of our Health Subcommittee has joined us on this hearing. Thank you so much, and I'm pleased to recognize you, Congresswoman Eshoo, for 5 minutes.

Ms. Eshoo. Thank you, Madam Chairwoman, for extending the courtesy to have me join your Oversight Committee today. And thank you to all of the witnesses. I've listened in since much earlier this morning, and I want to say bravo to the companies in the work that has been done, the scientists, and everyone that is part of the effort to develop the vaccines.

Vaccines are extraordinarily difficult to develop. I think that this is a moment in the history of our country, a moment of great pride amidst great sorrow because of the enormous loss of life in our country. So thank you to all of you.

I have two questions, and I hope they haven't been asked before I joined. The first is about the clinical trials, and they certainly have been the most closely watched in history, I think. And I believe that companies spoke to achieving racial diversity in the trials, and so I want to learn more about what has been achieved in the trials relative to

this issue. I don't believe that any of the trials achieved racial representation based on disease impact.

So my essential question is: Why? What's worked for a diverse trial recruitment? What did you invest in order to get there? Do you have recommendations to the Congress on policies that could reduce the barriers for diverse recruitment?

I have said many times that we have many preexisting conditions in our country, and we know that, in the minority communities, that they are hard-hit by this pandemic.

So that's my first question about diversity and the trials.

And the other is: I authored the Best Pharmaceutical for Children's Act many, many years ago to specifically address the need for pediatric studies. It provided the incentive of an additional 6 months patent exclusivity if a company performed pediatric studies. How do you think we could update this act to address the barriers we're seeing in performing vaccine trials for children?

So, to each one of the witnesses, there you go, and thank you again.

Mr. Young. So thank you for your -- thank you for your question. Let me just say, you know, we've worked extremely hard to ensure that the recruitment of patients -- participants in our vaccine study was representative of the demographics of the disease. In fact, in total, 42 percent of our total study population were minorities. I know the patients who participated in our study from the United States, 30 percent were minorities. So we came very close, and we worked very hard to accomplish that.

We certainly agree that there are barriers, you know, for minorities being able to either access healthcare systems or providers, you know, to enable them to participate in clinical trials, not something we -- and we certainly welcome Congress' continued support for that.

I would just say very quickly on your second question that we're starting to think that's a very intriguing idea as to whether there are some further incentives or measures that could be put in place to ensure that all clinical studies really includes a population that is representative of the population of the United States.

Dr. Hoge. Thank you. And I would also echo many of the things that have been said. We worked incredibly hard in our phase 3 trial to enroll a representative, the demographic community.

In our trial, which was exclusively done in the United States, 37 percent of our participants were from communities of color. And so, overall, we did represent the demography of the country at a high level, but we did not represent the demography of the disease, as you point out. And so we can always do better.

Learnings from that, we certainly -- you know, we ran into the challenges that you know well, that most of the public health community knows well, around trust, and how do you build trust between communities that have historically been underrepresented or disenfranchised in terms of healthcare?

It took time. Our approach was to actually slow down enrollment so that we could actually build those relationships through the local investigators and physicians in the communities on their parts.

Dr. Nettles. I can answer very quickly. We're very happy with the enrollment that we've seen in our phase 3 clinical trial, where we had 45 percent of the enrollment Hispanic, 19 percent Black or African American, and 9 percent Native American.

With regard to lessons learned, it's developing long-term relationships with national and local organizations that represent the minority populations. And that's what I'd advise us to continue to do moving forward.

Dr. Dobber. [Inaudible] at AstraZeneca, we are very happy with the minority

population in our clinical trial. Hopefully it will read out very soon so that you'll see the numbers.

Equally, we have a global trial in countries like Chile and Peru, so we feel very comfortable. And we acknowledge the importance of including minorities in the [inaudible]. So we're very supportive. And [inaudible] one of the witnesses remarked about building trust in those communities, and we are doing an [inaudible] amount of work in order for that to happen.

Mr. Trizzino. Thank you for the question.

Novavax worked very diligently with ICON, our clinical trial partner, as well as the NIH clinical trial network in order to make sure that we had representation from minority populations, and that was 39 percent were represented from minorities.

We also worked very closely with traditional Black colleges, Howard University specifically here in D.C., in order to make sure that we got the representation that we desired.

So, you know, we're satisfied that we accomplished a significant goal in the recruitment of our 30,000-subject trial that just finished its recruitment.

Thank you.

Ms. Eshoo. I think my time has expired, Madam Chairwoman. I thank you again for the legislative courtesy.

I thank all the witnesses, and bravo to the scientists. This is -- they are a blessing, not only to the people of our country but the entire world.

Thank you.

Ms. DeGette. Thank you so much, Ms. Eshoo.

The chair now recognizes Mr. Carter for 5 minutes.

Mr. Carter. Thank you, Madam Chair, and thank all of you for being here. I

appreciate it very much.

As a member of the Doctors Caucus and as also a pharmacist, I felt it was very important for me to set an example, and so I entered into the clinical trials here in my home town, and I was actually very fortunate to get the vaccine. After I was unblinded, I found out that I had gotten the vaccine during the clinical trials. Of course, as you well know, it's a double blind study. But it was very important.

And I want to highlight the -- what I feel like is the important role pharmacists have been playing in this -- in the administration and also obviously in the distribution and administration of the vaccine.

One of the things that they have been doing is what's called pooling, and that is, in the multidose vials, they may have a little bit left over, and, in order to combine that, they can actually get some extra shots.

Now, I understand that you may be a little sensitive to responding to that or commenting on that because of the -- because of the role that you play, but I just want you to know that, as one thing -- one of the many things that pharmacists are doing that is really enhancing and helping us to get more vaccines out there -- and this is something that is common among pharmacists that we do and something that traditionally has worked very well and is helping us to get more vaccines out there.

Anyone want to comment on that event?

Well, I understand.

But I want to mention one thing, and I suspect you won't want to comment on this either. However, it is very important. I got a phone call this morning from an independent retail pharmacist. I myself was an independent retail pharmacist. Already, we've got pharmacists that are being audited by PBMs for the claims that they have submitted for the COVID-19 vaccine.

And I find that to be very alarming. And, in fact, I find it to be despicable. These PBMs are out of control. And I know that you're in a very precarious position to be able to comment on this, but I want you to know that these PBMs already are auditing these pharmacists who are administering these COVID-19 vaccines.

And that's the last thing we need right now is for them to be bullying the pharmacies, like they so often do, and intimidating them and actually discouraging them from getting the COVID-19 vaccine.

And I know all of you are aware of what's going on with PBMs, and I know that you're going to have trouble commenting on it, but I'm just wondering. Anyone want to comment on that?

I didn't think so. Maybe -- and I'm not trying to put you on the spot. I know how you feel, and I know you're in a very precarious position, as I say, but I want you to be aware that that's going on because I think that is very despicable.

Finally, I wanted to ask you about vaccine hesitancy, particularly in the communities of color. I represent a very Republican district. However, I've got a large minority population in my district, and it's something that I'm very concerned with. This is my home town where I've lived all my life and where I intend to live the rest of my life, and I'm very close to the community of color.

And it's very important to me. Now, as I said, I wanted to set an example, and I did by entering into the clinical trials. But, you know, I'm not a person of color, and, therefore, I try to set the best example I can as a pharmacist, as a healthcare professional, but, at the same time, is there anything we can do as healthcare professionals, as Congress people, anything as Members of Congress, anything that we can do, do you think, Mr. Young, that we might be able to enhance the acceptance of vaccines?

I mean, vaccines are the single most lifesaving innovation in the history of

medicine. We all know that. And how we get that point across and get more acceptance with the vaccines, not only with communities of color, but we are having trouble here in the State of Georgia with getting healthcare professionals to take it. It's just -- it's just baffling to me.

Mr. Young. I thank you. I think it's an incredibly important question, and I think that, you know, vaccine hesitancy is one of the great threats to public health in the middle of this pandemic. So I think all of us have a responsibility to play our part in making sure that we can be open and transparent, people can be confident in the information that they see, that they're able to get information from reliable sources rather than from unreliable sources, and that all of us, the companies represented on this panel and others, Congress, healthcare professionals, and government agencies all have responsibility to make sure that we can get the message across, that, if a vaccine is approved by the FDA, that it's safe and it is effective.

Mr. Carter. Mr. Hoge, anything?

Dr. Hoge. I would agree with what -- Mr. Young's comment. I do think we have that obligation collectively, and we're doing our very best to do our part.

Mr. Carter. Good. Well, again, I want to thank you. Look, I'm a big fan. I'm a -- as a pharmacist, a practicing pharmacist for over 30 years, I've seen nothing short of miracles come out of the result of research and development.

And one thing that I hope happens through this process, the Operation Warp Speed, is that some of the improvements we've made in speeding up the process -- I hope we don't just go straight back to the way we used to do it. I hope we've learned and that we can expedite the process.

I know that there are people out there -- I have patients out there who are waiting on lifesaving medications, such as these vaccines. And anything that we can do to speed

it up -- and I get it. During a pandemic, it's different. But, when we get back to whatever normal is going to be, I hope that we will look at the process. I hope the FDA will look at the process and that we can make improvements on the approval of medication because this is extremely important.

One last thing -- and I thank the Madam Chair -- is just --

Ms. DeGette. The gentleman's time has expired.

Mr. Carter. -- don't forget what I said about PBMs. They're the Devil.

Thank you, and I yield back.

Ms. DeGette. I thank the gentleman.

And I believe everyone has -- that I see has been able to ask their questions. I'd ask the ranking member, does he have any last words of wisdom for us?

Mr. Griffith. Well, I would be interested, because the witnesses testified in -- to answering your questions that they were confident that they would meet their goals and meet their commitments to the Federal Government.

And then, with Congressman Joyce, they suggest or they answered that they didn't have any shortages in raw materials. Given that we're all partners in this fight, I want to confirm: Is there anything else you need from the Federal Government in order to meet your commitments or to continue to ramp up your companies' production, or do you feel that you have everything you need at this point?

Mr. Young. Thank you for the question.

At Pfizer, we currently believe that we have everything we need to be able to meet the commitments that we've outlined today. Thank you.

Dr. Hoge. From Moderna, it's the same. All we need is the continued partnership from the government that we've benefited from.

Mr. Griffith. And, in the interest of time, is there anybody who doesn't -- who

feels like there is something we need to do? That's probably a better way to put it.

All right.

Ms. DeGette. Great.

Mr. Griffith. I yield back, Madam Chair. Thank you so much for the followup.

Ms. DeGette. Thank you. Thank you so much.

And I really do want to thank all of the witnesses. We all have a lot of respect and admiration for the work that you've done. We just want to make sure we stay on track to get all of these shots into Americans' arms by the summertime.

And I also want to thank for the great participation of all of our members.

I'd like to remind members that, pursuant to committee rules, they have 10 business days to submit additional questions for the record to be answered by the witnesses who have appeared before the subcommittee.

I ask that the witnesses agree to respond quickly to any such questions should you receive any.

We have had unanimous consent by Mr. Tonko to insert records for the record -- documents for the record, and we have reviewed them, and now we would like to insert them by unanimous consent: a letter from Representative Tonka to Moderna's chief executive officer, dated February 17, 2021; and a letter from Representative Tonka to Pfizer's chairman and chief executive officer, dated February 17th, 2021.

Without objection, so ordered.

[The information follows:]

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

Ms. DeGette. And I believe we don't have any further business, so, with that, the subcommittee is adjourned.

Thanks again.

[Whereupon, at 1:30 p.m., the subcommittee was adjourned.]