

PATHWAY TO PROTECTION: EXPANDING AVAILABILITY OF COVID-19 VACCINES

VIRTUAL HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SEVENTEENTH CONGRESS FIRST SESSION

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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, DC.

The subcommittee met, pursuant to call, at 10:30 a.m., via Cisco Webex online video conferencing, Hon. Diana DeGette (chair of the subcommittee) presiding.

Members present: Representatives DeGette, Kuster, Rice, Schakowsky, Tonko, Ruiz, Schrier, Trahan, O'Halleran, Pallone (ex officio), Griffith (subcommittee ranking member), 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; Jessecia Boyer, Professional Staff Member; Jeffrey C. 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, Digital Assistant; Kevin McAloon, Professional Staff Member; Kaitlyn Peel, Digital Director; Peter Rechter, Counsel; Tim Robinson, Chief Counsel; Chloe Rodriguez, 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, Oversight and Investigations; 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, Oversight and Investigations; Michael Taggart, Minority Policy Director; and Everett Winnick, Minority Director of Information Technology.

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

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.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Today, the Oversight and Investigations Subcommittee holds the first hearing of the 117th Congress, on an issue that holds the promise to finally end this pandemic: the rollout of the COVID-19 vaccination program.

This committee has conducted relentless oversight of the COVID-19 pandemic response from the very start. Last year, we saw endless dysfunction and chaos as our country was left adrift by the absence of strong, competent Federal leadership.

As bad as it was last spring, this winter has brought an even more dangerous surge.

In recent weeks, cases and hospitalizations were soaring all over the country, and as many as 4,000 Americans were dying every day from this awful virus.

As the title of this hearing makes clear, we have no time to lose. We must act with a sense of urgency and use every resource available—at the Federal, State, and local levels—to fight the spread of this virus, end the suffering and death, and return to a sense of normalcy.

The Biden administration has its work cut out for it. Indeed, it faces the greatest and most immediate challenge of any presidential administration in modern memory. But we are already seeing signs of the ship turning around.

The Biden administration recently announced a comprehensive national strategy for the COVID-19 pandemic, something this committee has long called for. This plan advances urgently needed solutions to mount a successful vaccination program, restore trust with the American people, and mitigate the spread of the virus, while providing the emergency relief Americans desperately need.

We will continue to engage with the administration on what the Federal Government needs from Congress to execute this plan and get America on track.

The key task we are faced with now is the rollout of COVID-19 vaccines.

The Federal-private partnership to research and develop these vaccines, test them in clinical trials for safety and efficacy, and get them authorized for use was an enormous undertaking and a profound victory for the country.

But that was only the first step. If we do not ensure that every American is able to get vaccinated quickly, those efforts will have been in vain. Those charged with administering the COVID-19 vaccine program around the country—including our excellent witnesses today—have a tremendous opportunity and responsibility to ensure equitable and expeditious administration of these life-saving vaccines.

That is why we are convened today: to hear from State leaders on the front lines about how we can significantly ramp up vaccinations.

As we will hear today, States are mobilizing to expand who will be eligible to receive the vaccine next, with a special emphasis on ensuring equity for those most vulnerable to COVID-19 and historically marginalized communities.

For instance, my home State of Colorado recently announced plans to hold pop-up vaccination clinics in 50 high-density, low-income, communities of color.

Despite these efforts, we have also been seeing a lot of frustration and confusion. Since the rollout started in December, one consistent theme has been the lack of transparency about how many vaccines are coming and when. Compounding matters, surveys indicate that, while the majority of Americans want to get the COVID-19 vaccine, some adults continue to have reservations.

Thankfully, the Biden administration has committed to changes—such as transparent data for the States and the public—that will address some of those issues, so that we can build trust and work to get every available vaccine administered quickly and equitably.

Indeed, the biggest challenge I'm hearing from most States now is simply a lack of supply. After some initial challenges administering the vaccines, States and local communities are reporting that the demand for the vaccine far exceeds the supply. And they stand ready to vaccinate many more Americans, if they are given the doses they need.

We have an excellent panel today, representing five States aggressively working to end this pandemic. I thank them for their efforts, and I'm grateful for the time they've committed to provide critical testimony on how to improve our fight against this pandemic. I look forward to a candid discussion with the panel about what is working and what is not working. I hope they will also elaborate on what more the Federal Government and Congress can do to improve the partnership in this fight.

The end of this nightmare is in sight. Now is the time to double-down on our efforts, and finally turn the corner on this pandemic.

Ms. DEGETTE. 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?

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

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:]

PREPARED STATEMENT OF HON. H. MORGAN GRIFFITH

Thank you, Chair DeGette, for holding 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.

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However, as we heard at a subcommittee hearing a few weeks ago with representatives from a handful of States—vaccine supply remains 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 manufactures 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 ensuring 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 easily and quickly. Thankfully, vaccine manufacturers are already looking at 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, and I want to thank you all for the important work you've already done.

Thank you, Madam Chair, I yield back.

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.

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

Mr. PALLONE. 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 manufacturers 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 Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today, we convene the Energy and Commerce Committee's first hearing of the 117th Congress to examine the urgent need to increase COVID-19 vaccinations across the country. This committee's top priorities this year are to combat this pandemic, provide relief to struggling families, and rebuild our economy. In the coming months, we will push an aggressive agenda that will ensure the Biden administration has all the tools and resources it needs to crush this terrible virus.

This goal is more pressing than ever. Thousands of Americans continue to die each day from COVID-19, while new, more contagious strains are emerging in the United States. We are now in a race to keep vaccines ahead of new virus variants—and the stakes could not be higher.

The pandemic's toll on the Nation is tragic. To date, nearly 440,000 Americans have lost their lives from COVID-19—surpassing the total number of U.S. soldiers killed during World War II. More than 10 million Americans are unemployed, while 1 in 3 households struggles to make ends meet. It's no wonder Americans' assessment of their mental health is worse than at any point in the past two decades. Experts warned of a dark winter, and unfortunately, they were right.

Amid these dark days, we're now seeing the rollout of some of the most powerful tools we have to contain the virus: safe and effective vaccines. Unfortunately, the initial rollout has been marked by confusion and delays. It's no secret that the demand for vaccine is outpacing supply—leading to canceled appointments, endless lines, and mounting concerns.

Limited transparency into the Nation's vaccine supply, as well as conflicting accounts about a reserve held by the Federal Government, have all contributed to uncertainty and frustration.

Thankfully, the Biden administration is already taking action to address these issues, including purchasing additional doses that will increase our vaccine supply by 50 percent by the end of summer. I hope to learn today what more Congress and the Federal Government can do to provide more certainty and help accelerate vaccinations across the country, while ensuring equitable access for those most vulnerable to COVID-19.

Despite the issues we've encountered with the vaccine rollout and the painful road still ahead, I'm optimistic that we are finally on a path to beating the virus.

As I mentioned, there are currently two extraordinarily effective and safe COVID-19 vaccines authorized by the Food and Drug Administration—and more could soon be on the way.

States have stretched their limited resources to implement an unprecedented vaccination program, reaching 26 million Americans and counting.

And we now have a new administration that will be guided by science and a comprehensive national strategy to beat the pandemic—something I have long called for.

So there is hope on the horizon, but we have much work to do to get there. That starts with tackling the biggest challenges standing in the way of containing the pandemic: getting vaccines into as many arms as possible, as quickly as possible.

This nationwide vaccination campaign is truly historic, and it will require substantial support from Congress to succeed.

To that end, Democrats in Congress are moving swiftly to pass the American Rescue Plan—a bold, comprehensive proposal from the Biden administration that would fund vaccination efforts and provide Americans much-needed relief. Critically, the plan would invest \$20 billion in a national vaccination program to help ensure greater accessibility and availability of vaccines across the country.

It includes critical financial support to State and local governments, which have been pleading for any support from the Federal Government to assist in their efforts to combat this virus.

I hope my Republican colleagues will join me, without delay, in supporting this bill for the American people. There is simply no time to waste.

I welcome the State health officials with us and look forward to their on-the-ground assessments of the national COVID-19 vaccination effort. You are our vital partners in this extraordinary campaign, and you are being called upon to execute innovative solutions to unparalleled challenges. Thank you for dedicating your valuable time to sharing your important perspectives with the committee today.

The COVID-19 vaccines authorized in the United States are potent tools in our fight against the virus. But vaccines in vials don't protect people—vaccines in arms do. We must act now to overcome the remaining logistical hurdles and strengthen the Nation's COVID-19 vaccination campaign. There is no time to lose.

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.

**OPENING STATEMENT OF HON. CATHY McMORRIS RODGERS,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF
WASHINGTON**

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 1 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 life-saving 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 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:]

PREPARED STATEMENT OF HON. CATHY MCMORRIS RODGERS

Thank you, Chair DeGette and Republican Leader Griffith, for holding this hearing on expanding COVID-19 vaccine availability.

People are still struggling to get access to COVID-19 vaccines. The problem is that we need more supply.

Earlier this month, witnesses representing five State governments testified that there wasn't enough vaccine, and that each of the States could distribute more if they had more supply.

With more supply, we can accelerate our vaccination efforts and protect Americans from severe disease, COVID-19 hospitalizations, and death as quickly as possible.

In addition, the COVID-19 variants that have been detected thus far seem to spread more easily and quickly than other variants, which can lead to more cases of COVID-19. Swift vaccinations may be able to help us combat the rising threat of the virus' mutations, and we may need to respond and pivot at some point in the future to address variants with things like booster shots.

While our current situation of limited vaccine supply is frustrating to the American people and may seem dire, we have reasons to be hopeful that the vaccine supply will skyrocket in the coming months and that we will be well-positioned to deal with the variants.

The Nation's vaccine rollout is improving. According to the latest CDC data as of February 17, over 72.4 million doses have been delivered and over 56.2 million doses have been administered. Recently, the U.S. administered 2 million vaccine doses a day, which is at twice the pace of the President's goal for his first 100 days. In fact, the U.S. vaccine rollout, for all of its reported problems, is ahead of almost every country in the world.

The manufacturers are getting better, more efficient, and faster at making the vaccine. Pfizer projects it will supply 120 million doses to the U.S. by the end of March—20 million more doses than initially promised. Moderna also expects to provide 100 million doses 2 months earlier than expected.

Other manufacturers have submitted an Emergency Use Authorization (EUA) or expect to submit an EUA soon. For example, Johnson & Johnson submitted an EUA to the FDA earlier this month, and the Vaccine and Related Biological Products Advisory Committee has scheduled a meeting for this Friday to discuss the request for an EUA. If the FDA authorizes the Johnson & Johnson vaccine, the U.S. supply will be further boosted, especially since the Johnson & Johnson vaccine only requires one dose.

As the President has noted, Pfizer and Moderna are projected to provide 600 million doses to the U.S. by the end of July, which is enough to vaccinate 300 million people. This is well more than the estimated 260 million people who are currently considered eligible for the vaccines.

This is due to the accomplishments of vaccine manufacturers, with the strong backing from the Federal Government, including Operation Warp Speed, actions taken by the Trump administration to use the Defense Production Act, and the career professionals who continue these efforts in the Biden administration. This is a strong foundation that needs more appreciation.

Further, Congress has already provided a tremendous amount of support, including funding to the States to fight the virus. Much of these resources remain unspent, including \$4.5 billion given to States to improve vaccine rollouts in the December COVID-19 relief package.

The COVID-19 variants pose a continuing threat. It is anybody's guess how much the variants could slow down our progress or worse. However, even here, there is room for optimism. 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 hospitalization and death.

Bringing in new manufacturers, increasing production capacity, or modifying a vaccine in response to a variant would take several months' lead time before additional supply will be ready. Our ability to get through the immediate threat of the variants will rely on a combination of mitigation measures, improved vaccine allocation and administration, advances in vaccine production, and the use of therapeutics.

While there is progress regarding vaccine supply, unfortunately, distribution and administration challenges remain in the States. For example, an investigation by the Seattle Times revealed that the Washington Department of Health neglected in

its vaccine rollout to plan for basic logistics that would have allowed for quick vaccination of those most vulnerable to the virus. Just last week in my district, Governor Inslee foolishly interfered with Whitman County's plan to vaccinate teachers and school staff by threatening to withhold vaccines. I realize that the witnesses before us today don't have a role in distribution and administration efforts, especially at the State level, but I wanted to raise the issue since it remains a concern in my home State.

We will get through this pandemic by pulling together, not through the dictates of misguided leadership.

Thank you, Madam Chair, I yield back.

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.

STATEMENTS OF JOHN YOUNG, CHIEF BUSINESS OFFICER, PFIZER; STEPHEN HOGE, M.D., PRESIDENT, MODERNA, INC.; RICHARD NETTLES, M.D., VICE PRESIDENT OF U.S. MEDICAL AFFAIRS, JANSSEN INFECTIOUS DISEASES AND VACCINES, JOHNSON & JOHNSON; RUUD DOBBER, Ph.D., EXECUTIVE VICE PRESIDENT, BIOPHARMACEUTICALS BUSINESS UNIT, AND PRESIDENT, NORTH AMERICA, ASTRAZENECA; AND JOHN TRIZZINO, EXECUTIVE VICE PRESIDENT, CHIEF COMMERCIAL OFFICER, AND CHIEF BUSINESS OFFICER, NOVAVAX

STATEMENT 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:]

**Written Testimony of
John Young, Chief Business Officer, Pfizer**

Hearing on "Pathway to Protection: Expanding Availability of COVID-19 Vaccines"

**United States House Committee on Energy and Commerce Oversight and Investigations
Subcommittee**

February 23, 2021

Chairwoman DeGette, Ranking Member Griffith and Members of the Subcommittee, thank you for inviting me to testify today. I am honored to be part of this panel. My name is John Young and I am the Chief Business Officer at Pfizer.

When I appeared before this Committee last July, we were in the middle of our journey to develop a potential COVID 19 vaccine. Since that time, 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 demonstrated our vaccine met the FDA's stringent safety requirements and indicated vaccine efficacy of 95%. Efficacy was consistent across age, gender, and racial demographics, in a study that recruited participants that reflected the diversity of the United States population.

As of February 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 these vaccines to points of use, we provide the U.S. government a rolling forecast of vaccine doses available for shipment each week that enables the U.S. government to provide states with three weeks of data.¹ The U.S. government allocates doses weekly to states, which is their purview. Providers submit orders through CDC's VTrackS system, which are submitted to us. Weekday orders are shipped the day after.

Because of the dire need to vaccinate more people, we have ramped up production of doses. Since July, we have increased projected 2021 global production from 1.3 billion doses, to at least 2 billion doses.

This is possible because Pfizer has made *significant* investments in our U.S. manufacturing sites including Saint Louis, MO; Andover, MA; Kalamazoo, MI; and Pleasant Prairie, WI. In addition, we have added new lines at our site in McPherson, KS, started lipid production at our site in Groton, CT; and added two contract manufacturers. Further improvements have come from FDA's recent

¹ All estimates regarding forecasted shipments reflect the number of doses we expect to make available for shipment to points of use as directed by the U.S. government.

approval of a 6-dose label for each vial, the doubling of our batch sizes, increased yields per batch, and reduced cycle times, as well as deployment of faster laboratory tests to reduce release times.

As a result of these improvements, we expect to increase the number of doses we make available for shipment 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. And, we anticipate all 300 million contracted doses will be made available for shipment by the end of July, enabling the vaccination of up to 150 million Americans.

We continue to gather evidence on safety and efficacy to potentially support the use of the vaccine by important subpopulations of patients not indicated under the current EUA.

We are conducting studies in patients between 12-15 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 SARS-CoV-2 virus could have on the ability of our vaccine to protect against COVID-19.

The mRNA platform of our 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 they might reduce protection from the current vaccine.

With 95% protection against the original strain, we have now performed in-vitro studies on immune responses elicited by the vaccine against new variants, such as those from the UK and South Africa. Based on the responses we believe that the vaccine should provide protection from those variants as well. Real world evidence from the UK and Israel appears to confirm this in-vitro data related to the UK strain, and we have seen no real world evidence to date that suggest a significant reduction in protection provided by our current vaccine.

However, we are preparing to respond quickly and initiating a study to investigate the effectiveness of a third-dose booster of our current vaccine in trial participants who have already received 2 doses.

We are also discussing clinical study designs with the FDA to investigate the 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 the thousands of Pfizer and BioNTech scientists, clinicians and manufacturing professionals, many of whom have worked literally day and night, knowing every moment matters.

Thank you for the opportunity to be with you today.

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.

STATEMENT OF STEPHEN HOGE, M.D.

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:]

**Hearing Before the House Energy and Commerce Committee
Subcommittee on Oversight & Investigations**

**Testimony of Dr. Stephen Hoge
President, Moderna, Inc.**

February 23, 2021

Chairwoman DeGette, Ranking Member Griffith, 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, Inc. (“Moderna”). Since we last spoke in July, the collaborative effort to end this pandemic has made remarkable progress. We have also confronted new challenges and continued human suffering and hardship. We know that much work remains. Today, I will update you on the status of our continued efforts at Moderna to help stop this pandemic.

When I testified before this Subcommittee in July, Moderna was just four days away from dosing the first participant in our Phase 3 clinical trial. We did not yet have proof that our vaccine was effective against COVID-19. Despite that, we were preparing for the future. With the support of the U.S. government, Moderna had 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 our vaccine if the Food and Drug Administration (“FDA”) determined it was safe and effective.

We have made significant progress since then. In November, we announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19 and a 100% efficacy rate against severe COVID-19. In December, after robust review, the FDA granted an emergency use authorization (“EUA”) for our vaccine. By the end of 2020, we had delivered 17.8 million doses to the federal government. To date, we have delivered over 45 million doses of our vaccine, with tens of millions more at different stages of the production process. We are on track to meet our commitment to deliver 100 million doses by the end of March. We have doubled our monthly deliveries since late 2020, and we are aiming to double them again by April to more than 40 million doses per month. Based on this progress scaling up manufacturing, we recently agreed to move up our delivery timeline: we now are aiming to deliver a second hundred million doses by the end of May and a third hundred million doses by the end of July.

This work could not be more pressing. The pandemic continues to have a devastating impact. Nearly half a million people have died in the United States alone. Many more have been ill, some severely. As you all know, the pandemic has also cost jobs, shuttered businesses, closed schools, burdened families, and disrupted countless traditions and routines. All of us have been profoundly impacted by this. We also know that communities of color and essential workers have disproportionately borne the burdens of COVID-19. We must bring this pandemic to an end.

We understand the significant interest in Moderna’s vaccine, along with the vaccines and vaccine candidates of other companies, including those testifying today. We also understand how important it is that large quantities of every approved vaccine be produced rapidly—with

robust commitment to safety and quality—and that vaccines be made available widely, transparently, and equitably. I hope that my testimony today will provide useful information to this Subcommittee as you continue your oversight over these important matters.

Over the past year, Moderna has been pleased to collaborate with the U.S. government in accelerating the development, production, and delivery of our vaccine. As we continue these efforts, we remain committed to ongoing dialogue with key U.S. government agencies to ensure that our work proceeds as quickly and safely as possible.

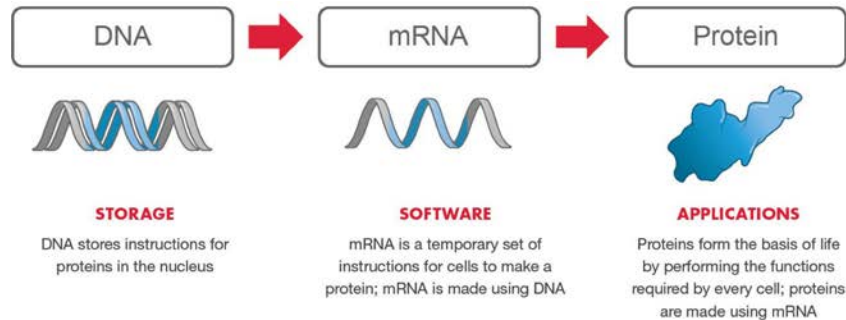
In my testimony today, I will provide an update on our work. *First*, I'll give you a brief overview of our company and mRNA technology. *Second*, I'll explain the process we used to create our COVID-19 vaccine. *Third*, I'll provide an update on the clinical trial process and the FDA's issuance of an EUA for our vaccine. *Fourth*, I will provide an overview of the manufacturing process and update you on our work to manufacture the vaccine.

I deeply appreciate the opportunity to appear before you today, and we at Moderna are profoundly grateful for the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic.

I. Moderna is an Innovative Company That Has Built Unique mRNA Technology

Moderna is a young, innovative biotechnology company that seeks to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA ("mRNA"). Founded in 2010, we are proud to be an American company, with our headquarters and a major manufacturing facility in Massachusetts. Moderna has grown over the past decade into a dynamic company with over 1,300 employees. This exceptional team—which has worked in collaboration with leading biopharmaceutical companies, U.S. government agencies, and private organizations focused on public health—has disclosed twenty-four therapeutic and vaccine development programs to date. These programs span a wide range of diseases and conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases.

At Moderna, we create medicines by using mRNA, which plays a fundamental role in human biology. All human genetic information is stored in DNA located in a cell's nucleus. In order to access that information, cells need to make a working copy of it—that is mRNA. Unlike DNA, mRNA molecules move out of a cell's nucleus; once outside the nucleus, mRNA molecules transfer the information they encode to the cellular machinery that make all the proteins required for life. Each mRNA molecule contains the instructions to produce a specific protein with a distinct function in the body. mRNA thus plays a central role in all biological processes, including in human health and disease, which is why we call it the "software of life."



Our approach fundamentally differs from traditional approaches to medicine. Rather than introduce a protein or chemical to the body, we send tailored mRNA into cells to instruct them to produce specific proteins. We built Moderna on the guiding premise that if mRNA can be used as a medicine for one disease, it could work for many diseases. Instead of starting from scratch for each new vaccine or therapy, our mRNA approach leverages the technology and fundamental components that we have been researching and developing since our founding. By building off our prior research and learning, we believe we can improve how we discover, develop, and manufacture medicines.

We designed our strategy and operations to realize the full potential value and impact of mRNA over a long time-horizon. Since 2010, we have built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body. Our prior research and clinical trials taught us valuable lessons about designing vaccines—particularly how to manufacture and formulate mRNA that can be safely injected into people and induce an appropriate immune response. We believe this platform can be used to pursue mRNA medicines for a broad spectrum of diseases.

Creating a new generation of medicines is a challenging endeavor. Over the past ten years, Moderna raised over \$5 billion in funding from our strategic collaborators and investors who recognize the potential of our unique mRNA approach. We are also grateful for approximately \$58 million in grant funding from the Defense Advanced Research Projects Agency (“DARPA”) and the Biomedical Advanced Research and Development Authority (“BARDA”). And in April, BARDA committed to fund up to \$483 million to accelerate the clinical development and manufacturing scale-up of our coronavirus vaccine candidate. In July, we amended our agreement with BARDA to provide for an additional commitment of up to \$471.6 million to support late-stage clinical development of Moderna’s COVID-19 vaccine candidate, including the execution of a 30,000-participant Phase 3 study in the United States. In August, we signed a contract with the U.S. government to provide millions of doses of our prospective vaccine to the American people.

II. Moderna Used its mRNA Platform to Create an Effective COVID-19 Vaccine

Our mRNA technology is flexible and quickly adaptable; that allowed Moderna to step forward and pursue the rapid development of a COVID-19 vaccine candidate named mRNA-1273. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (“NIAID”), a part of the National Institutes of Health (“NIH”), in January 2020 to try to accelerate our vaccine candidate.

The story of mRNA-1273 really begins before any of us had ever heard of COVID-19. Since 2015, Moderna has worked to develop mRNA vaccines for coronaviruses, such as the SARS and MERS viruses. And in 2016, we began building our U.S. manufacturing facility, based on our early clinical data, and our belief that the mRNA platform would be necessary to address diseases in the future. Those experiences, and Moderna’s own proprietary technologies developed through years of research, put Moderna in a unique position to respond to the current pandemic.

For example, a key challenge in developing mRNA vaccines and treatments has been to develop a vehicle for getting the mRNA into the body’s cell—in other words, the “packaging” for shipping the mRNA software into the cell. You need technology that both protects the mRNA in transmittal and will not be targeted by the body’s natural defenses. After years of effort, Moderna has developed a proprietary lipid nanoparticle delivery system that enhances safety and tolerability. We have also invested significantly in the manufacturing process to invent the technological capabilities necessary to manufacture our potential mRNA medicines.

We were able to research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines and other mRNA-based medicines. In addition to the technology described above, this prior knowledge included our understanding of the safety of our platform and our experience producing over 100 batches of mRNA for use in human clinical trials in the two years before the COVID-19 virus emerged.

In our prior work on coronavirus mRNA vaccines, we identified a key protein on the surface of coronaviruses, called the Spike protein, as a good vaccine candidate. The identified Spike protein has two primary functions: it (i) facilitates the attachment of the coronavirus to the host cell in an individual; and (ii) contributes to the entry of the coronavirus into the host cell by fusing viral and host membranes. We began to develop mRNA-1273 by reviewing the genetic sequence of the SARS-CoV-2 Spike protein. Based on the sequence for the Spike protein, we designed and synthesized a corresponding mRNA sequence—in other words, the genetic software that instructs a human cell to create the Spike protein. Using our validated mRNA vaccine platform, we have been able to formulate this mRNA by incorporating lipid nanoparticle technology into a vaccine that can be administered directly to a patient. Once injected, the mRNA molecule causes the patient’s cells to produce the Spike protein; the body’s immune system then attacks that protein, triggering a protective immunological response.

Our approach to a COVID-19 vaccine differs from traditional vaccine development because we are not injecting into the body a dead or weakened version of the novel coronavirus or one of its components. Instead, we use the information from the virus to teach the cells in a

patient's body how to make the virus's Spike protein, which itself provokes a protective immune response. Using this novel approach, we progressed from genetic sequencing to a vaccine ready for human testing in just 63 days—a testament to the 10 years of investment and hard work on our platform.

III. Clinical Trials Led to the FDA Emergency Use Authorization for mRNA-1273

Working closely with the government, Moderna put mRNA-1273 through a rigorous set of clinical trials to test its safety and efficacy. This process began extraordinary quickly. We began work on mRNA-1273 immediately after the genetic sequence of the novel coronavirus was released on January 11, 2020. Only 25 days later, on February 7, 2020, Moderna completed its first clinical batch of mRNA-1273. The Phase 1 study, led by NIH, dosed its first participant on March 16, 2020. On May 18, 2020, we announced positive interim results from the mRNA-1273 Phase 1 study, showing the generation of neutralizing antibody titer levels in all eight initial participants. In July 2020, the NIH and other authors published a fuller set of interim data and results of the Phase I study in the *New England Journal of Medicine*. Those results indicated that the vaccine produced neutralizing antibody titers in all forty-five participants evaluated.

The first participants in our Phase 2 study were dosed on May 29, 2020, and we completed enrollment of all 600 subjects in our Phase 2 study on July 8, 2020. While the Phase 2 study was pending, we began our Phase 3 study in July 2020. We enrolled 30,000 participants in a randomized and placebo-controlled study, which was conducted in collaboration with NIAID. Recognizing the importance of including a representative population in this important study, we and NIAID made a concerted effort to enroll participants from communities that have historically been under-represented in clinical research and have been disproportionately impacted by COVID-19. The study ultimately included more than 11,000 participants from communities of color, representing 37% of the study population. On November 30, 2020, we announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19. Efficacy was consistent across age, race and ethnicity, and gender demographics. The interim results from the Phase 3 trial were later published in the *New England Journal of Medicine* and confirmed the efficacy and safety of the vaccine. The data from our Phase 3 trial also suggest that our vaccine prevents severe cases of COVID-19, with no severe cases of the disease occurring in the trial participants who received the vaccine.

On December 18, 2020, the FDA authorized Moderna's COVID-19 vaccine for distribution under an Emergency Use Authorization. The next day, the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices unanimously voted to recommend the use of Moderna's COVID-19 vaccine in people 18 years of age and older. In the days and weeks that followed, additional countries authorized the use of Moderna's vaccine. Canada authorized the use of our vaccine shortly before the end of the year, while Israel, the European Union, and the United Kingdom authorized the vaccine in the first days of 2021.

IV. Moderna Is Working with Partners to Produce and Deliver mRNA-1273

We are now focused on working closely with our manufacturing partners and the federal government to produce, fill, and deliver vaccine doses rapidly, with robust commitment to safety and quality. I will provide a brief overview of our production process and give you a status update.

A. Overview

Producing and delivering a vial of mRNA-1273 is a multiple-stage process. The first stage is to create large batches of the drug substance: mRNA encapsulated in a lipid nanoparticle. For the U.S. supply line, this stage takes place in two places: Moderna's manufacturing facility in Norwood, Massachusetts, and a facility in Portsmouth, New Hampshire operated by our contract manufacturing partner, Lonza Ltd. ("Lonza"). The use of such partners is common in the biopharmaceutical industry, and Lonza is one of the world's leading contract manufacturers. This first stage is itself a multistep process that requires the availability of raw materials and consumable supplies, such as the custom-made plastic bags that line the tanks in which the drug substance is made.

The second major stage of the production process is filling vials with the drug substance. As is common in the industry, we have partnered with a contractor, Catalent, Inc. ("Catalent"), that specializes in this "fill-finish" process. Catalent is filling vials with our vaccine at its biologics facility in Bloomington, Indiana. We are in the process of onboarding another fill-finish partner with a U.S. facility to expand our capacity at this stage of the process. As with the first stage, putting mRNA-1273 into vials is itself a multistep process that depends on the availability of supplies.

The third major stage of the production process is inspecting, testing, and packaging the filled vials for delivery. Catalent also manages this multistep stage, and our capacity will be supplemented when we fully onboard an additional fill-finish partner.

On any given day, millions of doses of mRNA-1273 will be at different stages of this process. Over time, the buildup of the product and other necessary supplies generally allows subsequent stages to operate more efficiently. The pace of production also increases as the process gets refined and the highly skilled and experienced personnel operating that process gain greater familiarity with it.

I want to be clear that, throughout this process, Moderna and its partners are committed to maintaining the highest standards of safety and quality. That commitment requires careful planning and specialized learning; it can also extend the production timeline. It is essential, however, to maintain public confidence in biopharmaceutical products like our vaccine.

B. Production Update

Moderna and its partners began to raise additional investor capital to modify and expand our manufacturing and distribution chains for mRNA-1273 well before the FDA authorized the vaccine for use in the United States. Those efforts were complimented by additional funding from BARDA, which also facilitated our agreements to collaborate with Lonza in May 2020 and

with Catalent in June 2020. Working with those partners, we began to scale up the production process and manufacture doses for potential distribution under our supply agreement with the U.S. government.

We began delivery to the federal government promptly after the FDA issued its EUA. By the end of December, we had delivered 17.8 million doses to the federal government. To date, Moderna has delivered over 45 million doses of our vaccine to the federal government. Tens of millions of doses are at different stages of the production process. We are on track to meet our original commitment of delivering the first 100 million doses to the federal government by the end of March.

Less than two weeks ago, we reached an agreement with the federal government to accelerate the delivery of the second hundred million doses and to deliver a third hundred million doses on an advanced schedule. We are now planning to deliver the second hundred million doses by the end of May, rather than the end of June. We plan to complete delivery of the third hundred million doses by the end of July, moved up from the end of September. We plan to ship doses as they are released. We are able to accelerate these delivery timelines—while maintaining a robust commitment to safety and quality—thanks to the highly-skilled and experienced workers at our Massachusetts facility, our raw material suppliers, our contract manufacturing partner Lonza, and our fill-finish contractor Catalent.

Since the end of 2020, we have doubled our monthly deliveries to the U.S. government, and we are working to double them again by April to more than 40 million doses per month. As we work to meet these goals, we are continually learning and working closely with our partners and the federal government to identify ways to address bottlenecks and accelerate our production. For example, one of the recently identified constraints on our production process has been the capacity of the fill-and-finish process. To reduce this constraint, we studied the possibility of adding more doses to each vial of vaccine. Doing so would improve output because it allows us to complete manufacturing runs more quickly; it also reduces the need for consumable materials in high demand. The FDA has given us positive feedback on our proposal, and we are pursuing a plan that may allow up to 15 doses to be drawn from each vial. This will allow us to produce and deliver more doses more quickly. We will continue to collaborate with our manufacturing partners and the federal government to increase the efficiency of our production process without compromising quality or safety.

* * * * *

During this period, Moderna is continuing research and development efforts to address the COVID-19 pandemic. For example, we are closely monitoring emerging variants and testing the performance of our vaccine against them. We are also studying potential booster shots, either of the existing vaccine or of a version that has been adjusted to address significant variants. We are also conducting a trial of the safety and efficacy of our vaccine in younger populations, with the hope of being authorized to provide our vaccine to adolescents aged 12 to 18 by the fall.

This pandemic remains a challenge unlike anything that we have faced in recent memory. At Moderna, we are grateful for the opportunities we have had to collaborate with the

government on our efforts to deliver a safe COVID-19 vaccine. We are also grateful for the many companies around the world, including my colleagues testifying today, that are working to deliver COVID-19 vaccines and treatments.

Finally, I would like to thank this Subcommittee for its commitment to this cause, as well as the diligent work of your staff. We deeply appreciate 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 your questions.

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

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

STATEMENT OF RICHARD NETTLES, M.D.

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 populations. 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:]



Statement of

Dr. Richard Nettles, M.D.
Vice President of U.S. Medical Affairs, Janssen Infectious Diseases and Vaccines
Johnson & Johnson

before the

Subcommittee on Oversight and Investigations, Committee on Energy and Commerce
U.S. House of Representatives

February 23, 2021

Chairwoman DeGette, Ranking Member Griffith, and Members of the Subcommittee, thank you for the opportunity to discuss Johnson & Johnson's efforts to develop, produce, and distribute a vaccine to protect against the virus that causes COVID-19. As you know, my colleague Dr. Macaya Douoguih testified before the Subcommittee last year about our research and development efforts for the vaccine. I am pleased to have the opportunity to update you today on the remarkable progress that we have achieved over the past several months, which has allowed us to request emergency use authorization (EUA) from the Food and Drug Administration (FDA) less than three weeks ago. Although we are cautious not to prejudge the outcome of the ongoing FDA review process, we believe that our single-dose COVID-19 vaccine will be a critical tool for fighting this global pandemic.

Johnson & Johnson is the world's largest and most broadly based healthcare company. We are committed to using the full breadth of our expertise and experience to improving health outcomes around the world. A century ago, Johnson & Johnson played a leading role in combatting the 1918 flu pandemic, and our history of confronting global healthcare challenges continues to the present day, including with the European approval of our Ebola vaccine last year.

We brought this same approach to the COVID-19 pandemic when, in January 2020, we launched a major research and development effort for a vaccine. The pace of development over the past year was extraordinary. We conducted an intensive evaluation of vaccine candidates, culminating in the selection of a candidate for a single-dose regimen. We began initial human clinical trials in July, launched our large-scale pivotal clinical trial in September, released topline interim results last month, and sought an EUA on February 4.

Even with this accelerated timeline, Johnson & Johnson adhered to our principles of putting patients first by committing to high-quality Phase 3 studies, taking extra steps for safety oversight, seeking diverse populations for our clinical trials, and performing rigorous scientific examinations of the trial data. As an infectious disease physician, I have decades of experience fighting challenging diseases around the globe. Johnson & Johnson's work to date, along with others in the industry, has been remarkable. I am pleased to provide an update on our efforts.

Trials, Results, and FDA Application

During last summer's hearing before the Subcommittee, Johnson & Johnson was on the cusp of initiating our first trials in humans after observing positive results in non-human primates. In July 2020, we began a Phase 1/2a first-in-human clinical trial in healthy volunteers in the United States and Belgium. We also launched a Phase 1 study in Japan, and a Phase 2a study in the Netherlands, Spain, and Germany. Interim results from the Phase 1/2a trials demonstrated the safety profile and immunogenicity of the vaccine after a single dose.

In September 2020, Johnson & Johnson launched ENSEMBLE, a large-scale, randomized, Phase 3 clinical study. We used sophisticated predictive models to recruit diverse participants, including from sites where new variants of COVID-19 have emerged. Ultimately, the trial included nearly 45,000 participants from eight countries across three continents, including a diverse and broad population in the United States, Central and South America, and South Africa. In January 2021, we announced that our single-dose vaccine met the study's primary and key secondary endpoints.

The study showed that our single-dose vaccine addresses the most important healthcare need in the pandemic: the prevention of COVID-19 related hospitalization and death. Importantly, this result was achieved across emerging variants, including the virulent B.1.351 variant first observed in South Africa, and the P2 variant first observed in Brazil. Specifically, the study showed the following outcomes, twenty-eight days after vaccination:

- The vaccine provided complete protection against COVID-19 related hospitalization and death, as compared to those study participants who received a placebo.
- The vaccine demonstrated 85% effectiveness overall in preventing severe disease, including across countries with newly emerging variants.
- The vaccine demonstrated 72% effectiveness in the United States (and 66% effectiveness overall) at preventing moderate to severe disease.

Based on these clinical trial data, Johnson & Johnson earlier this month submitted an application to the FDA for emergency use authorization for the vaccine. The FDA subsequently announced that the agency's Vaccines and Related Biological Products Advisory Committee will meet to review the vaccine this week, on Friday, February 26. We are working with the FDA to ensure that the agency has the information necessary to reach a decision based on the data relating to the safety, efficacy, and quality of the vaccine.

Production and Distribution

We are working around the clock to develop and broadly scale our manufacturing capabilities to supply the United States, and we are appreciative of the ongoing and extensive collaboration and partnership with the U.S. government. Assuming necessary regulatory approvals relating to our manufacturing processes, our plan is to begin shipping immediately upon emergency use authorization, and deliver enough single-doses by the end of March to enable the vaccination of more than 20 million Americans. We are confident in our plans to

deliver 100 million single-dose vaccines to the United States during the first half of 2021, and we are continuing to partner with the U.S. government to explore all options to accelerate delivery.

We are working with urgency, in collaboration with the government and others, to continue to increase production significantly throughout the year. To that end, we have been working to expand our own manufacturing capacity and to contract with established third-party vaccine manufacturers for additional production. Our current manufacturing plans are designed to meet our objective, which we announced last year, to produce the vaccine at a rate of one billion doses globally by the end of 2021.

Throughout the pandemic, Johnson & Johnson has focused on building a global supply network in parallel with the research and development of our vaccine. We began preparing for clinical vaccine production in our facility in the Netherlands in July 2020. Since then, we have increased manufacturing capacity significantly and continue to activate new manufacturing sites as quickly as possible, subject to approvals by the relevant health authorities. Our goal is to have seven COVID-19 vaccine manufacturing sites active by midyear. We have entered into agreements to expand our manufacturing capability, including by collaborating with established manufacturers in the industry, and we continue to pursue opportunities to expand our manufacturing capabilities with additional production sources.

The production of our vaccine is a highly complex process that requires very particular capabilities and experiences. As a result, there are significant challenges inherent in scaling manufacturing output and accelerating the timeline needed for a COVID-19 vaccine.

Over the past several months, we assessed nearly 100 different potential production sites, and we selected eight sites that were able to support an accelerated timeline. Three sites have produced process performance qualification batches of the vaccine, and we expect additional capacity to become available in the second quarter of 2021.

The production of the vaccine generally consists of two separate processes – the manufacturing of the drug substance and the manufacturing of the drug product. Attached to my testimony is a fact sheet on our vaccine production and distribution process.

The production of the drug substance takes about two months, due to the time necessary to grow the required biological cells and then purify the active vaccine. Our current plans call for the production of drug substance at sites in the United States, Europe, and Asia. The site in the United States is in Maryland. Production will occur both on existing production equipment and on new specialized equipment being activated for our vaccine.

The manufacturing of the drug product takes about five to six weeks to produce, test, and release. The necessary production timeline is also driven by the time required for cellular growth and sterility. Our plan is to manufacture drug product at sites in the United States, Europe, Asia, and Africa. In the United States, the drug product production sites are in Indiana, Michigan, and Pennsylvania. As with the drug substance, the production of the drug product will occur both on existing production equipment and new specialized equipment. Regulatory inspections and approvals for these sites are ongoing.

In the event that the FDA grants our request for an emergency use authorization, we have doses ready to ship immediately upon authorization. In the United States, Johnson & Johnson will distribute our vaccine through an agreement with the U.S. government for the production of 100 million vaccine doses. Pursuant to our agreement with the government, Johnson & Johnson will deliver the vaccine to a distributor that will create a vaccination kit containing our vaccine and the necessary ancillary equipment, such as syringes and personal protective equipment.

In addition to our commitment to provide millions of vaccine doses in the United States, Johnson & Johnson recognizes the global nature of the pandemic and the need for broad access to COVID-19 vaccines. We have therefore pledged to provide vaccine doses to lower income countries beginning this year. We committed to provide vaccine doses to COVAX, the initiative led by the Global Alliance for Vaccines and Immunization, the World Health Organization, and others, to provide equitable access to COVID-19 vaccines.

Importantly, the characteristics of our vaccine permit it to be distributed using the existing cold supply chains that we use to transport other medicines today. We estimate that the vaccine will remain stable for up to two years at -20° Celsius, and at least three months at routine refrigeration temperatures between 2° and 8° Celsius. Because the vaccine is compatible with standard vaccine distribution channels, it does not require new infrastructure for its distribution. We believe our current distribution channels include enough temperature-controlled trucks, containers, and planes to deliver the vaccine as needed. In addition, each vaccine pallet will include tracking technologies that will give us real-time location, temperature, and other information needed to maintain the quality and integrity of the vaccine.

Vaccine Technology

Johnson & Johnson's AdVac technology is the foundation of our COVID-19 vaccine. We have employed the same AdVac technology to develop our Ebola vaccine, which received European Commission approval last year, and to construct our vaccine candidates for HIV, respiratory syncytial virus, and Zika. We have significant clinical experience with vaccines based on the AdVac technology. Vaccines based on this technology have been administered for more than a decade to a wide variety of populations, such as adults, people over age 65, infants, children, and pregnant women.

To develop the COVID-19 vaccine, we combine DNA that codes for the coronavirus spike protein and the AdVac technology that uses a nonreplicating adenovirus as a carrier. The resulting combination mimics components of the COVID-19 pathogen and triggers the immune system while not leading to infection. When the body encounters this antigen, it produces antibodies and T cells. If the body later encounters the actual COVID-19 pathogen, the body will be able to respond faster and more effectively, as immune cells and antibodies specific to the pathogen are produced rapidly in the body to prevent the pathogen from inducing disease.

Vaccine Safety, Transparency, and Diverse Populations

In September 2020, Johnson & Johnson joined with eight other companies working on COVID-19 vaccines to reiterate our commitment to develop and test potential vaccines in accordance with high ethical standards and sound scientific principles regarding the conduct of

clinical trials and the rigor of manufacturing processes. The companies pledged to make the safety and well-being of vaccinated individuals the top priority, as well as to work to ensure a sufficient supply and range of vaccine options, including those suitable for global access. The companies also pledged to submit the vaccines for regulatory approval or emergency use authorization only after demonstrating safety and efficacy through a Phase 3 clinical study consistent with the requirements of expert regulatory authorities.

For Johnson & Johnson's Phase 3 COVID-19 vaccine studies, we established independent expert vaccine Safety Advisory Boards to consult and advise on safety risk management. In addition, independent Data and Safety Monitoring Boards oversee the safety of the entire clinical program. These measures are in addition to our standard oversight of safety during the course of our studies.

Johnson & Johnson is committed to disclosing the trial data on external public registries, such as ClinicalTrials.gov and the EU Clinical Trials Register. We expeditiously seek publication of all results from clinical trials in patients in peer-reviewed medical journals and will do the same for our vaccine trials. To that end, our preclinical studies were published in scientific papers, and our Phase 1/2a study data were published in the New England Journal of Medicine. For our Phase 3 COVID-19 vaccine studies, the Clinical Study Reports and clinical trial participant data will be made available for sharing through the Yale University Open Data Access Project after regulatory approval.

Johnson & Johnson has led efforts to ensure that clinical trials include a wide variety of populations, including historically underrepresented communities. In our COVID-19 vaccine trials, we employed an engagement strategy to reach underserved and underrepresented communities. The ENSEMBLE study of 45,000 participants included diverse and broad populations. Among the participants worldwide, 45% were Hispanic or Latinx, 19% were Black or African American, 9% were Native American, and 3% were Asian. More than one-third of participants were over age 60. For participants in the United States, 15% were Hispanic or Latinx, 13% were Black or African American, 6% were Asian, and 1% were Native American.

Pricing and Government Support

As my colleague indicated last year, Johnson & Johnson committed to making our COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. The not-for-profit price will be determined based on one cost structure, with all appropriate costs included. In addition, we have committed to one price globally.

Finally, I want to note that the U.S. government's support has been an important contributor to Johnson & Johnson's ability to develop our vaccine on an accelerated pace. Last year, the Biomedical Advanced Research and Development Authority provided a total of approximately \$900 million to support Johnson & Johnson's vaccine research and development. Along with our own investment of approximately \$800 million, building on our significant prior investment in our vaccine platform over the past decade, the government's support was an important contributor to our ability to conduct Phase 1 and Phase 2 clinical trials and to conduct the Phase 3 ENSEMBLE studies. In addition, last summer, the government and Janssen entered into an agreement for the demonstration of large-scale manufacturing and delivery of up to 100

million doses of the vaccine by June 30, 2021. This commitment to purchase our vaccine, if authorized by the FDA, was important for our ability to invest in the increased production capacity that will enable us to bring millions of vaccine doses to Americans in the coming months. In addition, Johnson & Johnson has committed more than \$1.5 billion to develop and secure manufacturing capacity for the vaccine.

* * *

Thank you for the opportunity to provide this update regarding our efforts to develop, produce, and distribute a vaccine against COVID-19. I would be happy to answer any questions that you may have.

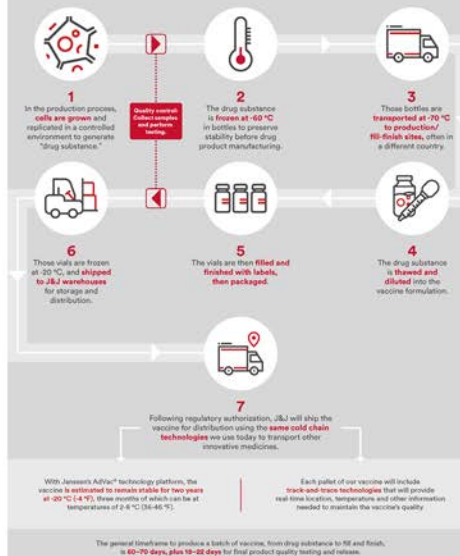


Janssen Supply Chain

COVID-19 Vaccine Manufacturing

At Johnson & Johnson (J&J), we take seriously our responsibility to supply our COVID-19 vaccine candidate around the world upon approval, and are confident we have the capabilities, collaborations, and rigorous safety and quality standards to do so.

Vaccine Production and Distribution Process



Global Manufacturing Collaborations

Given the unprecedented nature of the pandemic, Johnson & Johnson is expanding its global manufacturing capacity. We have established new U.S. vaccine manufacturing capabilities and are scaling up capacity in other countries.

In addition to our existing manufacturing capacity in Leiden, the Netherlands, we have entered into multiple agreements to expand our manufacturing capability of our COVID-19 vaccine candidate.

Manufacturing Partners



Due to the global interconnectivity of our production and supply chain processes, one batch of the J&J COVID-19 vaccine will likely visit multiple countries through the course of various manufacturing stages in its journey from drug substance to a finished vial for injection.

For more information on Johnson & Johnson's approach to help combat COVID-19, visit www.jnj.com/coronavirus.

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Ms. DEGETTE. Thank you so much, Dr. Nettles.
And I'm now pleased to recognize Dr. Dobber for 5 minutes.
Dr. Dobber?

STATEMENT OF RUUD DOBBER, Ph.D.

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 the United States and across the world.

AstraZeneca is a global science-led biopharmaceutical company which focuses on the discovery, development, manufacturing, and commercialization of innovative 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 the 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:]

**Statement of
Ruud Dobber, Ph.D.
Executive Vice President BioPharmaceuticals Business Unit and
President, North America
AstraZeneca**

**Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives**

Pathway to Protection: Expanding Availability of COVID-19 Vaccines

February 23, 2021

Chairwoman DeGette, Ranking Member Griffith, and Members of the Subcommittee, I am Ruud Dobber, PhD, Executive Vice President BioPharmaceuticals Business Unit and President, North America, at AstraZeneca. I have been with Astra and, through its merger with Zeneca Group, AstraZeneca, since 1997, and I am responsible for product strategy and commercial delivery for cardiovascular, renal and metabolism, respiratory, and immunologic diseases, including our vaccine and long acting antibody. I am here today to convey AstraZeneca's strong commitment to ongoing efforts to develop and manufacture the AZD1222 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 and commitment to delivering safe and effective solutions for fighting the COVID-19 pandemic in the United States and across the world.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, manufacturing, and commercialization of innovative medicines, primarily for the treatment of diseases in the following therapeutic areas: Oncology, Cardiovascular, Renal & Metabolism, and Respiratory and Immunology. We are proud to call Wilmington, Delaware home to our North American Headquarters, and that one of our three global R&D headquarters is located in Gaithersburg, Maryland. Overall, we have approximately 13,000 employees in the United States, with operations in 12 different states and Puerto Rico (California, Delaware, Indiana, Kentucky, Maryland, Massachusetts, New Jersey, New York, North Carolina, Ohio, Pennsylvania, and Texas), including eight manufacturing sites. These sites account for nearly one-third of our total manufacturing footprint. In addition to our U.S. presence, we have an additional 18 manufacturing sites throughout the rest of the world. In total, AstraZeneca operates in over 100 countries, and we are leveraging our global workforce and resources to address this worldwide crisis.

Today, I will focus on four key elements of AstraZeneca's development and manufacturing program for AZD1222:

- *First*, as previously conveyed to the Subcommittee in July 2020, our strategic approach for AZD1222 has focused on partnering with scientists, governments, multilateral organizations, like CEPI and GAVI, and manufacturers to establish agreements for the

development, supply, and distribution of the vaccine in an equitable manner across the world. AstraZeneca has entered into an exclusive licensing arrangement with the University of Oxford for the global development, production, and supply of AZD1222, which also includes vaccine redevelopment to combat variants of the virus. To support our goal of providing broad and equitable access as quickly as possible, we have entered into agreements with the United States and certain other governments and organizations, for supply of hundreds of millions of doses of our vaccine. The cost of the doses of the vaccine under those agreements will provide no profit for AstraZeneca. In addition to our vaccine efforts, we have also collaborated with the government and academia on the development of monoclonal antibodies for the prevention and treatment of COVID-19.

- *Second*, AstraZeneca is continuing to progress through global clinical trials to support the approval and emergency use authorization of AZD1222 in the U.S. and across the world. While clinical studies are ongoing, analyses and studies conducted to date indicate that AZD1222 is well tolerated and effective for the prevention of COVID-19. In addition, we have completed enrollment in our U.S. Phase III trial to support U.S. Food and Drug Administration (“FDA”) authorization in the U.S.
- *Third*, prior to receiving authorization in the U.S., we began scaling up our manufacturing operations to manufacture the vaccine so that doses will be available in the U.S. upon emergency use authorization to avoid any delays. We operate our vaccine manufacturing operations in the U.S. at or near full capacity and are not currently experiencing significant material or equipment constraints.
- *Fourth*, AstraZeneca has initiated studies to address the emerging threats posed by new variants. Initial analyses, while still ongoing and subject to verification, suggest AZD1222 shows promise against the U.K. variant of the virus, and Oxford University is already developing next generation adenoviral vector vaccines incorporating the genetic changes to the spike protein found in the new Brazil and South Africa variants.

I. Collaboration

The progress that AstraZeneca has made in identifying and developing AZD1222 would not have been possible without our collaborations with academia and government agencies. These joint efforts have been essential in expediting the development program for the vaccine. As the Subcommittee is aware, our exclusive global development and distribution agreement with the Jenner Institute at the University of Oxford and the Oxford Vaccine Group gave AstraZeneca a license to develop and to distribute the University’s novel recombinant adenovirus vaccine candidate AZD1222, formerly known as ChAdOx1 nCoV-19. Notably, this licensing agreement covers the redevelopment of the ChAdOx1 platform for variants of SARS-CoV-2.

We have also entered into two agreements with the U.S. government for the development, production, and supply of 300 million doses of AZD1222 should it receive authorization. The development program under these agreements includes a Phase III clinical trial with over 30,000 participants, which began in August 2020 and concluded enrollment in mid-January. Our

agreements with the U.S. government also include a pediatric program that is scheduled to begin in the coming months. We expect high level results from our Phase III trial soon, and, assuming a positive trial, we plan to file for emergency use authorization shortly thereafter. The U.S. government will own the doses of vaccine that we produce and will determine how the doses are distributed. We are very pleased that the U.S. government has moved with speed to advance critically important agreements and provide ongoing support to AstraZeneca, and I would like to take this opportunity to thank the U.S. government for its commitment to advancing these efforts.

II. Vaccine Development

Following rolling submission to regulatory authorities of data from our ongoing global clinical trials, we have received conditional marketing or emergency use authorization for AZD1222 in more than 50 countries. Phase II/III trials are ongoing in the U.K., U.S., Chile, Peru, and Brazil, while Phase I/II trials are ongoing in South Africa, Japan, and Kenya. The trials are collectively assessing efficacy, safety and immune responses in up to 60,000 participants across a broad age range and diverse racial, ethnic and geographic groups.

The primary analysis of the Oxford-led clinical trials from the U.K., Brazil, and South Africa, as detailed in a recent paper submitted for publication, indicated that AZD1222 is well tolerated and effective at preventing COVID-19 based on 17,177 participants. Patients in these studies generally received two doses of AZD1222 in dosing intervals ranging from four weeks to over 12 weeks. The analysis found the vaccine was 100% protective against severe disease, hospitalization and death more than 22 days after the first dose, was 76% effective overall three weeks after the first dose that is maintained to the second dose, and could result in a reduction in disease transmission of up to 67%. In addition, the primary analysis of overall vaccine efficacy at more than 14 days after the second dose was approximately 67%. The analysis also showed that efficacy increased up to 82% with a longer inter-dose interval of at least 12 weeks or more. It is possible that increasing the interval between doses could potentially allow more people to be vaccinated in the first instance, as well as maximize efficacy after two doses. Accordingly, we are discussing with regulators how best to investigate this further.

The ongoing Phase III trial in the U.S. is a randomized, double-blind, placebo-controlled multicenter study assessing safety, efficacy and immune response of two doses of AZD1222 given 28 days apart in over 30,000 participants over the age of 18 years across 100 sites. In addition to sites in the U.S., this trial was extended to sites across Chile and Peru. Trial participants who were healthy or had medically-stable chronic diseases and were at increased risk for exposure to the SARS-CoV-2 virus and COVID-19 were randomized in a 2:1 ratio of AZD1222 to placebo. This ratio was intended to increase the number of participants receiving the vaccine and, therefore, increase the size of the safety database that supports approval and authorization.

To help ensure confidence in use of AZD1222 in diverse patient populations, participants in this trial include diverse racial and ethnic groups who are healthy or have stable underlying medical conditions. We have worked with the National Institute of Allergy and Infectious Diseases' new clinical trials network to recruit and enroll participants in communities where there is a strong minority representation, including African American, Hispanic, and Native American populations. We have also worked closely with principal investigators at study sites to achieve

enrollment across diverse populations in all age groups and all populations older than 65 years of age.

We are happy to report that recruitment for this trial is now complete. Because availability of the data will be based on local spread of the disease, we cannot reliably predict the timing of data readouts. However, because the attack rate has been high, we are hopeful that the readout of the data will be available in the coming weeks. These data will be submitted to the FDA when they become available. It is important to mention that the dosing interval used in this trial is four weeks, which may not maximize efficacy. In the UK, a vaccination strategy based on a three month dosing interval is underway and real world evidence should become available in the next few weeks, providing additional real life evidence of the impact of the vaccine in different cohorts of patients, including older patients.

At the heart of AstraZeneca's core values is to "follow the science" and establishing the safety and efficacy of the vaccine through rigorous science is of paramount importance. Although our development program is progressing rapidly, our submissions for authorization for AZD1222 to date have met the stringent requirements established by regulators around the world. Further, earlier this month, the World Health Organization Strategic Advisory Group of Experts issued interim recommendations for the use of AZD1222 against COVID-19. We have made efforts to ramp up manufacturing of the vaccine while increasing personnel and resources to enable quicker trial recruitment. Two independent Data and Safety Monitoring Boards oversee the studies to ensure safety and quality, such as by monitoring safety and efficacy results, evaluating cumulative safety and other clinical study data at regular intervals, and making appropriate recommendations based on the available data. In addition, the U.S. Phase III trial has a two-year follow up period to monitor participants for efficacy and safety. The other current clinical trials will monitor participants for efficacy and safety over 12 months, and we will continue to evaluate the need to extend these trials to monitor efficacy and safety over a longer duration.

III. Vaccine Manufacturing and Supply

As noted, even prior to any approvals or authorizations, we proceeded to ramp up manufacturing for our COVID-19 vaccine with the support of the U.S. and other governments. We made this decision so that the vaccine will be ready for distribution and administration as soon as possible following regulatory approval or emergency use authorization. In order to support our goal of producing billions of doses of the vaccine for markets around the world as safely and quickly as possible, we have built more than a dozen regional supply chains in parallel across the world with our partners to support broad and equitable access at no profit during the pandemic period and we continue to forge additional partnerships to deliver this commitment. Supply chains have been set up to meet the needs of specific government or multinational organization agreements and the vaccine produced from the supply chains are generally country or region specific and we have tried to prioritize local manufacturing wherever possible. Our supply chain includes multiple manufacturing facilities across each stage of production (*i.e.*, drug substance, drug product and finished packaging). While we have been challenged by lower yields in some parts of the world despite our best efforts, we continue to make progress with our U.S. supply chain, with the goal of supplying doses upon emergency use authorization. We are working closely

with the U.S. government to ensure transparency around our progress and challenges. We also appreciate the tremendous support received from BARDA along the way. We are not currently experiencing significant material or equipment constraints.

With respect to our U.S. supply chain, we are proud that the vaccines covered by our agreements with the U.S. government are being manufactured in the United States. We are conducting filling and packaging activities at our West Chester, Ohio site. In addition, we have partnered with other U.S. pharmaceutical contract development and manufacturing organizations to manufacture the drug substance and drug product for the vaccine as well as handle certain packaging operations. Our Operations and Procurement teams have worked to secure and accelerate a global supply chain of critical raw materials, reagents and consumables in collaboration with our suppliers. At this time, we have secured sufficient supply of vials and stoppers to support our internal global supply chain, based on 10 doses per vial. Syringes are being sourced directly by the government vaccination teams and we believe that the U.S., among others, has secured adequate supply. In addition, since the Defense Production Act Title I priority rating was put in place, our suppliers have not communicated any significant delays of materials or equipment. FDA site visits have been conducted at all of these sites to ensure the proposed manufacturing facilities were suitable for production and had appropriate controls in place.

Despite the speed in scaling up our manufacturing operations, safety and quality standards have been, and remain, of paramount importance. Numerous safety tests and quality control measures are carried out during the manufacturing process, including on the final packaged product. We have built an extensive analytical network and are rapidly transferring our analytical methods to these laboratories. The impact of factors such as heat, light, radiation, environmental changes as well as interaction with container materials have also been determined for the vaccine through testing. Storage and handling conditions are defined at each stage of the production process to optimize product stability, shelf life, and ensure safety and quality is maintained. Our vaccine can be easily stored, transported and handled at refrigerated conditions (2-8°C/36-46°F) for at least six months and administered within existing healthcare settings, which facilitates access and supply. We are also continually identifying and implementing new ways of working that will accelerate production of AZD1222 and reduce the time to reach communities while maintaining the highest standards of quality.

IV. Addressing SARS-CoV-2 Variants

AstraZeneca has initiated studies to address the emerging threats posed by new variants, especially the U.K. variant. Sub-analyses of the Phase II/III trial data in the U.K., which were published as a pre-print in *The Lancet* this month and are still ongoing and subject to verification, suggest that the vaccine's efficacy is similar in participants with the U.K. variant and in those without this strain. We are particularly encouraged by these results, as the Centers for Disease Control and Prevention and Dr. Anthony Fauci have hypothesized that this strain may become the dominant strain in the U.S. Early data from a small Phase I/II trial in South Africa conducted by a local expert in coordination with Oxford University, and studying AZD1222 in predominantly young, healthy adult participants with an average age of 31 years has shown limited efficacy against mild to moderate disease, primarily due to the South Africa variant. Importantly this

analysis was not statistically significant, and no conclusions could be drawn regarding efficacy in severe disease. It is well recognized that achieving protection against mild disease is a higher hurdle for a vaccine, and there is often a gradient of increasing efficacy from mild to severe disease. This has also been observed with vaccines against SARS CoV-2, including AZD1222. Hence, depending on the mix of case severities in a trial, different levels of efficacy may be observed. Efficacy against severe disease is, of course, the most important outcome measure for public health. The South African study was not able to properly ascertain efficacy against severe disease, given the participants were predominantly young, healthy adults with an average age of 31 years. No severe disease or hospitalizations were observed in vaccine or control participants. We are in communication with the South African Ministry of Health to support the evaluation of AZD1222 for use against severe disease and hospitalization caused by the South African variant.

The Oxford University platform technology can be adapted to help address challenges with the new variants, and our collaborators have already started developing the next generation adenoviral vector vaccines incorporating the genetic changes to spike proteins found in the new variants in Brazil and South Africa. Although the adenoviral vectored vaccine genetic code can be altered to match new variants quickly in the laboratory, additional steps will be required to ensure the quality and effectiveness of the new vaccine, and it is likely the process from start to finished product would take 8 to 9 months to complete. In addition, it will be important to test the effectiveness of the new vaccine against the new variants in a clinical trial. Given that we will have substantial safety data on the vaccine platform and there would be relatively small changes in the vaccine and its manufacturing, we are discussing a path forward with regulators globally. We welcome further discussions with the FDA and other regulators as part of the bigger picture of addressing vaccination needs going forward. Establishing a potential pipeline of future vaccines will be essential, and this can only be achieved in an efficient and effective manner with collaboration across industry and regulatory authorities globally.

* * *

AstraZeneca is fully committed to fighting the COVID-19 pandemic, helping to save lives through the expedited, science-based development and manufacture of AZD1222 and other potential prophylactic and therapeutic options. Our team is continuing to make progress in our development and manufacturing programs, and we fully intend to provide broad access to AZD1222, if approved or authorized under an emergency use authorization, in the U.S. and across the world.

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. We appreciate your keen interest in these important issues, and I look forward to answering your questions.

Ms. DEGETTE. Thank you so much.
And now, last but not least, Mr. Trizzino, you're recognized for 5 minutes.

STATEMENT 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.

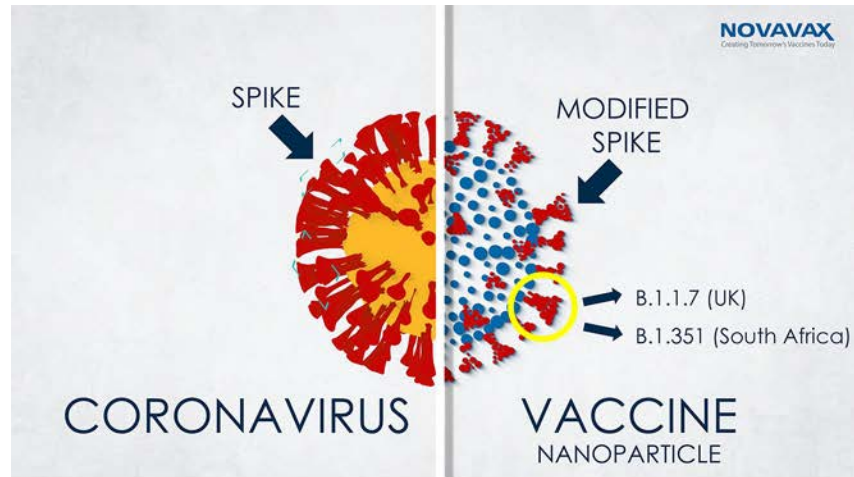
As you'll hear, our technology was built for this moment. Our scientists continually scan the landscape for emerging threats, and we started development of our COVID-19 vaccine candidate in January 2020.

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.

[Slide follows:]



Mr. TRIZZINO. 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:]



Testimony of John Trizzino
Executive Vice President
Chief Commercial Officer and Chief Business Officer
Novavax

Submitted to the Subcommittee on Oversight and Investigations
U.S. House of Representatives, Committee on Energy and Commerce

Pathway to Protection: Expanding Availability of COVID-19 Vaccines

February 19, 2021

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 am executive vice president, chief business officer and chief commercial officer at Novavax. I have been with Novavax for a total of 10 years and have held a number of leadership roles that have given me a deep understanding of the company. I also have more than 25 years of direct vaccine industry experience in pediatric and adult immunizations as well as influenza pandemic preparedness, all of which is directly related to the COVID-19 pandemic response.

I. Novavax

Novavax is a biotechnology company focused on the development of next-generation vaccines for serious infectious diseases. The company is headquartered in Gaithersburg, Maryland. We are proud to be at the forefront of the fight against COVID-19. While we initiated development of our SARS-CoV-2 vaccine candidate in January 2020, our company has been developing vaccines for almost two decades and for the past ten years we have focused on using our recombinant nanoparticle platform technology. This includes the production of vaccines for two coronaviruses, Middle East Respiratory Syndrome (MERS) in 2012 and severe acute respiratory syndrome (SARS) in 2003. We also have a late-stage respiratory syncytial virus (RSV) vaccine candidate and an influenza vaccine candidate, NanoFlu™, for which we concluded

a successful Phase 3 clinical trial in 2020. This extensive experience with our platform technology positioned Novavax to quickly initiate development of a SARS-CoV-2 vaccine candidate shortly after the virus was isolated. This testimony will walk you through our recombinant nanoparticle platform technology, development of our COVID-19 vaccine candidate, NVX-CoV2373, and our US manufacturing operations and supply chain.

II. Our Science

A. *Recombinant Nanoparticle Technology*

The two key features of our vaccine platform include a recombinant protein nanoparticle engineered from the genetic sequence of the target pathogen and our Matrix-M™ adjuvant. Together, they trigger protective immune responses needed to prevent disease. Our recombinant vaccine engineering takes a new approach to provide robust and functional immunity, which may be more efficacious than traditional vaccines. Using this technology, we are able to produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats.

Vaccines typically take years, or even decades to develop. In addition, many pathogens have evolved to avoid the immunity induced by recurring infections. Because of this, there are several advantages to using our recombinant nanoparticles in place of the old technology. First, our technology platform gives us the ability to tailor our vaccines to key components of pathogens to enhance functional immunity and lead to better protection against infection and disease. Our insect cell platform efficiently expresses native-conformation antigens, and these protein antigens are then processed into nanoparticles. Taken together, these features of our technology allow us to produce highly immunogenic vaccines in a scalable, efficient recombinant vaccine production system.

B. *Our Adjuvant*

Novavax's proprietary Matrix-M™ adjuvant improves immune responses and enables vaccine dose-sparing. Combined with the nanoparticle antigen we produce, our Matrix-M adjuvant means that our vaccines can use lower doses of antigen to achieve the desired immune response, which results in increased supply and manufacturing capacity. This means

that our technology platform could give us the ability to vaccinate more people in the US and worldwide.

Matrix-M is derived from saponin, which is found in the inner bark of the Chilean soapbark tree, *Quillaja saponaria*. After purification and processing, it is a critical component of our vaccine candidates, and increases the breadth and height of the immune response. Saponins have a multi-decade track record of use in experimental and licensed vaccines. Overall, this extensive clinical experience has demonstrated this class of adjuvants to be well-tolerated.

We learned from our experience with NanoFlu, our quadrivalent seasonal influenza candidate, that the Matrix-M adjuvant is a powerful tool in the fight against antigenic drift during the flu season. In a pivotal Phase 3 clinical trial, NanoFlu met or exceeded the primary and secondary endpoints, demonstrating safety and non-inferior immunogenicity for all four strains included in the vaccine compared to a U.S.-licensed quadrivalent influenza vaccine.

III. Development of NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence of the Wuhan SARS-CoV-2 strain, the virus that causes COVID-19 disease. NVX-CoV2373 was created using our recombinant nanoparticle technology as I described to generate antigen derived from the coronavirus spike (S) protein and is adjuvanted with Matrix-M to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

In early clinical testing of multiple candidates, two doses of NVX-CoV2373 administered 21 days apart evoked the strongest immune system response. Our vaccine candidate is stored at 2-8°C in a refrigerator-stable, liquid formulation, allowing for successful cold chain management with existing infrastructure. It is presented in ten-dose vials, is preservative-free, and is ready for use as an intramuscular injection using standard needles and syringes. Because our vaccine can be distributed through existing vaccine supply chain channels, it offers specific benefit to rural and underserved populations, which can be harder to reach.

Giving you a preview of what I will detail further, we recently announced that NVX-CoV2373 demonstrated high clinical efficacy against the original virus strain, and it was the first vaccine to demonstrate clinical efficacy against both of the rapidly emerging variants that are circulating in the United Kingdom and South Africa, and now known to be present in the US.

A. *Our Partners*

Novavax is working closely with US government partners as well as non-governmental organizations and industry partners to advance development of NVX-CoV2373. Our exceptional partnerships have enabled the progress we have made to date. In May 2020, we announced that based on our strong preclinical data, the Coalition for Epidemic Preparedness Innovations (CEPI) would invest up to \$399 million to support our Phase 1 and 2 clinical trials and dramatically increase large-scale manufacturing capacity for antigen and adjuvant production in multiple locations outside of the USA.

In June 2020, Novavax was awarded a contract by the US Department of Defense for up to \$60 million to support Novavax in its production of several components of the vaccine that are being manufactured in the US, and the delivery of 10 million doses of NVX-CoV2373 for the DoD.

In July 2020, Novavax was selected to participate in Operation Warp Speed (OWS) and was awarded up to \$1.6 billion (recently increased to \$1.75 billion) by the federal government to complete late-stage clinical development in the US, including a pivotal 30,000 subject Phase 3 clinical trial; establish large-scale US-based manufacturing; and deliver 100 million doses of NVX-CoV2373. This essential funding, together with the dedicated partnership of the US government, has provided Novavax the ability to conduct a timely and robust clinical development program while simultaneously establishing a dedicated US manufacturing and supply chain for this pandemic.

B. *Phase 1 / Phase 2*

Turning to our clinical program, the NVX-CoV2373 development plan combined a Phase 1/2 approach to allow rapid advancement during the current coronavirus pandemic. In early August, Novavax announced positive results from the Phase 1 portion of the Phase 1/2 clinical

trial of NVX-CoV2373, and within a month, the data were published in *The New England Journal of Medicine*. The trial was randomized, observer-blinded, and placebo-controlled, and we enrolled 131 healthy adults 18-59 years of age. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. The Phase 2 portion of the Phase 1/2 clinical trial is ongoing and is being conducted in Australia and the United States to expand the evaluation of immunogenicity and safety of NVX-CoV2373 in a broader age range, including adults 60-84 years of age. We have reported that the vaccine was well tolerated by older adults and maintained its favorable safety profile.

In addition, we conducted and recently announced the successful results from a Phase 2b clinical trial to assess safety and efficacy in South Africa. The Phase 2b study enrolled over 4,400 volunteers beginning in August 2020, with COVID-19 cases counted from November through mid-January. During this time, the new South Africa variant was widely circulating in South Africa. Based upon preliminary results, of the COVID-19 cases with available genetic sequence data, 92.6% matched the South Africa variant. Overall, we observed 60% efficacy for the prevention of mild, moderate, and severe COVID-19 disease in the 94% of the study population that was HIV-negative. Importantly, the data from this trial suggests that prior infection with COVID-19 may not protect against subsequent infection by the South Africa variant, however, vaccination with NVX-CoV2373 provided significant protection.

C. Phase 3

NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the United Kingdom (UK) that completed enrollment in November and for which we reported preliminary results in January, and the PREVENT-19 trial taking place in the US and Mexico that began in December and has completed enrollment of over 30,000 participants.

The UK Phase 3 study enrolled more than 15,000 volunteers between 18-84 years of age, including 27% over the age of 65. The first interim analysis was based on 62 cases, of which 56 cases of COVID-19 were observed in the placebo group versus 6 cases observed in the NVX-CoV2373 group, resulting in a point estimate of vaccine efficacy of 89.3%. Preliminary analysis indicates that the UK variant strain that was increasingly prevalent was detected in more than

50% of the PCR-confirmed symptomatic cases. Based on PCR performed on strains from 56 of the 62 cases, efficacy by strain was calculated to be 95.6% against the original COVID-19 strain and 85.6% against the UK variant strain. The interim analysis included a preliminary review of the safety database, which was reassuring and showed that severe, serious, and medically attended adverse events occurred at low levels and were balanced between vaccine and placebo groups.

PREVENT-19 (the **PRE**-fusion protein subunit **Vaccine Efficacy Novavax Trial | COVID-19**) is a Phase 3, randomized, placebo-controlled, observer-blinded study in the US and Mexico to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 in up to 30,000 subjects 18 years of age and older compared with placebo. The trial was designed to ensure diverse representation of vulnerable populations and of ethnic and racial minorities and enrolled approximately 13% African American, 20% LatinX, 5% Asian American, and 6 % Native America, as well as 13% 65 years-of-age and over. The trial design has been harmonized to align with other Phase 3 trials conducted under the auspices of Operation Warp Speed, including the use of a single external independent Data and Safety Monitoring Board (DSMB) to evaluate safety and conduct an unblinded review when predetermined interim analysis events are reached. The trial's primary endpoint is the prevention of PCR-confirmed, symptomatic COVID-19. The key secondary endpoint is the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints will be assessed at least seven days after the second study vaccination in volunteers who have not been previously infected with SARS-CoV-2.

We have recently submitted a protocol amendment to the FDA to include a blinded crossover. This will allow all trial participants to decide to return to their trial site for a second set of injections; if the participant received placebo the first time, they will receive active vaccine in the second set and those that received vaccine will receive placebo. This protocol allows us to ensure that our trial participants are ultimately vaccinated, while also allowing us to continue to follow participants for safety. Participants will be eligible for the blinded crossover once the primary efficacy endpoint is met, and sufficient safety data has been collected.

D. *Taking on the Variants*

The emergence and circulation of COVID-19 variants poses challenges to vaccine delivery in the pandemic environment. Soon, subsequent vaccination boosters or new multivalent formulations may be needed. We commend the FDA for its commitment to publish guidance establishing a clear and efficient path for manufacturers to address these new variants, similar to the current regulatory approach for seasonal influenza vaccines.

Novavax is already aggressively working on a strategy to provide the broadest coverage. We initiated development of new constructs against the emerging strains in early January of this year and are already testing them in preclinical animal models. A hallmark of our technology platform is that our manufacturing processes are easily adaptable to producing other versions of the coronavirus spike protein that match the new strains. The company plans to begin clinical testing of these new vaccine candidates in the first half of this year.

A primary benefit of our platform is that it uses a very small amount of antigen, which provides the ability to create a bi- or multivalent vaccine and also the rapid creation and large-scale production of vaccine candidates that could potentially address multiple circulating strains of COVID-19. Combined with the reassuring safety profile that has been observed in our studies to-date with our COVID-19 vaccine in more than 30,000 participants, as well as prior studies in influenza, we are confident in our ability to rapidly adapt to evolving conditions.

IV. **US Supply**

A. *Dedicated US Manufacturing and Supply Chain*

Six months ago, we began to build out a global manufacturing operation to produce NVX-CoV2373 at commercial scale worldwide. This complex network includes a dedicated US supply chain, meaning vaccines we deliver to the US government are manufactured here in the US. We have a separate supply chain for foreign demand. Over the summer, we announced an agreement to manufacture bulk drug substance with FUJIFILM Diosynth Biotechnologies. The antigen produced at the Fuji sites in North Carolina and Texas are a critical component of our US supply chain. Our adjuvant is manufactured through our partnership with AGC Biologics in

Seattle, Washington, and final drug product fill and finish is completed by Par Pharmaceuticals in Michigan and Jubilant HollisterStier in Washington State.

B. *Dose Capacity and Distribution*

Our initial delivery of doses is dependent upon an Emergency Use Authorization (EUA) from FDA. We will be ready to ship doses once we have this authorization. We are prepared to deliver the 110 million doses included in our current agreements with the US government by the 3rd quarter of this year. Once all of our capacity comes online globally, which we expect to happen in the mid-point of this year, we will have a global capacity to produce approximately 2 billion doses per year, roughly 150 million doses per month. This includes all of our partners, including Serum Institute of India. During the pandemic, we believe that the federal government and state and local jurisdictions are in the best position to determine how doses are distributed and allocated. We will work with government leaders to ensure that those who need a vaccine get it. We look forward to informing this process as appropriate.

C. *Timing*

PREVENT-19, our US Phase 3 trial, is fully enrolled, and we are collecting data. This is an event-driven trial, meaning that the timing of our interim and final analyses are based on disease incidence and rates of transmission in the areas where participants are enrolled as well as other epidemiological factors. Novavax has been submitting data to FDA on a rolling basis under our open IND and we expect to be able to complete our filing with FDA in the second quarter of this year.

V. *Diversity and Inclusivity of Clinical Trials*

As we are all aware, this virus has had a disproportionate impact on some of our most vulnerable communities. Novavax is committed to a representative population enrolled in our clinical trials that reflects our diverse world and prioritizes populations at high risk for COVID-19, including traditionally under-represented minority groups, those over the age of 65, and those with comorbidities. Novavax has worked with community leaders within minority populations, including partnering with historically black colleges and universities like Howard University here in Washington DC, to carry out our Phase 3 trials. We believe that with

knowledge comes confidence. We designed our clinical trials to ensure they are truly representative of the American public and we have provided regular enrollment updates on our company website, including providing detail on both total enrollment as well as on the diversity targets in our enrollment. We have provided transparency in not only our trial protocol, which we have posted on our company website, and also in our data. If people know that participants just like them volunteered and took part in our clinical trial, we believe they will be more confident in rolling up their sleeves and getting vaccinated.

VI. Vaccine Confidence and Access

We know that vaccines don't save lives, vaccinations do. We commend Congress for their attention to the critical issue of vaccine confidence, and Novavax stands ready to inform the US government as our nation's leaders work with state and local officials to ensure that providers, individuals, and community leaders have the most evidence-based information to bolster confidence that an approved COVID-19 vaccine is safe and effective. As part of this effort, Novavax is committed to transparency and accountability, which are critical to public confidence in COVID-19 vaccines. Novavax has been transparent around our clinical trial protocols, enrollment numbers, and scientific data, which we believe is one of the top ways to ensure public confidence in any vaccine that will ultimately be authorized for use.

We also know that pandemics don't observe country borders. Novavax is committed to reasonable pricing, equitable distribution and allocation, and expansive access worldwide, which is what will be required to fully control the pandemic. To that end, we have built a strong partnership with Serum Institute of India, the world's largest producer of vaccines in terms of number of doses, whereby they will deliver significant numbers of doses of NVX-CoV2373 to low and middle-income countries throughout the world.

VII. Conclusion

Novavax is at the forefront of vaccine development and we are committed to producing a safe and effective vaccine to combat the COVID-19 pandemic, both today and as it evolves. We will continue to prioritize collaboration with the scientific community, partnership with the US government, and transparency in our contracts, our trial protocols, and our data.

Everyone on the Novavax team, with our partners, and in this room is interested in getting this vaccine in the arms of people and that is our priority and singular goal right now. Our team continues to work non-stop to get NVX-CoV2373 developed, authorized for use and ultimately delivered to vaccination clinics. I am proud of the progress that Novavax has made this year, and we at Novavax are proud of the advances the entire vaccine industry has made. We stand ready to work with Congress and the Administration to support the US supply chain of COVID-19 vaccines, which are essential to combat this urgent health threat.

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 amounts 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—yes. 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. OK. 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. OK. 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 disbursement 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. Yes.

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, "Yes, we're working on something for children under 16, and maybe even under 12."

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.

Mr. PALLONE. 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 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.

Mr. PALLONE. 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.

Mr. PALLONE. 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.

Mr. PALLONE. 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.

Mr. PALLONE. 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 our 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.

Mr. PALLONE. 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. OK. 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.

Mr. PALLONE. 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, Congresswoman, 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 completely 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, with a 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. KUSTER. 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. 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 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 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 it 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 thank 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, as this thing 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. OK. 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. OK. 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 fact.

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 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 halt 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 [continuing]. 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.—Mr. Trizzicki?

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 needed 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 to 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 volume syringes from the manufacturers concerned.

Mr. LONG. OK, 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 a 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 ask 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. 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 15:10 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 States 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 combat 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 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 States 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—

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 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. 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, 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. 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 Johnny the vaccine means Johnny 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 nosocomial 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. 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. 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 end-point 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. Eleventh 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, 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. Yes. 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. OK. 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 life-saving 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 reintroduce 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. 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—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. Yes. 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, 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. Yes. 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. Yes, 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, OK.

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 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 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 include 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 DC, 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 hometown, 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 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 hometown 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 Congresspeople, 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 [continuing]. 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 Tonko to Moderna's chief executive officer, dated February 17, 2021, and a letter from Representative Tonko to Pfizer's chairman and chief executive officer, dated February 17th, 2021.

Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

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.]

[Material submitted for inclusion in the record follows:]

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PAUL D. TONKO
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AND CLIMATE CHANGE
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SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON NATURAL RESOURCES
SUBCOMMITTEE ON NATIONAL PARKS, FORESTS,
AND PUBLIC LANDS
COMMITTEE ON SCIENCE, SPACE,
AND TECHNOLOGY
SUBCOMMITTEE ON ENVIRONMENT
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

February 17, 2021

Stéphane Bancel
Chief Executive Officer, Moderna
Global Headquarters
200 Technology Square
Cambridge, MA 02139

Dear Mr. Bancel,

I write on behalf of my constituents in the Capital Region of New York to request your help as we work in Congress to maximize the rapid production and distribution of COVID-19 vaccinations in the United States. In this pursuit, I would welcome your suggestions on how Congress and the Biden-Harris Administration can best support your efforts to quickly scale up production of safe, reliable COVID-19 vaccines across the nation.

With the emergence of dangerous new COVID variants, our nation continues to reach chilling new heights in this public health crisis. In recent weeks, my district in Upstate New York had been tracking more COVID-19 cases and recording more weekly deaths than at any time before, and our rate of spread continues to outpace the rate of vaccinations.¹ Ten million New Yorkers are currently eligible to be vaccinated, far more than my state's weekly allowance of these life-saving vaccines.² New York hospitals, local health departments, and other community organizations and providers, collectively prepared to administer vaccines to the public at a much faster speed, have requested additional doses and have been denied week after week. Meanwhile, a quarter of our hospital staff across the state have yet to be vaccinated.³

New York's large population of vaccine-eligible individuals and our established network of vaccination sites that are fully prepared to administer the shots at a rapid pace continue to surpass the state's supply of vaccines. We are positioned to make the most of any increase in

¹ Stanforth, Lauren. "Albany County Ends January With Record Number of Coronavirus Deaths." *Times Union*, January 31, 2021. <https://www.timesunion.com/news/article/Albany-County-ends-January-with-record-number-of-15912078.php>.

² "Governor Cuomo Announces New York City Indoor Dining Can Reopen on February 12." February 8, 2021. New York State Office of the Governor. <https://www.governor.ny.gov/news/governor-cuomo-announces-new-york-city-indoor-dining-can-reopen-early-february-12#>.

³ "Covid-19 Vaccine Tracker." New York State Department of Health. <https://covid19vaccine.health.ny.gov/covid-19-vaccine-tracker>.

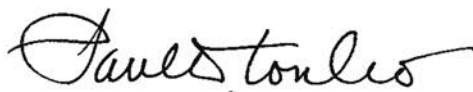
supply, and I am prepared to do whatever it takes to help accelerate vaccine production and significantly expand distribution in my home district and across the nation.

As I discuss possible solutions to this critical shortfall with my colleagues in the U.S. House of Representatives, I would appreciate your prompt response to the following questions:

- What are the primary factors or pain points limiting production of COVID-19 vaccines?
- Are your operations experiencing a shortage of raw materials needed for vaccine production? A shortage of human labor? A shortage of transportation vehicles or other logistics resources? A shortage of funding?
- Has your company experienced challenges in activating federal resources available through the Defense Production Act?
- How could Congress or the federal government better support, establish or expand public-private partnerships to accelerate the production of COVID-19 vaccinations?
- Do you foresee any challenges in meeting the Biden-Harris Administration's goal to increase the COVID-19 vaccine supply by 20 percent over the next three weeks? What will you need to increase supply more quickly?
- Are there other areas where the federal government or states could provide further assistance to companies producing COVID-19 vaccinations?

As a member of the House Committee on Energy and Commerce, I am monitoring this situation closely. As an engineer, I understand the challenges of increasing production efficiency to meet the demands of this national crisis. I greatly appreciate your efforts to help see our country through this critical time. Thank you for your prompt attention to this matter.

Sincerely,

A handwritten signature in black ink, reading "Paul D. Tonko". The signature is fluid and cursive, with the first name "Paul" and last name "Tonko" clearly distinguishable.

Paul D. Tonko
Member of Congress

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PAUL D. TONKO
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AND TECHNOLOGY
SUBCOMMITTEE ON ENVIRONMENT
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

February 17, 2021

Albert Bourla, DVM, Ph.D.
Chairman and Chief Executive Officer, Pfizer
235 East 42nd Street
New York, NY 10017

Dear Dr. Bourla,

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New York's large population of vaccine-eligible individuals and our established network of vaccination sites that are fully prepared to administer the shots at a rapid pace continue to surpass the state's supply of vaccines. We are positioned to make the most of any increase in

¹ Stanforth, Lauren. "Albany County Ends January With Record Number of Coronavirus Deaths." *Times Union*, January 31, 2021. <https://www.timesunion.com/news/article/Albany-County-ends-January-with-record-number-of-15912078.php>.

² "Governor Cuomo Announces New York City Indoor Dining Can Reopen on February 12." February 8, 2021. New York State Office of the Governor. <https://www.governor.ny.gov/news/governor-cuomo-announces-new-york-city-indoor-dining-can-reopen-early-february-12#>.

³ "Covid-19 Vaccine Tracker." New York State Department of Health. <https://covid19vaccine.health.ny.gov/covid-19-vaccine-tracker>.

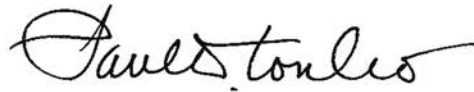
supply, and I am prepared to do whatever it takes to help accelerate vaccine production and significantly expand distribution in my home district and across the nation.

As I discuss possible solutions to this critical shortfall with my colleagues in the U.S. House of Representatives, I would appreciate your prompt response to the following questions:

- What are the primary factors or pain points limiting production of COVID-19 vaccines?
- Are your operations experiencing a shortage of raw materials needed for vaccine production? A shortage of human labor? A shortage of transportation vehicles or other logistics resources? A shortage of funding?
- Has your company experienced challenges in activating federal resources available through the Defense Production Act?
- How could Congress or the federal government better support, establish or expand public-private partnerships to accelerate the production of COVID-19 vaccinations?
- Do you foresee any challenges in meeting the Biden-Harris Administration's goal to increase the COVID-19 vaccine supply by 20 percent over the next three weeks? What will you need to increase supply more quickly?
- Are there other areas where the federal government or states could provide further assistance to companies producing COVID-19 vaccinations?

As a member of the House Committee on Energy and Commerce, I am monitoring this situation closely. As an engineer, I understand the challenges of increasing production efficiency to meet the demands of this national crisis. I greatly appreciate your efforts to help see our country through this critical time. Thank you for your prompt attention to this matter.

Sincerely,

A handwritten signature in black ink, reading "Paul D. Tonko". The signature is fluid and cursive, with the first name "Paul" and last name "Tonko" clearly distinguishable.

Paul D. Tonko
Member of Congress

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on
“Pathway to Protection: Expanding Availability of COVID-19 Vaccines”
February 23, 2021

John Young, Group President, Chief Business Officer, Pfizer

The Honorable Anne McLane Kuster (D-NH)

- 1. Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?**

Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. Pfizer relies on both domestic and foreign sources for its vaccine manufacturing supplies, and we are continuing to qualify multiple sources for all key raw materials. Pfizer has manufacturing sites across the U.S., and we are leveraging three of them for the COVID-19 U.S. commercial vaccine program including: Saint Louis, MO for raw material manufacturing; Andover, MA for drug substance; and Kalamazoo, MI for formulation, fill and finish. Pfizer’s Puurs, Belgium, site is being used for primarily European supply but will also serve as a backup supply to Kalamazoo for the U.S. market.

- 2. Considering the federal government’s actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?**

Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

- 3. What changes should be made for you to prioritize using domestic sources?**

Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

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4. Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.), are currently preventing the production of more vaccines?

Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

5. Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?

Response: We appreciate the commitment of Congress to bring an end to this pandemic, including the recent passage of the American Rescue Plan. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible.

Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. Pfizer's COVID-19 vaccine development costs have been entirely self-funded. We have already invested more than one billion dollars at risk and continue bearing the costs of all development, in an effort to help find a solution to this pandemic. We decided to self-fund our efforts so we could move as fast as possible.

Because of the urgent need to vaccinate more people, we have ramped up production of doses. We have increased projected 2021 global production from 1.3 billion doses, to at least 2.5 billion doses globally. This is based on continuous improvements and expansion at our current facilities, the updated 6-dose label, and adding more suppliers as well as contract manufacturers.

The Honorable Lori Trahan (D-MA)

1. T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or “herd immunity” against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a “vaccine task force” to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?

Response: Yes. On July 20, 2020, Pfizer and BioNTech announced that initial data from an ongoing German Phase 1/2 non-randomized dose-escalation trial demonstrated a concurrent

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induction of T cell responses against SARS-CoV-2. On December 14, 2020, Pfizer and BioNTech announced that additional data on neutralizing antibody and T cell responses from the Phase 1/2 trial with BNT162b2 conducted in Germany was available. The data analysis showed a broad immune response with SARS-CoV-2-specific neutralizing antibodies, TH1 type CD4+ T cells, and strong expansion of CD8+ T cells of the early effector memory phenotype.

2. **When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices—whether by allowing smaller shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?**

Response: Pfizer is committed to ensuring everyone has the opportunity to have access to our vaccine. There are several options for effective vaccine storage for our vaccine, and over the past several months, we have worked closely with state and local officials, as well as health care providers, to provide guidance on our storage requirements to help ensure our vaccine can reach people in rural and other harder to reach communities across the U.S. Recently, we received approval for an update to our label from the U.S. Food and Drug Administration to permit 2 weeks of storage at standard pharmaceutical freezer temperature. This will help improve the ability to distribute our vaccine in rural and harder to reach communities.

The U.S. government and Pfizer are continuing to explore optimized packaging that meets the needs of our customers for vaccine planning, distribution, and administration. Through this exploration, we understand that smaller packaging is needed. Based on revised requirements to support the U.S. government, we need to design a new solution versus what was proposed. Packaging, however, is only one lever to optimize the distribution process. To this end, Pfizer has ongoing stability studies that may open up more flexible distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

In addition, to date, we have trained over 25,000 health care providers and state, local, and tribal nation immunization leaders on our vaccine shipping, storage, and administration requirements. We continue to make these trainings regularly available, which allows us to provide up-to-date information on our vaccine and respond directly to questions about managing our vaccine in different circumstances.

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- a. **What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?**

Response: The U.S. government and Pfizer are continuing to explore optimized packaging that meets the needs of our customers for vaccine planning, distribution and administration. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we work on manufacturing and distribution.

The Honorable Morgan Griffith (R-VA)

1. **What types of process improvements and innovation can lead to boosting vaccine production?**

Response: Because of the urgent need to vaccinate more people, we have explored innovative plans to increase the number of doses we are able to produce globally by the end of 2021. We're making any improvements and enhancements that can accelerate or increase the number of doses we are able to produce. This includes:

- Making process improvements to our existing production lines – in essence more doses from the current lines;
- Expanding the supply of raw material from existing suppliers and bringing on new suppliers;
- Doubling our batch sizes in order to minimize time between batches;
- Increasing the yield per batch;
- Reducing cycle times at every step; and
- Deploying faster laboratory test methods to reduce release times.

2. **Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?**

Response: As we have said in the past, we selected the mRNA platform because it is flexible enough to enable boosting doses if needed and also allows for a more rapid response in addressing changes that might be needed in the vaccine if a variant were to significantly reduce protection from the current vaccine. Pfizer and BioNTech have been working to understand whether emerging variants of concern of SARS-CoV-2 could impact our vaccine's ability to protect against COVID-19. We are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any variant of concern that significantly reduces the protection afforded by our current vaccine.

3. **Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?**

Response: Pfizer partnered with BioNTech to jointly develop their COVID-19 vaccine. This collaboration announced on March 17, 2020 aimed to rapidly advance multiple COVID-19

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vaccine candidates into human clinical testing based on BioNTech's proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine if approved and while leveraging Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

Pfizer is investing significant resources to develop and manufacture the novel technology to provide a safe and effective vaccine. Where appropriate, we will work with our contract manufacturers, but we do not plan to provide drug product or drug substance to third parties.

a. Is your company looking to develop additional partnerships?

Response: Pfizer is continuing to explore all viable options and mechanisms to expand capacity internally and externally as needed to ensure that any potential treatment or vaccine to address the coronavirus pandemic is accessible for those who need it.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

Response: Pfizer's COVID-19 vaccine development costs have been entirely self-funded. We have already invested more than one billion dollars at risk and are prepared to continue bearing the costs of all development in an effort to help find a solution to this pandemic. We decided to self-fund our efforts so we could move as fast as possible.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

Response: Pfizer and BioNTech have been working to understand whether emerging variants of SARS-CoV-2 could impact our vaccine's ability to protect against COVID-19.

- Our in vitro study provided data that demonstrated that sera from individuals immunized with the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) neutralized SARS-CoV-2 with spike protein mutations found in the Brazil, U.K. and South African virus variants.
- On February 25, Pfizer and BioNTech announced an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine to understand the effect of a booster of the current vaccine on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the Phase 1 study in the United States who will be offered the opportunity to receive a 30 µg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose against evolving variants.
- On March 11, Pfizer and BioNTech announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with the Pfizer-BioNTech COVID-19 Vaccine, underscoring the observed substantial

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public health impact of Israel's nationwide immunization program. The latest analysis from the Israeli Ministry of Health shows that two weeks after the second vaccine dose protection is even stronger in this population – vaccine effectiveness was at least 97% in preventing symptomatic disease, severe/critical disease and death. Findings from the analysis were derived from de-identified aggregate Israel MoH surveillance data collected between January 17 and March 6, 2021, when the Pfizer-BioNTech COVID-19 Vaccine was the only vaccine available in the country and when the more transmissible B.1.1.7 variant of SARS-CoV-2 (formerly referred to as the U.K. variant) was the dominant strain.

As we've said in the past, we selected the mRNA platform because it is flexible enough to enable boosting doses if needed and also allows for a more rapid response in addressing changes that might be needed in the vaccine if a variant were to significantly reduce protection from the current vaccine.

While we continue to examine emerging data, we are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any strain that significantly reduces the protection afforded by our vaccine.

6. **As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?**

Response: On February 25, Pfizer and BioNTech announced an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine to understand the effect of a booster on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the Phase I study in the United States who will be offered the opportunity to receive a 30 µg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose against evolving variants.

While we continue to examine emerging data, we are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any strain that significantly reduces the protection afforded by our vaccine.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. **One of the greatest inhibitors of distributing the COVID-19 vaccine to rural areas is the lack of cold-chain technologies to store the RNA vaccine. Additionally, as we consider logistics in distributing the vaccine abroad to third-world countries where power may not be available, the Moderna or Pfizer vaccine may not be an option. Are Moderna or Pfizer conducting any research on ways to incorporate new technologies to make the RNA vaccines stable to store at room temperature to allow for broader distribution?**

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Response: In February, we submitted new data to the U.S. Food and Drug Administration demonstrating the stability of our COVID-19 vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. The FDA authorized this update which allows for vaccine vials to be stored at these temperatures for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

Pfizer has ongoing stability studies that may open up new distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

2. **Pfizer has agreed to supply the United States with 300 million doses of the COVID-19 vaccine. During last summer, the U.S. purchased 100 million doses while the vaccine was still undergoing trials, and 100 million additional doses were purchased by the U.S. in December. In February, the United States announced it would be exercising its option to purchase 100 million additional doses of the Pfizer COVID-19 vaccine. Can you explain the structure of the contracts between the United States and Pfizer, and clarify the basis on which the options to exercise the decision to purchase additional vaccinations were formed?**

Response: Pfizer has entered into two contracts with the U.S. government for a total of 300 million doses. On July 22, 2020, we announced an agreement with the U.S. government for 100 million doses to be provided after successful manufacture and approval or authorization from FDA. On December 23, 2020, we announced a second agreement, in the form of a supply contract for an additional 100 million doses, bringing the total contracted number of doses to 200 million. The December 23, 2020 agreement also provided the government an option to acquire up to an additional 400 million doses of our vaccine. On February 12, 2021, we announced the U.S. government has exercised its option for an additional 100 million doses of our vaccine.

3. **Did the Previous Administration's invocation of the Defense Production Act impact the production of Pfizer's Covid-19 vaccine? If so, was it important, and how did it help?**

Response: Pfizer worked with the previous Administration and is working with the current Administration to help the U.S. Government deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. Government meet on a regular basis regarding manufacturing and distribution of the vaccine.

The Honorable Billy Long (R-MO)

1. **What are you doing to evaluate and incorporate technology to make vaccines stable at room temperature so they can be more widely distributed, especially if we are faced with annual vaccination efforts against COVID-19 as suggested by some experts? Additionally, are you aware the Infectious Disease Research Institute, located in Washington State, has pioneered technology that allows RNA vaccines to be freeze-dried and stored nearly a year at room temperature or 2 years under simple refrigeration. It's my understanding that this technology, once approved, could be applied to the Pfizer and Moderna vaccines to ensure long-term stability. Is this a technology your company would consider exploring?**

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Response: Last month, we submitted new data to the U.S. Food and Drug Administration demonstrating the stability of our COVID-19 vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. The FDA authorized this update which allows for vaccine vials to be stored at these temperatures for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

Pfizer has ongoing stability studies that may open up new distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

Pfizer will consider all viable options and mechanisms as needed to ensure that any potential treatment or vaccine to address the coronavirus pandemic is accessible for those who need it.

**Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

Hearing on “Pathway to Protection: Expanding Availability of COVID-19 Vaccines”

February 23, 2021

Dr. Stephen Hoge, President, Moderna
Submitted: April 5, 2021

The Honorable Anne McLane Kuster (D-NH):

1. Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?

The manufacturing process for Moderna’s U.S. supply of its COVID-19 vaccine is domestic. Our supply chain includes a number of raw materials, some of which have been sourced internationally because they are almost exclusively produced abroad. We work to secure that supply in advance of when it is needed for production.

2. Considering the federal government’s actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?

Moderna is grateful for the investment and efforts that the federal government has made to secure our supply chain and facilitate access to the raw materials that we need. Some of the raw materials that are used in our vaccine manufacturing process are produced almost exclusively in Europe. So while we rely on those raw materials as part of our process, the manufacturing process for our U.S. supply is located in the United States.

3. What changes should be made for you to prioritize using domestic sources?

Moderna has prioritized domestic sources where feasible. We are currently focused on protecting patients by producing our COVID-19 vaccine as efficiently as possible consistent with our commitment to high standards of quality and safety. Once we have addressed this pressing challenge, Moderna would support an assessment of the raw material supply chain and whether lessons learned from responding to this pandemic may be useful in making improvements for the future.

4. Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.) are currently preventing the production of more vaccines?

Moderna is continually looking for ways to improve the efficiency of our manufacturing process. One of the recently identified constraints on our production has been the capacity of the fill-and-

finish process. To reduce this constraint, we studied the possibility of adding more doses to each vial of vaccine. We determined this would improve output because it allows us to complete manufacturing runs more quickly; it also reduces the need for consumable materials in high demand. The FDA recently approved our proposal to increase the amount of vaccine in each vial to allow vaccine administrators to draw up to 15 doses. This will allow us to produce and deliver more doses more quickly. We will continue to collaborate with our manufacturing partners and the federal government to increase the efficiency of our production process without compromising quality or safety.

5. Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?

At Moderna, we are currently focused on protecting patients by producing our COVID-19 vaccine as efficiently as possible consistent with our commitment to high standards of quality and safety. Moderna is grateful for the investments that the United States government made to support the ramp up of manufacturing for COVID-19 vaccine candidates and is encouraged by the government's continued partnership in the manufacturing process. We are still assessing the potential impact of the American Rescue Plan, but legislation furthering these efforts is welcome.

The Honorable Lori Trahan (D-MA)

1. T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or “herd immunity” against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a “vaccine task force” to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?

Yes, as part of its animal studies and in the mRNA-1273 Phase I trial, Moderna studied both T-Cell and antibody-mediated immune responses to its vaccine. The vaccine generated robust responses in both arms of the adaptive immune system, including T-Cell responses that were at least equivalent to that seen in individuals who obtained immunity through a prior COVID-19 infection.

2. When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of

vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices—whether by allowing smaller shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?

a. What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?

Under its current contract, Moderna delivers vaccines to the federal government, and the government is responsible for vaccine distribution. We have and will continue to work with the government to provide our vaccine in the format or formats that will best accommodate distribution to the American public. Moderna strongly believes that its vaccine should be distributed equitably, and that it must be a priority to afford access to individuals and communities of color, the elderly, the sick, and others who have seen greater rates of suffering and death during this pandemic.

The Honorable Morgan Griffith (R-VA)

1. What types of process improvements and innovation can lead to boosting vaccine production?

Moderna has been able to consistently scale up its production as we continue to refine our manufacturing process and gain experience in producing the vaccine. We are also continually looking for ways to improve the efficiency of our manufacturing process. For example, one of the recently identified constraints on our production process has been the capacity of the fill-and-finish process. To reduce this constraint, we studied the possibility of adding more doses to each vial of vaccine. We determined that this would improve output because it allows us to complete manufacturing runs more quickly; it also reduces the need for consumable materials in high demand. The FDA recently approved our proposal to increase the amount of vaccine in each vial to allow vaccine administrators to draw up to 15 doses. This will allow us to produce and deliver more doses more quickly. We will continue to collaborate with our manufacturing partners and the federal government to increase the efficiency of our production process without compromising quality or safety.

2. Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine

manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?

Moderna is encouraged by new data, which suggest that the two-dose regimen of mRNA-1273 should protect against the most widespread variants detected to date. Out of an abundance of caution, Moderna has also undertaken a two-pronged strategy to proactively address the pandemic as the virus continues to evolve: First, we are testing an additional booster dose of mRNA-1273 to study its ability to further increase immunity against emerging strains. Second, leveraging the flexibility of our mRNA technology, we are conducting a study on a variant-specific booster to see if it would be more effective at specifically neutralizing a specific variant.

One of the great benefits of mRNA technology is that it is highly adaptable. That gives us hope that we can, if necessary, quickly develop boosters to respond to emerging variants. Moderna will continue to work with federal officials and other stakeholders to monitor and identify any emerging variants of concern.

3. Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?

Yes. In addition to operating its own manufacturing facility in Norwood, Massachusetts, Moderna has partnered with one of the world's leading contract manufacturers, Lonza, to manufacture our vaccine. Lonza has facilities in both the U.S. and Switzerland, allowing us to scale-up for production both domestically and abroad. For the fill-finish, inspection, testing, and packaging parts of our production process, we have partnered with Catalant, a contractor that specializes in this "fill-finish" step. We also recently announced that Baxter BioPharma Solutions will provide "fill-finish" services and supply packaging for approximately 60-90 million doses of the Moderna COVID-19 Vaccine in 2021.

a. Is your company looking to develop additional partnerships?

Moderna is open to additional partnerships that would allow it to further scale our manufacturing process consistent with our commitment to high standards of quality and safety.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

Moderna has not utilized the CIADM program because we have not required that assistance.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

One of the great benefits of mRNA technology is that it is highly adaptable. That gives us hope that we can, if necessary, quickly develop boosters to respond to emerging variants. Moderna

will continue to work with federal officials and other stakeholders to monitor and identify any emerging variants of concern.

a. The current vaccination rollout has been staggered in phases due to the limited supply of COVID-19 vaccines in comparison to the high demand. There is worry that this slow, phased type of rollout will occur again should the U.S. government need to distribute booster shots to protect against the new variants. The current dose for the Moderna vaccine is 100 micrograms. Is it possible to reduce the dose of the booster shot, and if so, by how much?

Moderna is studying the possibility of using a smaller dose for a potential booster shot. We will know more about the feasibility of that approach after further study.

6. As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?

Moderna is studying the possibility of using a smaller dose of 50 µg for a potential booster shot. We will know more about the feasibility of that approach after further study. It is possible that a smaller dose size would increase the speed at which Moderna is able to produce vaccine doses.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. One of the greatest inhibitors of distributing the COVID-19 vaccine to rural areas is the lack of cold-chain technologies to store the RNA vaccine. Additionally, as we consider logistics in distributing the vaccine abroad to third-world countries where power may not be available, the Moderna or Pfizer vaccine may not be an option. Are Moderna or Pfizer conducting any research on ways to incorporate new technologies to make the RNA vaccines stable to store at room temperature to allow for broader distribution?

Moderna recently began clinical trials of our next-generation COVID-19 candidate. This is a potential refrigerator-stable ready-to-use vaccine in liquid state that could facilitate easier distribution and administration in a wider range of settings, including potentially for rural communities and developing countries. We also recently obtained authorization from the FDA for our vaccine to be kept at room temperature conditions for 24 hours, an increase from the previous 12 hours. The FDA also authorized a punctured vial to be used for up to 12 hours, an increase from the previous 6 hours. We remain committed to investigating options to help solve this public health emergency.

The Honorable Billy Long (R-MO)

1. What are you doing to evaluate and incorporate technology to make vaccines stable at room temperature so they can be more widely distributed, especially if we are faced with annual vaccination efforts against COVID-19 as suggested by some experts? Additionally, are you aware the Infectious Disease Research Institute, located in Washington State, has pioneered technology that allows RNA vaccines to be freeze-dried and stored nearly a year

at room temperature or 2 years under simple refrigeration. It's my understanding that this technology, once approved, could be applied to the Pfizer and Moderna vaccines to ensure long-term stability. Is this a technology your company would consider exploring?

Moderna does employ its own freeze-dried technology, called lyophilization, in other vaccines in clinical development. But in part because the lyophilization process is time-consuming, Moderna determined that developing a next-generation candidate is a superior approach for the current COVID-19 crisis. Moderna recently began clinical trials of its next-generation COVID-19 candidate, a potential refrigerator-stable ready-to-use vaccine in liquid state that could facilitate easier distribution and administration in a wider range of settings, including potentially for rural communities and developing countries. As circumstances evolve, we will continue to pay close attention to this issue and will consider a range of possible solutions.

The Honorable Neal P. Dunn, M.D. (R-FL)

1. In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics? That is to say anti-virals that could potentially have a broader spectrum of activity across the coronavirus variants?

Moderna is engaged in the research and development of therapeutics. Moderna has 23 development candidates across a range of infectious diseases and therapeutic areas. Moderna is not currently developing any anti-virals related to the COVID-19 or variants.

Dr. Richard Nettles, M.D., Vice President of U.S. Medical Affairs, Janssen Infectious Diseases and Vaccines, Johnson & Johnson

Responses to Questions for the Record

Subcommittee on Oversight and Investigations, Committee on Energy and Commerce
February 23, 2021

The Honorable Ann McLane Kuster (D-NH)

1. Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?

Johnson & Johnson's global manufacturing and supply network has enabled us to develop our COVID-19 vaccine at an extraordinary pace since January 2020. In addition to our manufacturing facility in the Netherlands, the partners who are central to our global supply network include: Merck & Co. (US); Emergent BioSolutions (US); Catalent (US, Italy); Grand River Aseptic Manufacturing (US); Sanofi Pasteur (France); IDT Biologika (Germany); Reig Jofre (Spain); Biological E (India); and Aspen Pharmacare (South Africa).

2. Considering the federal government's actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?

In general, we have used the sourcing that is most conducive to developing and producing a safe and effective vaccine at an accelerated pace. We have a substantial manufacturing and supply network located in the United States. In our view, government actions should take into account the need to use a global supply chain to allow manufacturing plants to operate at maximum capacity without disruption or slowdown.

3. What changes should be made for you to prioritize using domestic sources?

As noted above, we have a substantial manufacturing and supply network located in the United States, and we have expanded our network as part of our effort to produce our vaccine at a rate of one billion doses globally by the end of 2021. We do not currently believe changes are needed.

4. Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.), are currently preventing the production of more vaccines?

We have been working since the beginning of the pandemic to expand our global manufacturing and supply network, including by contracting with established third-party vaccine manufacturers for additional production. Our current manufacturing plans are designed to meet our objective, which we announced last year, to produce our vaccine at a rate of one billion doses globally by the end of 2021. Currently, we are witnessing some disruptions in the global consumables market (components needed for manufacturing), which we are closely monitoring.

5. Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?

We support Congress's efforts to strengthen the vaccine supply chain as we work collectively to optimize and accelerate our response to COVID-19 and ensure we are better prepared for emerging epidemic threats in future. We also believe continued investment is needed to ensure that domestically we have the highly specialized and technical competencies required for both current and next-generation manufacturing jobs. The free flow of essential supplies and equipment across borders also needs to be assured to allow facilities to operate at maximum capacity without disruption or slowdown, which could allow for greater quantities of vaccine to reach more people more quickly.

The Honorable Lori Trahan (D-MA)

1. T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or "herd immunity" against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a "vaccine task force" to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?

Yes, we are studying T-Cell response in our COVID-19 vaccine development program. Our vaccine drew a strong antibody and T-Cell response in humans, as described in the data from our phase 1/2a clinical trial published by Sadoff et al. in the January 13, 2021 New England Journal of Medicine – <https://www.nejm.org/doi/full/10.1056/NEJMoa2034201>.

2. When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices— whether by allowing smaller

shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?

The Janssen COVID-19 vaccine is well suited to community deployment, including via physician offices and pharmacies, because it remains stable for two years at -20°C, three months of which can be at temperatures of 2°C to 8°C. During the emergency pandemic period, we are operating under the special circumstances of the federal coordinated response to COVID-19. Our priority is to deliver supplies of the Janssen COVID-19 vaccine to the federal government as part of this response, and the government then coordinates all aspects of vaccine distribution.

a. What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?

As noted above, our vaccine is well suited to community deployment, including via physician offices and pharmacies, because it remains stable for two years at -20°C, three months of which can be at temperatures of 2°C to 8°C. The U.S. government's support has been an important contributor to Johnson & Johnson's ability to develop our vaccine on an accelerated pace, and the government's commitment to purchase our vaccine was important for our ability to invest in the increased production capacity necessary to bring millions of vaccine doses to Americans.

The Honorable Morgan Griffith (R-VA)

1. What types of process improvements and innovation can lead to boosting vaccine production?

We have invested in process improvements and innovation, including through the development of technologies such as our AdVac® platform. Additionally, in response to the urgent public health demands of the pandemic, we have worked around the clock to develop and broadly scale our manufacturing capabilities to supply the United States and other countries. Currently, our focus is on working with our partners to scale up the production process. The production of our vaccine is a highly complex process, requiring very particular staff capabilities and experiences.

2. Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?

A key advantage with our AdVac® technology platform is its versatility in facilitating vaccine candidates for a range of infectious diseases, as well as viral variants that may emerge over time. The same platform is used for our Ebola vaccine and is being explored in our vaccine candidates for HIV and respiratory syncytial virus.

We anticipate an accelerated timeline for developing versions of our COVID-19 vaccine tailored to viral variants, if needed. We also welcomed FDA's recent guidance outlining a streamlined approach for clinical studies. It is important to monitor the evolution of the pandemic closely in order to determine whether, and exactly how, vaccines should be updated. For example, it is possible that the variants that we are concerned about now are not the ones that may have the

biggest impact on COVID-19 infection rates in the future.

3. Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?

Yes. Beyond our manufacturing facility in the Netherlands, the partners who are all central to our global manufacturing and supply network include: Merck & Co. (US); Emergent BioSolutions (US); Catalent (US, Italy); Grand River Aseptic Manufacturing (US); Sanofi Pasteur (France); IDT Biologika (Germany); Reig Jofre (Spain); Biological E (India); and Aspen Pharmacare (South Africa).

a. Is your company looking to develop additional partnerships?

We continue to evaluate opportunities to expand our manufacturing capabilities with additional production sources. Since the time of the hearing, we have announced additional partners. At this time, we believe we have sufficient manufacturing capacity secured to support the production of up to one billion vaccines in 2021.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

We recognize CIADM as an excellent and worthwhile initiative, and a review of CIADM participants and their respective skill sets informed our manufacturing planning in the early stages. Ultimately the partners that we have engaged in our manufacturing network meet our stringent criteria to ensure that technology transfers could be successfully executed.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

Our vaccine utilizes our AdVac® technology platform, which allows for updates on an accelerated timeline should newly emerging SARS-CoV-2 variants of concern dictate that need. We welcomed FDA's recent guidance outlining a streamlined approach for clinical studies.

6. As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?

We will continue to use the science as our guide as to new variants, and we will continue to utilize our expanded global manufacturing and supply network for our vaccine.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. It has been brought to my attention that the Johnson and Johnson COVID-19 vaccine uses abortion-derived cell lines in the vaccine production process. Is it possible to improve and move beyond this controversial technology in future vaccine development and production?

Our vaccine contains no fetal tissue. Rather, our vaccine is produced using a harmless cold-like virus into which we insert a piece of the coronavirus spike protein.

The technology platform uses cells that were engineered and grown in labs from a single cell more than 30 years ago into a fully engineered cell line. This cell line enables us to manufacture hundreds of millions of single-shot COVID vaccines that can be transferred and stored without the need for deep freezing.

The Honorable Neal P. Dunn, M.D. (R-FL)

1. **In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics? That is to say anti-virals that could potentially have a broader spectrum of activity across the coronavirus variants?**

Yes. In addition to accelerating the clinical development, manufacturing, and distribution of the Janssen COVID-19 vaccine, we have been working in collaboration with the U.S. government and other research partners to identify potential therapeutic solutions by screening a library of compounds and conducting clinical trials to explore potential therapeutics. For example, we are participating with the NIH in a master protocol study called ACTIV-1 Immune Modulators (IM) which is evaluating REMICADE®, a Janssen-developed Tumor Necrosis Factor (TNF) inhibitor or anti-TNF, as a potential treatment for hospitalized patients with inflammatory complications of COVID-19. From the start of the pandemic, Janssen also has collaborated with BARDA to share research and development costs and mobilize resources to screen a library of compounds (both ours and other companies') for activity against SARS-CoV-2. Currently, none of our medicines have been approved for use in treating COVID-19.

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Attachment—Additional Questions for the Record

**Subcommittee on Oversight and Investigations Hearing on
“Pathway to Protection: Expanding Availability of COVID-19 Vaccines”
February 23, 2021**

Ruud Dobber, Ph.D., Executive Vice President and President,
BioPharmaceuticals Business Unit, AstraZeneca

The Honorable Anne McLane Kuster (D-NH)

1. Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?
We source some of the vaccine components globally but we manufacture all vaccine supply for the US government in the US.
2. Considering the federal government’s actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?
Domestic availability of some supplies make it necessary for us to source certain components globally.
3. What changes should be made for you to prioritize using domestic sources?
For our vaccine, we have had to source some components globally to ensure adequate access and speed in manufacturing.
4. Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.), are currently preventing the production of more vaccines?
We are not currently experiencing significant material or equipment constraints that affect our ability to manufacture.
5. Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?
Access to more large scale manufacturing capacity and capabilities on the scale needed for a pandemic would be helpful. It can be challenging when multiple companies are trying to access the same space/service and supplies.

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The Honorable Lori Trahan (D-MA)

1. Since October 2020 you have refused to extend mandatory 340B program discounts to the safety-net providers that we are relying on to distribute and administer COVID-19 vaccines – including publicly funded community health centers. Community health centers rely on 340B discounts to stretch scarce federal resources to medically underfunded communities, which is exactly what Congress intended when it established the program. Will you commit to resuming 340B drug sales to qualified safety-net providers and their contracted pharmacies and commit to refunding overcharges to those providers on qualifying outpatient drugs purchased since October 1, 2020 as a condition of receiving additional public funding?

AstraZeneca is strongly committed to the 340B Program and to ensuring that any patient prescribed an AstraZeneca product has access to that medicine. AstraZeneca continues to offer its products to all covered entities at the 340B price or better, and under its policy also makes 340B drugs available through a designated contract pharmacy for any covered entity that lacks an in-house pharmacy. In 2020, we changed our approach to help mitigate the significant compliance issues that have been well documented in audits performed by GAO regarding contract pharmacy arrangements. AstraZeneca's policy is not directed at cutting the costs of complying with the program. Rather, it was adopted in response to serious, documented abuses of the program by contract pharmacies.^[1] AstraZeneca's approach to contract pharmacy arrangements fully complies with all operative requirements and continues to support the mission of the program to provide a healthcare safety net for the most vulnerable patients in our country. It is important to note that our policy change should not impact a patient's ability to access our medications. Indeed, AstraZeneca remains committed to ensuring that all patients have access to our medications, regardless of their ability to pay. Through our various patient assistance programs, we offer free medicines and other assistance to eligible patients in need.

2. T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or "herd immunity" against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a "vaccine task force" to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?

Two papers have been published in the same issue of Nature Medicine (December 17, 2020) from additional analysis conducted from the Phase I/II COV001 trial. T-cell responses were induced, peaking by day 14 after the first dose and were maintained two months after injection, regardless of dose level and number of doses.

^[1] See, e.g., HRSA, *Program Integrity: FY19 Audit Results*, <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results>; Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* (Oct. 2020), <https://bit.ly/3owtUwa>; Gov. Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018), <https://www.gao.gov/assets/700/692697.pdf>; Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of the Inspector Gen., Dep't of Health and Human Servs., *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014), <https://oig.hhs.gov/oig/reports/oei-05-13-00431.pdf>; Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Resources and Servs. Admin. (March 27, 2013), <https://bit.ly/3kFquVS>; Gov. Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 23, 2011), <https://www.gao.gov/assets/330/323702.pdf>.

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3. When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices—whether by allowing smaller shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?

We would be willing to work with the government on this issue. Currently, we have agreed to deliver to government distribution centers and the government handles deliveries beyond that point.

- a. What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?

If it was determined that this was the most efficient way to distribute the vaccines, AstraZeneca would work with the government to move forward a mutually agreed upon plan.

The Honorable Morgan Griffith (R-VA)

1. What types of process improvements and innovation can lead to boosting vaccine production?
Ensuring access to large scale manufacturing during a pandemic would be helpful. We are not currently experiencing problems but it can get difficult when multiple companies are trying to access the same space/service.
2. Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?
Because viral-vectored vaccines can be engineered in the laboratory, as the virus mutates, we can adapt the platform technology to keep at pace with the new variants, if needed. Oxford University have already started developing the next generation adenoviral vector vaccines incorporating the genetic changes to spike protein found in the new variants. The adenoviral vectored vaccine genetic code can be altered to match new variants of coronavirus spike protein in a matter of days in the laboratory. It is important to remember though that additional steps will be required to ensure the quality and effectiveness of the new vaccine.
Following the molecular changes to the spike protein, there are crucial manufacturing processes needed to ensure the vaccine can be produced in mass quantities. This is a biological process and it takes time to create the virus seed stock and host cell banks to ensure the vaccine can be made efficiently. Host cells are grown in a series of bioreactors of increasing scale and act as

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mini-factories to produce the final vaccine. This step cannot be speeded as the host cells take a finite time to grow and divide, and our experience from production and scale up of the vaccine in 2020 suggests it will likely take 3-4 months.

In parallel, as vaccine stocks increase it will be important to test the effectiveness of the new vaccine against the new variants in a clinical trial. Given we will have a wealth of safety data on the vaccine platform, it is likely a smaller Phase 2/3 efficacy study could be designed to primarily assess efficacy within a few months. This approach would require discussion and approval by regulators.

We currently estimate the whole process from start to finished product would take about 6-8 months to complete.

Of course, we need to consider and assess how best to address the global need going forward. Establishing a potential pipeline of future vaccines, on the assumption that we will need them in either this ongoing pandemic or an endemic setting, as we do with flu, will be essential. Careful ongoing safety monitoring over the longer term, efficient clinical evaluation with immunology and early safety assessment will be critical.

Effective collaboration between global regulatory authorities on requirements and government investment in advanced manufacturing capabilities to enable an efficient global rollout will also be important.

3. Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?

Yes, we are partnered with other companies that assist in certain steps of the drug manufacturing process.

- a. Is your company looking to develop additional partnerships?

Not at this time.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

We are not currently experiencing significant material or equipment constraints that affect our ability to manufacture.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

AZD1222 is a viral-vectored vaccine, not an mRNA. As stated above, viral-vectored vaccines can be engineered in the laboratory; this means as the virus mutates we can adapt the platform technology to keep at pace with the new variants, if needed.

6. As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?

Not at this time, but we are working on that question.

Ruud Dobber, Ph.D.
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The Honorable Neal P. Dunn, M.D. (R-FL)

1. In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics? That is to say anti-virals that could potentially have a broader spectrum of activity across the coronavirus variants?

Yes, we are at the early stages of research with our long acting monoclonal antibody candidate and our focus currently is to prove its efficacy and tolerability as a potential prevention and treatment against COVID-19. We started Phase III clinical trials in December 2020 and look forward to working with regulators as we move forward.

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Attachment—Additional Questions for the Record

**Subcommittee on Oversight and Investigations
Hearing on
“Pathway to Protection: Expanding Availability of COVID-19 Vaccines”
February 23, 2021**

John Trizzino, Executive Vice President, Chief Commercial Officer, and Chief Business Officer,
Novavax, Inc.

The Honorable Anne McLane Kuster (D-NH)

1. Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?

At this time, there is minimal reliance on foreign sources for our US supply chain. Some raw material components have foreign manufacturing sources as well as a portion of the adjuvant utilized in NVX-CoV2373. Our facilities in the US will provide vaccine doses for the US. We have a separate supply chain for foreign demand. Over the summer, we announced an agreement with Fujifilm Diosynth Biotechnologies for the manufacture of bulk drug substance and Jubilant HollisterStier to provide fill/finish manufacturing services. The protein antigen produced at the Fuji sites in North Carolina and Texas are critical components of our US supply chain. Adjuvant production and fill/finish are also completed in the US as well.

2. Considering the federal government’s actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?

We have collectively seen tremendous success with vaccine development in the past year and that is only because the federal government and the private sector brought their full resources to bear against this pandemic. This pandemic response has required every mechanism available to create a resilient US-based supply chain, and it is important that these tools be used strategically and as part of a comprehensive approach.

3. What changes should be made for you to prioritize using domestic sources?

We are using domestic supply sources to the greatest extent possible and do not believe any changes need to be made at this time.

4. Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.), are currently preventing the production of more vaccines?

We are not facing any domestic supply constraints. The pandemic has created global material and supply constraints for all of the COVID vaccine developers. We are working closely with our supply chain partners to prepare for and find solutions for these challenges outside of the US.

John Trizzino

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5. Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?

Incredible progress has been made towards ending this pandemic, and that progress is in part due to the extensive support and investment provided by the federal government. Novavax was awarded up to \$1.75 billion by the federal government to complete late-stage clinical development in the US, including a pivotal 30,000 subject Phase 3 clinical trial; establish large-scale US-based manufacturing; and deliver 110 million doses of our COVID-19 vaccine candidate, NVX-CoV2373 to USG and DoD. This essential funding, together with the dedicated partnership of the US government, has provided Novavax the ability to conduct a timely and robust clinical development program while simultaneously establishing a dedicated US manufacturing and supply chain for this pandemic.

The Honorable Lori Trahan (D-MA)

1. T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or "herd immunity" against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a "vaccine task force" to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?

Novavax conducted a phase1/2 trial to evaluate the safety and immunogenicity of NVX-CoV2373 and secondary outcomes included T-cell responses (ELISpot and cytokine staining), among other things. The benefit of our vaccine with Matrix-M™ adjuvant was clear in the magnitude of the cytokine response with Th1 bias. Cell-mediated testing is ongoing for samples from our phase 3 study in the UK and will be conducted in our US phase 3 study as well. For additional discussion, please refer to our publication of this trial in the New England Journal of Medicine, *Phase 1–2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine*. While there may be some benefit to T-cell responses, the most important outcome is the efficacy of the vaccine against mild, moderate, and severe disease caused by COVID-19, which has been demonstrated with our vaccine in a pivotal Phase 3 trial in the United Kingdom and is currently being studied in over 30,000 participants in the US.

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2. When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices—whether by allowing smaller shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?
 - a. What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?

During the pandemic, the government made the decision to manage the distribution process. We will continue to work with government leaders to ensure patients who need a vaccine get it. When the pandemic is no longer a public health emergency, we will provide our vaccine through the existing vaccine distribution networks and do not anticipate needing any assistance from the government.

The Honorable Morgan Griffith (R-VA)

1. What types of process improvements and innovation can lead to boosting vaccine production?

There is significant value in the utilization of nanoparticle technologies because they can lead to highly potent antigen and combined with an adjuvant provide a dose-sparing effect. We have also found that utilizing a manufacturing process using fully optimized and mature platforms provides better yields in production and this is best achieved by investing in these platforms in advance of a pandemic. In addition, we have found that the incorporation of an adjuvant improves immune responses and enables vaccine dose-sparing. Our Matrix-M adjuvant means that our vaccines can use lower doses of antigen to achieve the desired immune response, which results in increased supply and manufacturing capacity. Finally, development of new manufacturing technologies for higher throughput can maximize existing facility capacity.

2. Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?

Novavax initiated development of new constructs against the emerging strains in early January

John Trizzino

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and is already testing them in preclinical models. Our vaccine platform is easily adaptable to producing other versions of the protein that match the new strain. The company plans to initiate clinical testing of these new vaccines in the second quarter of this year, and we are already producing newer versions of the antigen at small scale and are finalizing plans to produce at commercial scale.

3. Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?

- a. Is your company looking to develop additional partnerships?

Novavax has partnered with dozens of organizations around the country and world to maximize our ability to meet global and domestic demand once we receive the necessary regulatory authorizations. This includes our decision to license and transfer our technology to partners like the Serum Institute of India, Takeda, and SK Bioscience to ensure that our vaccine will be widely distributed and accessible to the world's most vulnerable populations. In addition, we recently announced that GSK will provide fill and finish manufacturing capacity for Novavax at its Barnard Castle facility in the North East of England beginning as early as May 2021.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

Novavax has partnered with Fujifilm Diosynth Biotechnologies Texas, a subcontractor of the CIADM, at its Flexible Biomanufacturing Facility in College Station, Texas, for production of the bulk drug substance for NVX-CoV2373.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

We cannot speak to the difficulty of developing an mRNA vaccine booster, but we can provide details on our protein-based vaccine. A primary benefit of our adjuvanted recombinant nanoparticle platform is that we can create new vaccine candidates quickly and it uses a very small amount of antigen, enabling large-scale production of new (or perhaps multivalent) vaccine candidates that could potentially address multiple circulating strains of COVID-19. Combined with the safety profile that has been observed in our studies to-date of our COVID-19 vaccine in more than 50,000 participants, as well as prior clinical studies in influenza, we are optimistic about our ability to rapidly adapt to evolving conditions. Ultimately, we also hope to study the use of our vaccine as a booster for other authorized COVID-19 vaccines, as we believe our technology is very promising in this respect.

6. As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?

Any monovalent vaccine will likely use the same dose we are assessing in phase 3 studies, yet we are also investigating an even lower dose which has the potential to be just as efficacious and dose sparing. Our safety data would allow for the creation of a multivalent vaccine with up to 5 times the amount of antigen in our current phase 3 trial vaccines.

John Trizzino

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The Honorable Neal P. Dunn, M.D. (R-FL)

1. In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics? That is to say anti-virals that could potentially have a broader spectrum of activity across the coronavirus variants?

Novavax is a biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. At this time, we are exclusively focused on bringing our COVID-19 vaccine candidate to the market and are not developing any therapeutics.